



August 31, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Asante Health System (OR)

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

Carolinas HealthCare System (NC, SC)

Community Hospital Anderson (IN)

Erlanger Health System (TN)

Forrest General Hospital (MS)

Health First Inc. (FL)

Mercy Medical Center (IA)

Our Lady of the Lake Regional Medical Center (LA)

Saint Joseph's/Candler Health System (GA)

Saint Joseph's Hospital (WI)

Sheltering Arms Rehabilitation Hospitals (VA)

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

Tri-City Medical Center (CA)

University Health System (TX)

Dear Ms. Frizzera,

Re: CMS-1414-P

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the 2010 Outpatient Prospective Payment System (OPPS) Proposed Rule, as published in the *Federal Register* on July 20, 2009.

The Provider Roundtable (PRT) includes representatives from 15 different health systems from around the country. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services under OPPS, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual OPPS policymaking and recalibration process. We appreciate the opportunity to provide our comments to CMS. A full list of the current PRT members is provided in **Appendix A**.

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

Sincerely,

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Carolinas HealthCare System
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Charlotte, North Carolina 28232-2861

Composite APCs

Multiple Imaging Composite APCs

The PRT commends CMS' decision to delay implementation of any new Composite APCs for CY 2010 in order to monitor the impact of the established composites currently in place. The PRT encourages CMS to maintain the current Composite APC structure until adequate claims data are available in order to thoroughly analyze the impact for both providers and beneficiaries.

As noted in our comments in response to the CY 2009 proposed rule, the PRT continues to believe that efficiencies are already being achieved related to the Imaging Composite APCs. Our comment at that time was that: *"The PRT continues to believe that CMS' current APC payment rate setting methodology already reflects an aggregation of resource costs related to both high-intensity and low-intensity encounters, and therefore captures the efficiencies CMS seeks. While the PRT recognizes that CMS believes there are further efficiencies to be gained, we think that all the inherent efficiencies may only be more readily discernable through the analysis of more accurate data. Before making any payment system changes, the PRT urges CMS to examine the impact of the cost reporting changes to the costs generated from providers' billed charges reduced to costs from the claims data for at least a two- to three-year period. This has been CMS' traditional approach to making other coding or data changes before creating new APCs. These data should be examined in detail before CMS moves forward with the creation of imaging composite APCs"*.

Unfortunately, CMS did not accept our suggestion to examine the cost reporting changes' impact and, instead, moved forward with the introduction of multiple imaging Composite APCs in 2009. We remain concerned about the payment rates associated with these Composites when more than two imaging procedures are provided on the same date of service. We urge, once again, that CMS analyze the frequency and median cost data associated with more than two imaging procedures from the Composite imaging families that occur on the same date of service.

The PRT also continues to support RTI's recommendation to create new, separate standard cost centers for CT and MRI, and to analyze the impact and related realized cost efficiencies, before creating or implementing any new composite APCs. We still believe that CMS' use of the claims data is impacted by the variation in how providers report their cost via the diagnostic radiology cost center on the Medicare cost report. Therefore, the PRT urges CMS to adopt RTI's recommendation to create new, separate, standard cost centers for Imaging Modalities, and specifically for CT and MRI, as part of its cost center updating process.

The RTI report raised serious concerns about the CCRs related to CT and MRI when these processes are separated from the Diagnostic Radiology cost center. It is clear that large variations exist in how providers structure and report both charges and costs. We believe this variation continues to impact the reported claims data CMS uses to develop APC payment rates for CT and MRI services, including the payment rates associated with the multiple imaging Composite APCs. The PRT believes that CMS must standardize the reporting of costs for both advanced imaging technologies and other problematic cost centers before making any methodological changes to the payment system. The creation of new standard cost centers and

the adoption of the revised revenue code to cost center crosswalk proposed by RTI¹ — and supported by the PRT — would result in significant shifts in the underlying CCRs for all APCs, thereby impacting all relative weights and payment rates across all services over time.

OBS/Extended Assessment and Management Composites (APCs 8002 and 8003)

In the 2010 OPSS Proposed Rule, CMS stated its intention to adopt the APC Panel recommendation to provide clarifying guidance regarding “start time” and the proper reporting of HCPCS G0378 in the Medicare *Claims Processing Manual* (Pub. 100-4), Chapter 4, Sections 290.2.2 through 290.5. The PRT believes that an *additional* issue should also be addressed when this clarification is published in a quarterly transmittal.

The PRT has learned that there are numerous interpretations being provided by contractors related to reporting Condition Code 44. In September 2004, CMS issued *Transmittal 299*, which outlined criteria for reporting Condition Code 44 when an inpatient order has been written by the physician but, after further review of the case, the patient’s clinical status is deemed not to meet inpatient criteria. The transmittal clearly indicated that this patient’s status can be changed from “inpatient” to “outpatient”. The PRT requests CMS to issue further guidance on the applicability of observation services and reporting of observation hours/time in such cases.

When a physician changes an order from “inpatient admission” to “observation services”, the patient’s status changes from inpatient to outpatient. Providers believe that it is appropriate for a physician to void the order for the inpatient service and correct the medical record to reflect the observation level of service. This resembles the CMS-approved process for the reverse scenario, by which physicians can correct a record to indicate that an inpatient level of service was appropriate. In the case of an inpatient level of service, claims reporting restrictions require the inpatient claim have a room and board service billed in order for the claim to be submitted to the FI. The parallel, in the PRT’s view, is for the physician to void the inpatient order and replace it with an order for observation services rendered from the beginning of the stay. Thus, the entire stay would be considered as an observation service because the physician’s original intent, which was based on the clinical situation, was for an inpatient level of service. Active monitoring is provided regardless of the status of the patient. The PRT respectfully requests that CMS issue clear guidance that observation service’s appropriate start time is the time indicated in the medical record when the service originally began. In other words, with supporting documentation of observation services rendered during the stay, the observation order should be retroactive to start at the beginning of what was amended to be an outpatient stay, rather than to start when the physician wrote the “corrected” order for observation services.

Ambulatory Surgery Centers (ASCs)

The PRT notes that, in the 2009 final OPSS rule, CMS specified that freestanding ASCs may keep patients up to 23 hours after a procedure in order to enable them to recover. We understand that there is an ASC requirement for a post-anesthesia assessment by a physician.

¹ Kathleen Dalton et. al., Refining Cost to Charge Ratios for Calculating APC and MS-DRG Relative Payment Weights, RTI International, 2008.

There does not appear to be, however, any required time frame in which this assessment must be performed prior to the patient's discharge from the ASC. The assessment could be written two hours after the surgery or two hours before the patient is discharged (which, beginning in CY 2010, could be up to 22 *hours* post-surgery). The 2010 proposed rule allows patients to stay at an ASC for up to 24 hours, but does not make any requirements for physicians to be either on-site or immediately available. In addition, there appears to be no direct physician supervision requirement for ASCs' post-acute care units (PACU). The PRT is concerned that patients may recover overnight in ASCs with no physician in attendance — and hence with no physician supervision.

This is of great concern, given the detailed oversight that CMS expects for physician supervision in the hospital outpatient setting that includes a significant amount of ambulatory surgery. We question why the same supervision requirements are not applied to ASCs. The PRT respectfully requests that CMS clarify this issue in the final 2010 OPPS/ASC rule. These variations in requirements create enormous inequalities between hospitals and ASCs – which provide many of the same services to beneficiaries.

Additionally, the PRT remains concerned with CMS' continued delay in requiring ASCs to participate in the hospital outpatient quality initiative. We understood CMS' delayed implementation of this requirement in 2008, which resulted from ASCs' migration from their existing payment system to the new payment system. But, we believe that further delays are unwarranted, since the payment system migration is almost complete. Furthermore, implementation of the quality initiative has almost no impact on ASCs' familiarization with the APC/OPPS reimbursement system. We believe that ASCs must be held to the same outpatient quality standards as hospitals are; we also believe that ASCs will not voluntarily suggest to CMS what these quality initiatives should be. Many of the surgical initiatives that have already been created for hospitals have merit in the ASC setting, since these facilities provide many of the same types of surgical care as hospitals do. We urge CMS to make a proposal to implement the outpatient quality initiative using applicable measures for ASCs beginning in calendar year 2011.

Hospital Outpatient Visits

The PRT appreciates CMS' continued analysis of the claims data and response to the cost differences seen between Level 5 Type A and Type B Emergency Department (ED) visits and supports CMS' creation of a new APC for the Type B Level 5 ED visit. The PRT notes, however, that CMS has not proposed any other changes with respect to hospital evaluation and management (E/M) visit codes or national guidelines. We are concerned about several issues concerning the unique challenges hospitals face in conforming to CPT concepts and principles that do not reflect the OPPS/APC system's nature. We share these concerns again with the hope that changes might be forthcoming.

We request that, at a minimum, CMS fully examine the administrative burden faced by providers in maintaining the definition of new and established patients for the sole purpose of reporting an evaluation and management visit CPT code. In the Proposed 2010 Physician Fee Schedule (PFS) rule, CMS admitted that physicians face difficulties in reporting consult codes, and has proposed eliminating these codes. The PRT is amazed that CMS proposes to eliminate a

set of CPT codes simply because they cause “administrative” burden for physicians, yet fails to extend the same understanding to hospitals, which are forced to use CPT codes that are not only administratively burdensome but also inapplicable in the hospital setting. We are deeply concerned by this variance in treatment between physicians and hospitals.

In March 2006, the Office of the Inspector General (OIG) published a report, “Consultations in Medicare: Coding and Reimbursement” (OEI-09-02-00030), of its audit of Medicare payments to physician practices for consultation CPT codes. This audit found that: *“Approximately 75 percent of services paid as consultations did not meet all applicable program requirements (per the Medicare instructions) resulting in improper payments. The majority of these errors (47 percent of the claims reviewed) were billed as the wrong type or level of consultation. The second most frequent error was for services that did not meet the definition of a consultation (19 percent of the claims reviewed). The third category of improperly paid claims was a lack of appropriate documentation (9 percent of the claims reviewed).”*

In the CY 2010 proposed PFS rule, CMS notes that it has engaged in many attempts to educate physicians on appropriate reporting of these codes, issued multiple education articles on this subject, worked with the AMA CPT committee, and continued to request clarification from physicians. CMS stated, *“We continue to hear from the AMA and from specific national physician specialty representatives that physicians are dissatisfied with Medicare documentation requirements and guidance that distinguish a consultation service from other E/M services such as transfer of care. CPT has not clarified transfer of care. Therefore, many physician groups disagree with our requirements for documentation of transfer of care. Interpretation differs from one physician to another as to whether transfer of care should be reported as an initial E/M service or as a consultation service.”*

CMS continued, *“Beginning January 1, 2010, we propose to budget neutrally eliminate the use of all consultation codes (inpatient and office/outpatient codes for various places of service except for telehealth consultation G-codes) by increasing the work RVUs for new and established office visits, increasing the work RVUs for initial hospital and initial nursing facility visits, and incorporating the increased use of these visits into our PE and malpractice RVU calculations. We believe the rationale for a differential payment for a consultation service is no longer supported because documentation requirements are now similar across all E/M services.”²*

As noted in the documentation from the MPFS proposed rule, CMS agrees with the OIG findings and used them as the basis for its proposal to delete consultation codes for Part B physician reporting. Were the OIG to conduct a similar audit of hospitals’ reporting of new and established evaluation and management visit codes under OPFS, we believe that similar issues would be identified concerning both the accuracy and the administrative burden associated with delineating new vs. established patients. The concept has simply been carried-over from the physician office setting, and has no relevance in the hospital setting. We have submitted this view to CMS on numerous occasions. While CMS perceives median cost differences between new and established patient visit codes, the PRT believes, and has stated repeatedly, that these

² 74, Federal Register, No. 132 / Monday, July 13, 2009 / Proposed Rules pp 33551 – 33553.

differences are merely random. As we have noted before, some providers continue to report either CPT code 99201 or 99211 as a “default code” when reporting clinic visits. This practice becomes apparent upon review of the median cost data for visits, which indicate that a Level 1 clinic visit has a higher median cost than a Level 1 Emergency Department visit. Use of 99201 and 99211 as default codes raises the costs generated by the claims data for these codes, and artificially impacts the overall APC rate setting process.

The PRT acknowledges CMS’ reluctance to use only one set of CPT codes (either the new or established patient visit codes) for hospitals to report all of their outpatient clinic visits because the actual code descriptors indicate the patient to be “new or established” and CMS has instructed hospitals to follow the CPT descriptions. CMS continually states that rate-setting should be based on hospital claims data. Yet, CMS makes rate-setting decisions based on data that are invalid and inaccurate due to the administrative burden stemming from hospital providers’ requirement to report a visit based on the “physician’s” definition of new versus established patients.

The PRT notes that, since the advent of the OPSS, CMS has stated that: *“the CPT definition for clinic visits does not reflect the hospital services and resources provided”* — a statement with which hospitals enthusiastically agree. The PRT continues to believe that the length of time between patient visits to the hospital has no bearing on the services or resources provided in a specific visit. The fact that a patient has been seen in a hospital outpatient department, or has been admitted as an inpatient, “within the past three years” has no impact on the resources required to evaluate, manage, and treat the patient’s current condition.

In addition to this information’s lack of relevance, there are significant operational issues involved with implementing the “three-year” definition, which we have commented on in the past. Information about whether a patient has had a visit at the hospital in the last three years is not necessarily available when he or she presents to an outpatient department. Medical information is covered under HIPAA law and is protected health information (PHI). For this reason, many facilities do not retain these data in easily accessible areas of their computer systems after a certain length of time. HIPAA privacy concerns also often limit hospital personnel’s ability to view a patient’s previous admission history. In fact, many facilities actually limit the ability to view past visits within their systems.

The PRT remains deeply concerned about the impact of this reporting methodology and RAC audits. CMS has instructed hospitals to report resource consumption through the use of an internal mapping system based on the resources expended. But, these resources are neither mapped nor related to the timing of the patient’s last visit at a specific facility. The PRT offered specific examples of this situation in our comments on the CY 2009 proposed rule, and we repeat them below for consideration by CMS:

Example 1 – “Patient A” is seen in a hospital ED for services related to a fall. An evaluation is completed and diagnostic tests are ordered and performed. Patient A is diagnosed with fractured ribs, receives a rib belt, a prescription for pain medication and is released. Three weeks later, Patient A is seen for the first time in the hospital’s wound care clinic with a new, stage III ulcer of the right leg and a new, stage II ulcer of the right

foot. The wounds are evaluated, debrided, treated, and dressed. Education is provided and a follow-up visit is scheduled. “Patient B”, who has never received services at this hospital, is seen in the wound care clinic with a stage I ulcer on the toe. The wound is evaluated, cleaned with an enzyme cleaner, and dressed. Patient B is scheduled for a follow-up visit.

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

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

In this example, Patient C is considered a “new patient” for the initial encounter when the lab work was drawn (even though a “new patient” E/M visit CPT code was not reported). At the second visit, the resources expended are much more intense, but the visit would have to be reported as an “established” patient visit to be in compliance with CMS’ current three-year delineation.

When it was first proposed, providers resisted implementing hospital-specific HCPCS codes at a different time than National E/M Guidelines. Creation of national guidelines has not been forthcoming, however, and CMS is receiving faulty claims data since hospitals do not uniformly report the new patient and established patient visit codes. The PRT supports the elimination of the distinction between new and established patient visit codes and the use of HCPCS codes to represent hospital resources expended for E/M visits. CMS did not support this solution, however. The PRT would like CMS to solicit providers’ comments on this issue through a proposed rulemaking process. We believe that the majority of providers will support hospital-specific HCPCS G-codes that do not distinguish between new and established patient visits. We suggest that — due to the burdens associated with applying the definition of new vs.

established patients, and the lack of documentation in the record pertaining to the status with respect to the date of the patient’s last visit — an audit by the OIG, MAC, and/or RAC will not be able to use the documentation to determine if the visit is new or established. They will be able to map the level of resources used based on documentation with the facility’s internal resource tool, but will not be able to validate the time-frame of the patient’s last visit.

In fact, it is unclear how the accuracy of this information could be validated, other than by using the CWF to determine if a visit has occurred within the last three years. Just as physicians have had issues with implementing the specific elements of consultation codes’ definition, this is applicable to hospitals for new vs. established patient classifications. CMS is setting a precedent on the physician side due to operational issues and should address the non-physician provider community’s burden as well. Because this area is a target for both RAC and OIG (based on already-documented audits and FAQs on CMS’ website), and there is a burden of proof for reporting the correct code, we believe it is imperative for CMS to query outpatient providers concerning G codes that are specific to hospital outpatient visits. CMS should investigate whether providers understand the entire picture – not just explore whether providers want G codes for an outpatient visit or not.

Physician Supervision

Direct Supervision of Therapeutic Services

The PRT appreciates CMS’ inclusion of non-physician practitioners (NPPs) to provide direct supervision within the scope of their practice acts. We believe that CMS should also include Licensed Clinical Social Workers (CLSW) and psychologists as NPPs who are capable of supervising outpatient hospital services within the scope of their practice acts, such as mental health services. The inclusion of NPPs is especially important for beneficiary access in critical access hospitals (CAH) and hospitals in rural and physician shortage areas where nonphysician providers are integral to hospital operations. The PRT does have several concerns about other proposals CMS has made related to physician supervision in the 2010 OPPTS proposed rule and appreciates the opportunity to provide detailed comments to CMS. These concerns are discussed below.

1. Guidance Prior to 2009/2010 – Unclear and Inconsistent

Under the Medicare statute, hospitals are allowed to provide services “as an integral though incidental part of a physician service”. Hospitals understand the necessity of compliance with the “incident to” rules specifying “*services and supplies must be furnished on a physician’s order and delivered under physician supervision*” as stated in the *Medicare Benefit Policy Manual* Section 20.5.1. Hospitals further understand the requirement that, “*during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often enough to assess the course of treatment and the patient’s progress and, where necessary, to change the treatment regimen.*” This is not a new concept and hospitals agree that this provision describes good quality care for medically appropriate and necessary services with the physician directing and being involved in the ongoing treatment of the patient.

In the preamble of the April 2000 OPPS final rule with comment period (65 FR 18525), CMS discussed physician supervision furnished in a hospital department and stated, “*We assume the direct supervision requirement to be met as we explain in section 3112.4(a) of the Intermediary Manual.*” CMS went on to state that “*We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital.*” In the CY 2009 OPPS/ASC proposed rule and final rule with comment period, CMS indicated that “*Some stakeholders may have misunderstood our use of the term ‘assume’ in the April 2000 OPPS final rule with comment period, believing that our statement meant that we do not require any supervision in the hospital or in an on campus PBD for hospital outpatient therapeutic services, or that we only require general supervision for those services.*”³

The PRT objects to the assertion that hospitals “misunderstood” CMS’ use of the term “assume”. The Merriam-Webster Online Dictionary defines “assume” as: “to take as granted or true”.⁴ Hospitals took as true their “assumption” that, because services were provided within the hospital, supervision requirements were met. We suggest that CMS’ imprecise wording has been chiefly responsible for providers’ misconceptions. In an August 18, 2005 report entitled, *Review of Medicare Outpatient Cardiac Rehabilitation Provided by Hospitals, (A-05-03-00102)*, the Office of the Inspector General reported variability in the way Cardiac Rehabilitation programs complied with physician supervision and incident to regulations, and attributed this variability to: “inconsistent guidance in the Medicare Coverage Issues Manual, Hospital Manual, and Intermediary Manual.”

Between 2000 and 2008, CMS and Medicare contractors issued little guidance or instructions to clarify this terminology. In response to hospital provider inquiries about physician supervision in relation to new therapeutic services being initiated, many Medicare contractors responded: “we assume the direct supervision requirement to be met on hospital premises” without further comment or additional explanation. The PRT submits that, given the lack of clarification provided by CMS and contractors, even after the publication of the OIG’s audit, hospitals consulted the Conditions of Participation (CoPs), the *CMS Manual*, and other CMS guidance in order to create a working process for meeting physician supervision requirements.

In the *Medicare General Information, Eligibility and Entitlement* manual (Publication 100-01), Chapter 5, Section 20, a hospital is defined as “an institution which is primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons; or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.” The instructions go on to state that “every patient must be under the care of a physician” but do not provide further instruction.

Section 482.54 of the Hospital CoPs discusses outpatient services. This section states, “If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice”; “services must be appropriately organized and integrated with inpatient services”; and the hospital must “have appropriate professional and

³ 73 Federal Register 41518 through 41519 and 73 Federal Register 68702 through 68704.

⁴ Add citation and website.

nonprofessional personnel available.” These requirements are easily interpreted that physician supervision arrangements for outpatient services should be consistent with those provided to inpatients. Based on this citation, the Hospital CoPs do not require the physical presence of a physician at all times that therapeutic services are occurring on hospital premises.

Section 482.12 (f) of the CoP discusses emergency services, stating “(1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55;(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate... (3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.”

Section 482.55 of the CoP defines emergency services, stating “the hospital must meet the emergency needs of patients in accordance with acceptable standards of practice” and defines these standards of practice: “if emergency services are provided at the hospital — (1) The services must be organized under the direction of a qualified member of the medical staff; (2) The services must be integrated with other departments of the hospital; (3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.” This section also defines the personnel standard for these services by stating that: “(1) the emergency services must be supervised by a qualified member of the medical staff; and (2) there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures”.

The PRT wholeheartedly agrees that patients should be under the care of a physician. We submit, however, that prior guidelines and instructions allow hospitals to decide the mechanisms and operational procedures to use to insure the safe and quality provision of care. In response to the supervision requirements, hospitals have a variety of arrangements to provide supervision of therapeutic outpatient services, some of which may be called into question with the new prescriptive instructions proposed for CY 2010. Many of these arrangements are effectively provided with no additional cost to the hospital or to the Medicare program. We believe that CMS should be concerned about ensuring what we believe to be the real question: whether hospitals have an established operational process in place to insure the provision of safe and quality care to all patients and to manage any adverse situation that arises.

The PRT is concerned that CMS is applying stringent and prescriptive requirements for direct supervision of therapeutic services provided in the hospital outpatient setting — even more stringent than what is prescribed in the inpatient setting or for ambulatory surgery centers. These stringent requirements will directly increase the cost to provide outpatient hospital services.

We request that CMS change the way that physician supervision for outpatient therapeutic services is discussed and clarify to the OIG and all CMS contractors that may audit hospital outpatient services that, prior to the CY 2010 OPSS rule, instructions related to direct supervision of outpatient therapeutic services were not clearly outlined and that this new

verbiage is a revised and stricter definition rather than merely a restatement of previous policy.

2. Definition of “Immediately Available”

The PRT is extremely concerned with CMS’ definition of “immediately available” to mean “without interval of time.” In fact, we find the term “without interval of time” to be very alarming. Availability of a physician to respond to patient needs should be defined for outpatient therapeutic services similarly to the time frame defined for overall hospital operations. The Hospital Conditions of Participation uses the term “in accordance with acceptable standards of practice”. Unless the hospital has a physician stationed directly at the side of each patient throughout every procedure or non-procedural visit (e.g. an encounter reported only with a “visit” HCPCS code), it will be impossible to meet the standard of “without interval of time”. Overzealous auditors would be free to interpret *any* direct supervision arrangement as being non-compliant if the physician has to move from one place to another to attend to the patient.

The PRT believes the application of this phrase makes requirements for outpatient therapeutic hospital services *more stringent* than those for acute inpatient services or for hospital code-blue response situations. Hospitals have strict policies and procedures that dictate that care of the patient begins at the time a code-blue is called. In a code-blue situation, the patient is cared for by hospital staff at the initiation of the event regardless of whether the patient status is inpatient or outpatient. The code team, consisting of a physician, respiratory therapists, lab technicians, and ICU-trained nurses, is paged and responds rapidly to the location of the event. The physician understands and agrees that he or she is responsible to respond in this situation.

The reality is that there will *always* be some interval of time required for physicians to get from one place to another, whether the distance is just down the hallway or up one floor in the hospital. The phrase “without interval of time” infers that the physician/NPP who is providing supervision must be in the same room as the patient. There is simply no other way to avoid the passage of an “interval of time”. This directly conflict with CMS’ other statements in the proposed rule, indicating that the physician/NPP does *not* have to be in the same room, but must be within the four walls of the hospital in order to be “immediately available.”

Over time, hospitals have absorbed the expense of providing many therapeutic services that are “costly” and less lucrative for physicians to provide in private office settings. The PRT has noted in prior comment documents that these services often operate with a low profit margin. In order to balance this reality while continuing to provide cost-efficient outpatient care for Medicare beneficiaries, hospitals have established numerous outpatient clinics (i.e., wound care, infusion centers, etc.) to provide appropriate sites of care for outpatient therapeutic services. The operational impact of requiring direct supervision “without interval of time” would create the need for hospitals to place a physician/NPP in every outpatient therapeutic department at all times. If hospitals must resort to coverage of this level, the cost of providing outpatient care will significantly increase.

We believe that, if a hospital has documented arrangements with a physician to be on the premises and available when needed, this arrangement should be sufficient for the facility to meet the supervision requirements (assuming all other requirements are also being met, of

course). Because of the contradictions in CMS' framing of this issue in the proposed rule, the PRT believes the subject must be clarified further in the final rule. For the reasons stated, the PRT believes that CMS should not include the phrase "without interval of time" in the final physician supervision policy for CY 2010. Even under EMTALA, hospitals are allowed discretion to make appropriate "on call" arrangements for emergent care. Like Emergency Departments, hospitals should be allowed flexibility in arranging direct supervision of their outpatient therapeutic services.

3. CAH and Rural Hospitals

It is of vital importance to acknowledge the impact of the newly proposed language on physician supervision on both CAH and rural hospitals' operations. These facilities are unlikely to have a physician/NPP on the premises 24/7. CMS has specific requirements for these types of hospitals that are tailored to their specific circumstances. These facilities would implement their prescribed policies in order to handle the situation as required for hospitals of that classification. We are concerned that the intersection of the EMTALA rules and the supervision rules will negatively impact many rural and CAH hospitals, possibly to the extent that CAH providers will be unable to operate their Emergency Departments at night.

For CAH hospitals, adding the prescriptive language "without interval of time" may require the hospital to close altogether, severely hampering beneficiaries; access to care. In many CAH hospitals, physician coverage is maintained by one or two physicians or non-physician staff for coverage. Under current law, registered nurses are allowed to provide the Medical Screening Exam (MSE), enabling patients to be screened (and possibly treated) with therapeutic services before the physician arrives on-site. Hospitals in rural areas practice in this manner today while following rules for EMTALA and providing safe, quality care for patients in rural settings.

For example, a patient is scheduled to receive IV antibiotics three times a day for five days to treat a serious infection. Some CAH hospitals lack the resources/physician practitioners to provide 24/7 practitioners on the premises. If CAHs cannot provide "direct supervision" as defined in the proposed rule, they would be required to send patients to a larger hospital. In this infusion example, patients would need to be sent to a larger hospital in the evening hours for the 8:00 p.m. infusion. This is just one small example, given the nature of "therapeutic services". We would be happy to provide additional examples, if requested.

If CMS implements the proposed definition and expectation of direct physician supervision occurring without an interval of time, the PRT is gravely concerned that these facilities will be unable to operate their emergency rooms or outpatient clinics, or to provide any hospital therapeutic services. Such a change would endanger access to outpatient services, especially in rural and CAH hospitals. It would additionally burden Medicare beneficiaries, who will be forced to travel long distances to larger, more metropolitan hospitals in order to receive outpatient therapeutic services that are compliant with the new direct supervision requirements.

In summary, if CMS' final rule includes the language requiring a response "without interval of time", hospitals will be forced, at a minimum, to provide therapeutic services through the more costly Emergency Department and/or to experience increases in physicians admitting

patients to the inpatient setting. When this shift occurs, it will cause further congestion in Emergency Departments and potentially increase the number of inpatient admissions.

The PRT asks CMS to discontinue the proposal to define “immediately available” as “without interval of time.” Using the terminology that hospitals should “meet emergency needs of patients in accordance with acceptable standards of practice” allows all facilities (whether they are small or large, rural or urban) to develop policies and procedures that meet their patients’ needs and are operationally feasible for the specific hospital.

4. Definition of “In the Hospital”

The PRT has concerns with CMS’ requirement that the supervising physician/NPP must be “in the hospital”. The PRT firmly disagrees with the proposed definition of “in the hospital” as noted in the proposed rule: *“in proposed new paragraph §410.27(g) to mean areas in the main building(s) of the hospital that are under the ownership, financial, and administrative control of the hospital; are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital’s CMS Certification Number (CCN).”* The PRT strongly recommends that CMS strike this language from the proposal.

Hospitals have many arrangements with physicians who lease space and bill as freestanding clinics and are located on the same hallway or in the same building as hospital outpatient departments. Hospitals have policies for physician call schedules by which the physician would respond to any emergency required. These physicians have agreed to respond to and supervise therapeutic services. Some hospitals have positioned their outpatient departments to be physically attached to physician offices or clinics for the sole purpose of creating easy access to a physician when needed. This physician office and the clinic may, or may not, be wholly owned and operated by the hospital; regardless, the physician is sufficiently capable of responding to patient needs and providing direct supervision.

CMS must allow some flexibility in hospitals’ arrangements to meet the supervision requirements for their patients’ care. Adding stringent requirements related to ownership, financial and administrative control, operations and billing, causes great concern over hospitals’ ability to continue many therapeutic services. It jeopardizes the facilities’ ability to meet the needs of their patient population and to maintain beneficiaries’ access to care. The PRT fails to understand the relationship between the ownership of a physical space and the CCN used to report services provided in that space, and whether the physician supervision requirements are being met.

As noted above, hospitals have expended great consideration in creating arrangements for providing direct supervision and we believe CMS should allow those arrangements to continue. For example, it is common for physicians to lease space in a hospital building that may be across the hall or one floor below an outpatient department providing therapeutic services. In this case, we believe the physician is easily able to provide supervision as they are readily available. Another example is that supervision may be provided by a physician who is located in his/her office space across the street from hospital outpatient therapeutic clinics and can again easily provide the direct supervision required; any emergent issues would be addressed under the hospital’s usual emergency procedures.

CMS' proposed, restrictive definition of "in the hospital" would appear to invalidate these arrangements without improving either supervision or quality of care. To truly meet the total definition proposed by CMS, physicians will be required to be in each hospital outpatient department, in case they are needed. Physicians are unwilling to provide their undivided attention in this way and to focus only on supervising hospital services without compensation — but hospitals lack the financial resources to provide this level of staffing in all of their settings. For this reason, this restrictive definition will shift services away from hospital outpatient facilities as physicians choose other sites of care, such as the ED or inpatient beds. If the goal of this restrictive language is to steer therapeutic services back to the physician office setting and away from the hospital outpatient department (and OPSS payment), the effort is likely to fail. The PRT doubts that physicians' offices will be able to handle the volume or have the necessary resources to provide the therapeutic services currently delivered by hospitals. History indicates that these patients will be sent to a hospital Emergency Department with orders for therapeutic services or be admitted as inpatient for the services.

The PRT strongly recommends that CMS strike the amendment to paragraph §410.27(g) that defines "in the hospital" to mean areas in the main buildings(s) of a hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital's or CAH's CCN. The PRT recommends that CMS reconsider the "restatement and clarification" of the current policy and articulate that this is *new* language that will burden hospitals, particularly rural hospitals and CAH. CMS must understand that finalizing such stringent requirements will jeopardize beneficiaries' ability to receive care in the most appropriate setting.

Summary

In summary, the PRT is very concerned that CMS is being ever more stringent and prescriptive in how it requires hospitals to meet the direct supervision requirement for therapeutic services provided in the hospital outpatient setting. The proposed guidelines are far more stringent than those required in either the inpatient setting or ambulatory surgery centers. The PRT strongly recommends that CMS strike the language regarding the physician's specific location and the requirement that no interval of time shall elapse.

Should CMS finalize the proposed changes, however, it is critical that the effective date be clearly stated as January 1, 2010. Without this clarification, CMS puts audited hospitals at great risk over the provision of past outpatient services. Until now, definitive restrictions on supervision of outpatient therapeutic services have not existed. Hospitals have worked diligently to create safe and high-quality environments in which to provide beneficiary care; they should not be penalized now, by CMS making these new definitions retroactive. We further request that CMS rescind Transmittal 101, Change Request 6320, Medicare Manual 100-02 (January 16, 2009). The PRT pleads for CMS' consideration and acknowledgement following review of the robust comments CMS sought during this comment period.

Supervision Requirements for ASCs

The PRT is concerned as stated above under the ASC discussion that there appears to be no direct physician supervision requirement for ambulatory surgery centers (ASCs) related to care provided in the post-acute care unit (PACU). The conditions of participation and proposed rule merely require a surgeon to create a discharge summary before the patient is released. Because there is no discussion of the timing of this summary, the assessment could be written two hours after the surgery or two hours before the patient is discharged, which, beginning in CY 2010, could be up to 22 hours post-surgery. In addition, the 2010 proposed rule states that patients may stay at the ASC for up to 24 hours, but does not require a physician to be on-site or immediately available. This policy creates significant inequalities and variations in the requirements for physician supervision between hospitals and ACS facilities, which provide many identical services.

Diagnostic Services

The PRT offers two recommendations with respect to outpatient diagnostic services. First, we recommend that CMS add the Physician Fee Schedules tables on diagnostic supervision requirements to the OPSS proposed rules as additional addenda. Doing so would make the information readily available to those who are searching for information under the Medicare website's hospital OPSS section. Since the supervision requirements are defined in the MPFS by CPT code, ideally, CMS could add a column in Addendum B that would reflect the supervision status and enable providers to quickly note the diagnostic services subject to the PFS supervision rules. Second, we recommend that CMS provide hospitals with additional education on how to determine diagnostic supervision requirements. This could be accomplished through transmittals, policies, and/or by including the PFS files as additional OPSS addendum the proposed and final rules.

Inpatient-Only Procedures

The inpatient-only list was originally created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the hospital outpatient prospective payment system (OPSS). Since the advent of the OPSS, CMS has made changes to the list when clinical information substantiated the safe provision of care in the outpatient setting for beneficiary-age patients. The PRT wishes to highlight, however, a major problem with the situation: the inpatient-only list is not binding on physicians. Since a physician can receive payment for performing an inpatient-only procedure on an outpatient basis, there is absolutely no incentive for physicians to be concerned about hospital reimbursement (or lack thereof) from CMS. This fact underscores another problem: *physicians* determine the care setting in which a procedure is performed — not hospitals. Hospital providers have consistently raised this issue during every comment period since OPSS' initiation.

In past final rules, CMS responded to hospital providers' concern by noting that it believes “*appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion.*” The PRT members (like other providers) have continually provided education to physicians, but this

alone has not resolved the problem, nor is it likely to. Physicians believe that these procedures can be performed, and are performed, on an outpatient basis for beneficiary-age patients. In fact, they perform these procedures successfully without compromising the patient’s quality of care. Moreover, physicians are not concerned about whether hospitals are paid or how they are paid. Hospitals and CMS provider education staff have made little, if any, progress changing physician practices with regard to the hospital inpatient-only list. For this reason, the PRT requests CMS to carefully and fully consider applying the inpatient-only list to the Part B providers as well. This would be no different than the requirements for Ambulatory Surgery Centers (ASC): physicians cannot perform a procedure in an ASC unless it is on the approved procedures list. The PRT does not understand why CMS believes that applying the inpatient-only list to physician services is any different.

Remove Procedures from the Inpatient Only List

The PRT requests that CMS remove a number of procedures from the inpatient-only list and allow them to be reimbursed under APCs when provided in the outpatient setting. The PRT has carefully reviewed the procedures listed in the table below, which we believe can be safely and appropriately provided to Medicare patients in the outpatient setting. Our research and investigation indicate that clinical criteria sets (such as Milliman Care Guidelines) support the safe provision of these procedures in outpatient settings. In addition, several PRT hospitals have physicians providing these procedures safely in the outpatient setting for non-Medicare patients who are in the same age group as the Medicare population. The PRT respectfully requests that CMS move these procedures off of the inpatient-only list and place them in a clinical APC for reimbursement beginning on January 1, 2010.

Where “None” is listed in the Milliman Recommendation column, it signifies that no specific criteria in Milliman indicate that no recommendations are found in Milliman for that specific procedure. Where “Ambulatory” is listed, it indicates that there are situations in which the identified procedure could be safely performed on an outpatient basis. Finally, where “Inpatient” is listed, it indicates that there are certain situations where an inpatient admission would be required based on the clinical information noted.

CPT/HCPCS	Code Description	Milliman Recommendation
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2	Ambulatory for 1-or 2-level fusions, fusions at or below C4-5, structural allograft, estimated operative time < 2 hours, no myelopathy or subjectively large neck, and presence of an appropriate discharge environment. Inpatient: Multilevel fusions may require an overnight stay
22858	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)	None
22851	Application of intervertebral biomechanical device, threaded bone dowel, to vertebral defect or interspace	None
37182	TIPS procedure	None

37215	Transcatheter placement of intravascular stent, cervical carotid artery, percutaneous, with distal embolic protection	None
44950	Appendectomy	Ambulatory for otherwise healthy w appropriate discharge plan/follow-up and home care support; Inpatient for toxicity, comorbid/complications or inability to arranged adequate OP support.
32662	Thoracoscopy, surgical; with excision of mediastinal cyst, tumor, or mass	Ambulatory for pleural or pulmonary biopsy and Inpatient for most VATS procedures
60505	Parathyroidectomy or exploration of parathyroid(s); with mediastinal exploration, sternal split or transthoracic approach	None
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord) single vertebral segment; lumbar	Ambulatory for patients undergoing limited and minimally invasive procedures. Inpatient for non-elective and extensive surgery patients.
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)	Ambulatory
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	Ambulatory for patients undergoing limited and minimally invasive procedures. Inpatient for non-elective and extensive surgery patients.

When procedures are not treated consistently by Part B, physicians *do not know* whether to admit the patient or treat the patient in the outpatient setting. If the physician deems that the outpatient setting is appropriate, there is no incentive for him/her to admit the patient. An example is the following: CPT code 63075 (“*Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace*”) is a status T indicator that is reimbursable under OPSS in the outpatient setting. CPT 63076 (“*Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)*”) is an add-on code that must be reported with CPT code 63075. Because CPT code 63076 is on the inpatient- only list, however, it causes the entire claim to be rejected. In this case, the physician would reasonably argue that a second level was done and there was no difference in the safety or care of the patient, making inpatient admission unwarranted. The physician would not understand the need for an inpatient admission because, although a second interspace was treated, there were no additional care requirements.

Intra-operative Procedures

The PRT would also like to comment on the 2009 OPSS Final Rule content about hospital providers’ reporting and receiving reimbursement for procedures which appear on the inpatient-only list that are performed intra-operatively due to the physician’s assessment of the patient’s condition. While we appreciate CMS’ acknowledgement of the PRT’s concerns in this area, we fear that the agency may not have fully understood our issues.

Specifically, we understand CMS’ reasons for maintaining the inpatient-only list. We agree with CMS that, if procedures from the inpatient-only list are scheduled for outpatient

settings, it is reasonable for Medicare to deny the entire claim and not reimburse the hospital. Our concern, however, stems from the fact that there are situations when an appropriate and scheduled outpatient procedure result in unforeseen complications that require immediate attention through the provision of an intra-operative procedure that appears on the inpatient-only list. In such a situation, the inpatient-only procedure performed is *truly* unscheduled since it is only done to address a condition or problem that has arisen during the scheduled outpatient procedure. CMS should recognize that such patients are unlikely to be admitted to the inpatient setting, when they can easily be treated in the outpatient setting

In addition, such an intra-operative procedure is not determined to be an inpatient-only procedure until *after* the surgeon dictates the operative report and the patient has been discharged from the outpatient setting. Hospitals do not concurrently code surgical procedures, nor are these procedures coded immediately after surgery or even while the patient is in the post-anesthesia recovery unit. The necessary documentation for coding these types of procedures is contained in the operative report, and physicians do not dictate these reports in “real time”. While hospitals work to educate physicians about the inpatient-only procedure list and explain that CMS only reimburses for these procedures when provided in the inpatient setting, physicians do not take these facts into consideration when treating and managing a patient. The bottom line is that, if a physician feels the patient’s situation can be safely managed in the outpatient setting, that is where the care will be provided — regardless of whether the intra-operative service being conducted is on the inpatient-only list or not.

The PRT believes that CMS may lack information on the types of inpatient-only procedures performed in hospital outpatient departments, since claims that include an inpatient-only procedure are returned to the provider via the Outpatient Code Editor (OCE). For this reason, CMS may lack sufficient data to make fully informed decisions about inpatient-only procedures provided in the outpatient setting. Unless we are mistaken, CMS never sees hospital claims data that include inpatient-only procedures performed on an outpatient basis on patients who are then safely discharged by the physician. The PRT believes that CMS should allow hospitals to report their inpatient-only procedures in a manner that allows the agency to begin to collect complete and accurate data on the hospital resources expended to care for these Medicare beneficiaries in a safe, effective, and efficient manner.

This could be accomplished by changing the OCE flag to one that denies the claim, rather than rejecting it. This would allow CMS to collect hospital-specific claims data that reflect the type and frequency of inpatient-only procedures. CMS could review these data and use them with data from physicians’ and Ambulatory Surgery Centers’ (ASCs) claims in order to determine the safety and efficacy of performing certain procedures on an outpatient basis. Over time, this information could help CMS migrate procedures from the inpatient-only list.

The PRT additionally believes that CMS could provide these data to the APC Advisory Panel for discussion and review in order to determine which inpatient-only codes could be allowed in the outpatient setting. The PRT wishes to clarify that CMS could make the proposed OCE edit change without paying providers for these inpatient-only procedures at this time. In other words, the PRT feels that providers would be willing to forgo reimbursement while CMS collects and discloses data, and uses them to make data-driven decisions about the inpatient-only

list. The data can also be cross-checked with information such as mortality data, hospital readmission rates, and treatment costs in the hospital and the outpatient setting. This information would facilitate CMS’ goal of ensuring quality and efficiency in the nation’s health care system.

In summary, the PRT requests that CMS:

1. Apply the inpatient-only list to Part B providers as this is no different than the list of procedures approved for performance in an Ambulatory Surgery Center;
2. Remove the procedures listed in the table above from the inpatient-only list;
3. Change the OCE flag for inpatient-only procedure claims so they are denied for payment, but not returned to the provider (RTP), so that CMS can gather claims data on the procedures that physicians feel may be appropriately performed on an outpatient basis.

Revenue Code to Cost Center Crosswalk

The PRT has the following comments concerning CMS’ proposal to include revenue code charges in the OPSS median calculations that drive the relative weight development for each APC, the revenue code to cost center crosswalk, and revenue codes that CMS considers to be “packaged”. CMS’ proposals for all three of these areas are included in Tables 2, 3 & 4 of the proposed rule. The PRT has created a separate table, below, which summarizes our comments and recommendations. (The table is also being provided electronically to CMS as an Excel file.) Finally, we believe it would be useful for CMS to include dates in the revenue code to cost center cross-walk documents to allow hospitals and CMS to easily track the effective dates for each change.

Revenue Code	Description	Revenue Code to Cost Center Crosswalk	Packaged Revenue Code Status	Comment
0253	Take Home Drugs	No - Not included in OPSS	Not a packaged revenue code.	Note that this revenue code is not included in OPSS because take home drugs are not a benefit under Part B or OPSS. No change in current CMS assignment is requested.
0273	Take Home Supplies	Yes - Included in OPSS	Yes, packaged under OPSS when HCPCS codes are required to be reported and these services are all non-OPSS services. If non-OPSS services, charges should not be packaged.	Why are non-covered take home supplies included in OPSS when similar non-covered take home drugs are excluded? Consistency and integrity of claims data demands treating these two revenue codes the same. Charges under this revenue code should not be packaged under OPSS.

0274	Non-implantable prosthetics/orthotics	Yes - Included in OPPS	No, not a packaged revenue code under OPPS	Non-implantable prosthetics/orthotics are not covered under OPPS, but rather DMEPOS. Yes, these charges are allowed to be billed on UB04 claims by hospitals to FI/MACs, but payment is via DMEPOS fee schedule. If CMS is proposing to E14exclude DME charges under revenue codes 0290 & 0292, then for consistency, this should also apply to 0274 charges.E17
0290	DME General Classification	Proposal to exclude from OPPS	Not a packaged revenue code.	We agree with the proposal to exclude charges under this revenue code from OPPS calculations due to the fact that charges under this revenue code are not covered OPPS services.
0291	DME Rental	Currently excluded from OPPS	Not a packaged revenue code.	The current exclusion of this revenue code is consistent with exclusion of charges under revenue codes used exclusively for non-OPPS services.
0292	DME Purchase New Equipment	Proposal to exclude from OPPS	Not a packaged revenue code.	We agree with the proposal to exclude charges under this revenue code from OPPS calculations due to the fact that charges under this revenue code are not covered OPPS services.
0293	DME Purchase of Used Equipment	Currently excluded from OPPS	Not a packaged revenue code.	The current exclusion of this revenue code is consistent with exclusion of charges under revenue codes used exclusively for non-OPPS services.
0294	DME effectiveness HHA only	Currently excluded from OPPS	Not a packaged revenue code.	The current exclusion of this revenue code is consistent with exclusion of charges under revenue codes used exclusively for non-OPPS services.

0299	DME - other equipment	Yes - Included in OPSS	Not a packaged revenue code.	As CMS states, DME is not a benefit under OPSS, CMS should exclude this revenue code from OPSS in the same manner as it proposes to exclude all the other DME revenue codes.
030x	Laboratory - all classifications	Yes - Included in OPSS	Not on the list of packaged revenue codes	Why are charges under these non-OPSS revenue codes included in OPSS rate calculations? These charges are covered and paid under the Clinical Lab Fee Schedule.
0500	Outpatient Services – General Classification	Current missing & excluded from OPSS	Not on the list of packaged revenue codes, but if included in OPSS, this revenue should not be on the list of packaged revenue codes.	We are concerned with the proposal to exclude charges under this revenue code from OPSS. If an inpatient stay is billed under Part B only, charges covered and paid under OPSS may be excluded from OPSS calculations.
0509	Outpatient Services - Other Outpatient	Current missing & excluded from OPSS	Not on the list of packaged revenue codes, but if included in OPSS, this revenue should not be on the list of packaged revenue codes.	We are concerned with the proposal to exclude charges under this revenue code from OPSS. If an inpatient stay is billed under Part B only, charges covered and paid under OPSS may be excluded from OPSS calculations.
052x	Free-standing clinic - all classifications	Currently, 0520, 0523, 0526 & 0529 are included & 0521 & 0522 excluded & 0524, 0525 & 0527 are missing.	Not on the list of packaged revenue codes	We agree with CMS that charges under all these revenue codes are not covered under OPSS and should be excluded from OPSS calculations.
056x	Home Health - Medical Social Services	Currently included in OPSS.	0560 & 0569 are included on the list of packaged revenue codes.	We agree that these charges are not OPSS charges and should be excluded. Therefore, for consistency, all of these revenue codes should be excluded from the list of packaged revenue codes as well.

0623	Surgical Dressings	Currently excluded from OPSS.	0623 is included on the list of packaged revenue codes.	This revenue code per claims manual instructions is used to bill take home surgical dressings in limited situations that are covered under the DMEPOS benefit. Yes, these charges are allowed to be billed on UB04 claims by hospitals to FI/MACs, but payment is via DMEPOS fee schedule. If CMS is proposing to exclude DME charges under revenue codes 0290 & 0292, then for consistency, this should also apply to 0623 charges. As a result, 0623 charges should not be included on the list of packaged revenue codes.
066x	Respite Care	Currently missing & excluded from OPSS.	Not on the list of packaged revenue codes.	We agree that these charges are not OPSS charges and should be excluded.
0709, 0719, 0749, 0759, 0779, 0799 & 0910	Reserved revenue codes	Currently included in OPSS.	0709 & 0719 are included on the list of packaged revenue codes.	We agree that charges under these revenue codes should be excluded from OPSS and as a result, should be excluded from the list of packaged revenue codes.
0722, 0723, 0724 & 0729	Labor room - various classifications	Currently included in OPSS.	0720 & 0721 are included on the list of packaged revenue codes, why then aren't revenue codes 0723, 0724 & 0729 also included on the list of packaged revenue codes.	We agree these charges should be included in OPSS and that these revenue codes should also be included on the list of packaged revenue codes.
0931 & 0932	Medical Rehabilitation Day	Currently excluded from OPSS but in Table 3 proposed to be crosswalked to cost center 6000 for clinic. Why would a crosswalk be needed for charges to be excluded from OPSS?	Not on the list of packaged revenue codes.	We agree that charges under these revenue codes should be excluded from OPSS.

0942	Other therapeutic services - education & training	Currently included in OPSS but no primary cost center appears on the Crosswalk. CMS proposes to crosswalk to primary cost center 6000 for clinic.	Included on the list of packaged revenue codes.	Education & training charges occur from numerous departments in a hospital, therefore, we believe the current practice of the overall outpatient CCR is preferable to using the clinic 6000 revenue code.
0948	Other therapeutic services - pulmonary education	Currently missing & excluded from OPSS. CMS proposes to crosswalk to 4900 for respiratory therapy, then 6000 for clinic.	Added to the list of packaged revenue codes.	We agree these charges should be included in OPSS. We agree with the crosswalk placement of this revenue code.

Drugs/Biologicals/Radiopharmaceuticals

The PRT is pleased that CMS has recognized the existence of charge compression and its impact on the APC reimbursement calculation for separately payable drugs. We commend CMS on its extensive data review and resulting acceptance that some dollars currently associated with packaged drugs should be reallocated from these drugs to separately payable drugs in order to address pharmacy handling costs. We also believe CMS must implement this reallocation without making other changes to drug payment policy, such as raising the drug packaging threshold to \$65, as this also influences the final payment rates computed for separately payable drugs. We detail our concerns about these and other issues below.

Drug Packaging Threshold

For CY 2010, CMS proposes to increase the drug packaging threshold to \$65. The PRT is very concerned about the impact this will have on CMS' calculation of separately payable drug APC reimbursement. We encourage CMS to freeze the current \$60 packaging threshold until it finalizes and updates its separately payable drug APC calculation methodology.

Once CMS understands and addresses charge compression further, and determines how to reallocate drug costs from packaged drugs to separately payable drugs, there will be more updated and accurate information upon which to determine a future increase or potential decrease to the current drug packaging threshold. The PRT believes that it jeopardizes OPSS' stability for multiple components of a methodology to change at the same time, as this makes it impossible to determine what causal factors are driving the methodological flaws

Furthermore, the PRT again notes that there is a lack of parity in drug reimbursement between hospital outpatient departments and the physician office setting. While we acknowledge that two separate payment systems govern the reimbursement for these settings, we believe that it is problematic for physicians to receive separate reimbursement for *all* of their drugs while hospitals receive separate reimbursement *only* for those drugs above the drug packaging threshold. Our hospitals have seen a shift of services whereby patients are being sent from the

physician's office to the hospital setting, especially for services that are deemed "less profitable" or "too costly" to be provided in the physician office setting. Currently, PRT member hospitals have seen an increase in referrals for injections of Neulasta, Neupogen and Procrit as physicians shift these patients from the physician office setting to the hospital outpatient facilities.

In addition to the site of service differential CMS creates with packaged drugs, the PRT also feels it is inappropriate for CMS to reimburse physicians for all of their drugs at the average sales prices (ASP) plus 6% (ASP+6%), while reimbursing hospitals at only ASP+4% and only for those drugs above the packaging threshold.

Finally, while the PRT understands that the 5-HT3 antiemetics are generally low-cost drugs, we do not believe they should be packaged. They have been separately payable for the last five years and we feel that CMS should maintain this separately payable status. The PRT has some concern that some providers may change their clinical practice to administer the injectable form of the drug. Alternatively, they may not provide the second and third day's doses at all, since separate reimbursement will no longer be provided for the oral formulation. Patients taking the oral drug may be forced to go to their local pharmacy to obtain it; if they cannot, their overall care will be compromised. For these reasons, the PRT urges CMS to maintain separate payment for 5HT3 antiemetics.

The PRT appreciates that CMS provided clarification on the skin replacement definitions; specifically, that biological materials be a "biological skin replacement material" rather than a "biological", and that synthetic materials be a "synthetic skin replacement material" rather than a "synthetic material".

Eligibility Period for Payment of Pass-Through Drugs

The PRT does not agree with CMS' proposal to revise the eligibility period for the payment of pass-through drugs. If we understand CMS' proposal correctly, it is clear that the overall payment period for pass-through drugs will be reduced. For some drugs, the pass-through payment period may simply be non-existent. This all appears to contradict the original intent to provide adequate reimbursement for new drugs in their early years of use.

The PRT believes that CMS should maintain its current pass-through eligibility process, whereby the period of pass-through payment begins after a pass-through application has been submitted and approved by CMS and a HCPCS code assigned. From this point forward, new drugs are paid under the pass-through payment mechanism for a period of two to three years. We believe this is the most appropriate way for CMS to continue paying for pass-through drugs; otherwise CMS could impact beneficiary access to new drugs and biologicals.

Finally, the PRT wants to stress to CMS that *hospitals* are typically at the mercy of others, such as drug or device companies, for submitting pass-through applications to CMS. Hospitals lack the resources to submit these applications; are not privy to background information related to the drug/device's FDA application and approval; and cannot track the new product's first date of sale in the U.S. This date is being proposed by CMS as the pass-through start date in 2010 and beyond. Most hospitals have no idea when a new drug or device was

approved for sale or first sold. The information becomes important to hospitals when a physician orders the new drug and hospitals must seek the information to ensure compliance with CMS billing requirements.

In order to ensure and preserve Medicare beneficiary access to new drugs and biologicals, the PRT strongly urges CMS to withdraw its proposal to change the pass-through eligibility period for drugs for 2010. The PRT also urges CMS to maintain an annual expiration period for pass-through drugs rather than quarterly, as proposed for 2010.

Separately Paid Drug and Biologicals without Pass-through Status

Over the past few years, the PRT has consistently asked CMS to provide reimbursement for separately payable drugs using the average sales price plus six percent (ASP+6%). We believe this reimbursement rate is adequate to cover our acquisition costs, while allowing CMS to create parity for drug reimbursement between the physician office and hospital settings. We continue to believe that CMS must account for our pharmacy handling/overhead costs, since separately payable drugs have greater overhead than packaged drugs. To that end, we truly appreciate CMS' recognition that differential drug mark-up policies for low-cost vs. high-cost drugs leads to "charge compression". With respect to drug reimbursement, the impact of charge compression is clear: CMS overstates the pharmacy handling/overhead costs of packaged drugs whose costs are allocated to non-drug APCs through CMS' single and pseudo-single claims rate-setting process. Charge compression also leads CMS to underestimate the cost pool associated with separately payable drugs that is used to derive the ASP-plus percentage.

We believe that, in this proposed rule, CMS finally acknowledged the underestimation of this cost pool when it noted that its usual separately payable drug calculation methodology would result in separately payable drug APC payment rates *less* than the ASP — specifically of ASP minus 2% (ASP-2).

The PRT appreciates CMS' recognition that such a payment rate is inappropriate. We recognize that this is why CMS proposes a reallocation methodology to move some costs associated with packaged drugs with HCPCS codes over to separately payable APCs. While the PRT generally favors reallocating costs from packaged drugs with HCPCS codes to separately payable drugs, we are deeply concerned that CMS may be underestimating the total value of the cost pool associated with packaged drugs with HCPCS codes due to provider billing practices. A review of our own hospitals' billing practices reveals a high degree of variability in how packaged drugs with HCPCS codes are reported to CMS. We outline these below:

1. Some of our hospitals report all drugs with HCPCS codes, whether packaged or separately payable, using revenue code 636. CMS receives the detail HCPCS data on these claims.
2. Some of our hospitals have not loaded HCPCS codes for packaged drugs into their Charge Description Master (CDM), since CMS does not require hospitals to report HCPCS codes for packaged drugs. Therefore, CMS does not receive HCPCS detail

for these packaged drugs because they are reported with only a revenue code, the dollar charge, and units.

3. Some of our hospitals *do* report packaged drugs with HCPCS codes through the use of revenue code 250. But, due to internal billing system constraints, the HCPCS codes do not print on the claim. Therefore, CMS will see a single line item by date of service for revenue code 250 with total charges and total units but will *not* see HCPCS code detail. Since hospitals are not required to report HCPCS codes for packaged drugs, this billing practice is appropriate. Nonetheless, it results in CMS not having charge data at the HCPCS level and not being able to accurately estimate the cost associated with these providers' packaged drugs with HCPCS codes.
4. Some of our hospitals have changed their billing systems to allow their packaged drugs with HCPCS codes reported using revenue code 250 to print in detail on the claim form. For these hospitals, all revenue code 250 line items do not roll up together. Instead, each line is reported separately with the detail HCPCS code. However, some FI/MAC claim processing systems do not allow providers to report HCPCS codes under revenue code 0250. In these cases, an RTP edit occurs and the claim is sent back to the hospital for "correction". Some hospitals will "strip" the HCPCS J-code and rebill the claim, allowing it to pass the edit; others change the revenue code from 250 to 636. CMS does not receive the packaged HCPCS code form the former hospitals (since it's been removed from the claim), but it does receive the detail HCPCS code for the latter hospitals.
5. Finally, several of our members have indicated that different non-Medicare payer contracting requirements related to reporting certain drugs in revenue code 636 vs. 250 may also impact the data CMS receives related to packaged drugs.

The PRT hopes the above examples are informative and will help CMS to see that it has probably not captured the true cost of packaged drugs with HCPCS codes.

The PRT believes that CMS' reallocation methodology is viable *as long as* some of the data issues raised above are addressed. Until then, the PRT believes the only reasonable and easily implementable option CMS has to reimburse separately payable drugs is to provide payment for separately payable drugs at ASP+6%. Therefore, the PRT advocates that CMS administratively set separately payable drug reimbursement at ASP+6% and freeze it there while working to better identify the total cost pool associated with packaged drugs with HCPCS codes. Once this is done, CMS should reallocate an appropriate amount of costs associated with pharmacy handling/overhead from packaged drugs with HCPCS codes to the pool of money associated with separately payable drugs. Over time, we expect that CMS will reimburse the acquisition cost of separately payable drugs at ASP+6% and will add on additional funds from the reallocation methodology to cover pharmacy handling/overhead costs associated with separately payable drugs.

If CMS elects to move forward with its reallocation methodology for 2010, then it must reallocate more than the proposed \$150 million to separately payable drugs in recognition of the

underestimation described above. In addition, if CMS expects to use its reallocation methodology in the future, it must instruct FI/MACs to have their systems accept HCPCS codes for packaged drugs reported under revenue code 250. Only by doing so will CMS ensure that it receives complete claims data and the total cost information associated with packaged drugs with HCPCS codes for its future reallocation consideration.

We recognize that CMS may not want to require providers to report HCPCS codes for all drugs under OPSS. Yet, it is not as burdensome for providers to report HCPCS codes now as it was when OPSS began, since many state Medicaid programs now mandate reporting of both HCPCS codes and NDC numbers/codes. Ultimately, CMS may elect to require HCPCS codes for all drugs, but a short-term solution is to instruct FI/MACs to remove any HCPCS J-code to revenue code edits in order to provide CMS with detailed HCPCS-coded drug data for both packaged and separately payable drugs. CMS should also add a brief explanation of the reallocation calculation methodology in the 2010 OPSS update transmittals. We believe that CMS would see an increase in the number of HCPCS codes reported for packaged drugs if hospitals understood that this information is used to glean pharmacy overhead and handling costs from claims data. The PRT fears some hospitals do not understand that CMS uses the HCPCS code data in this manner, despite the fact that CMS has noted it in the past. A direct example such as the allocation methodology would “prove” this to hospitals in a way they can easily understand.

Radiopharmaceuticals

Diagnostic Radiopharmaceuticals

The PRT would again like to reiterate that it does not support CMS’ packaging decision for diagnostic radiopharmaceuticals and contrast agents. We understand the need for packaging, as well as the “efficiency incentives” which CMS hopes to create through larger and larger bundles of payment. The PRT reiterates our comments from last year that our hospitals consider radiopharmaceuticals to be drugs rather than supplies. Radiopharmaceuticals are not ordered in bulk and do not sit on a shelf waiting to be used. Nor are they interchangeable, despite CMS’ assertion that packaging them will give providers flexibility in selecting the most efficient products, services, care delivery, etc. For example, a patient who presents for a bone study requires a radiopharmaceutical that is appropriate for that study even if it is more expensive than a radiopharmaceutical for a soft tissue study. CMS must recognize that hospitals simply cannot select the least expensive radiopharmaceutical and substitute it for a more expensive one — unless, of course, we restrict the patients we serve to only those needing certain types of scans.

Therefore, the PRT asks CMS to provide separate reimbursement for all diagnostic radiopharmaceuticals with a median cost greater than \$200. We believe that our recommendation is consistent with the APC Advisory Panel’s recommendation to CMS at its September 2007 meeting.

Therapeutic Radiopharmaceuticals

The PRT understands that for CY 2010 and beyond CMS has proposed to compute APC payment rates for therapeutic radiopharmaceuticals either by using manufacturer reported (voluntary) ASP data, if available or by following its usual charges-reduced-to-cost methodology.

The PRT is extremely concerned because CMS has instructed hospitals for many years that the charge for its drugs, biologicals, and radiopharmaceuticals should include all overhead and handling that is involved in the preparation of these items for administration to a patient. These overhead and handling costs are added to the hospital's cost, in this case, for the radiopharmaceutical as the item passes through the system. The manufacturer has only their cost information related to making the radiopharmaceutical available which does not include the cost(s) added on by the radiopharmacy for their part of this process nor will the ASP information reflect hospital overhead and handling costs. Therefore, the PRT believes CMS must be cautious in its use of ASP data and encourages CMS to obtain this data from all therapeutic radiopharmaceutical manufacturers across all therapeutic radiopharmaceuticals, not just a few. The PRT also urges CMS to compare manufacturer ASP submitted information for each therapeutic radiopharmaceutical to the cost estimate it derives from its usual methodology of reducing provider charges to cost. Such a comparison will enable CMS to better determine whether manufacturer ASP data provider appropriate reimbursement for both the acquisition and pharmacy handling/overhead cost for therapeutic radiopharmaceuticals. If CMS pursues the ASP method, at a minimum the same percentage above ASP that CMS recognizes for SCODs, should be paid.

In October 2004, two new revenue codes became effective for reporting radiopharmaceuticals – 0343 for diagnostic preparations and 0344 for therapeutic preparations. CMS should be able to use the information reported under these two revenue codes to establish the cost plus overhead/handling for all radiopharmaceuticals. We are concerned however, that for those hospitals reporting radiopharmaceuticals under these correct revenue codes, the costs may be rolled into the generic radiology cost center for cost-reporting purposes. While we have no barometer for how many hospitals report these substances correctly and under the correct revenue codes, CMS has instructed hospitals to report in this manner for several years.

Therefore, the PRT also recommends that CMS require hospitals that report charges under these two revenue codes to also report the expense as unique cost centers on the cost report. CMS can then use the information collected from these cost centers to set appropriate APC payment rates for therapeutic radiopharmaceuticals in the future. Until such time that this data is available, CMS should continue allowing cost-based reimbursement for therapeutic radiopharmaceuticals but if this is not possible then CMS should at least provide reimbursement at the higher of the manufacturer submitted ASP plus a percent or the APC rate computed from provider claims data.

Brachytherapy sources

The PRT understands that CMS has proposed to create APC payment rates for brachytherapy sources using its usual rate-setting methodology which relies on reducing provider

billed charges to costs and computing a median cost. We are concerned with CMS' movement away from current cost-based reimbursement for brachytherapy sources, due to the high variation in provider reporting practices. Brachytherapy sources are not reported consistently by all providers using a specific revenue center; therefore, we believe that CMS should maintain cost-based reimbursement until it has gathered improved data through the implementation of a new cost center for high-cost supplies. We believe that many hospitals may be considering brachytherapy sources as "supplies" and could be reporting them through revenue codes used for their low-cost supplies. If so, the same type of charge compression noted by CMS as affecting drugs and biologicals will also impact Brachytherapy sources. Furthermore, CMS should clarify that hospitals should report brachytherapy sources with revenue code 0278 for implants, which would also improve consistent reporting of revenue and costs.

Other drug, biologicals and radiopharmaceutical issues

The PRT supports CMS' proposal that packaging should occur on a drug by drug basis rather than by HCPCS code, since many drugs have multiple HCPCS codes representing different dosages. We also agree that CMS should use the weighted average methodology described in the proposed rule to determine the packaging status for drugs.

The PRT also concurs with CMS's proposal for OPSS 2010 to treat implantable biologicals that are surgically inserted or implanted as devices, since these biologicals have similar clinical uses and are appropriately categorized as devices. We also agree with the agency's position that HCPCS codes should not be reported when biological implants are inserted during a procedure. While we do not expect the volume of implantable biologicals to be high, we would urge CMS to continue to educate hospitals about when they should be reported with HCPCS codes, to ensure the accuracy of data used by CMS for the APC rate-setting process. We suggest that CMS consider publishing a list of procedures in which the HCPCS code for an implantable biological would not typically be reported separately to help providers report their services accurately. Additionally, the PRT encourages CMS to establish "reverse" device to procedure type edits for those procedures in which CMS would NOT expect to see the biological HCPCS code reported separately in conjunction with a procedure. Such edits are already in use with device-related procedure APCs. In this way, CMS could ensure that it receives correct claims data needed to reflect the costs of the biologicals involved while eliminating the manual burden of hospitals to review processed claims to determine whether or not a HCPCS code should be reported.

Drug Administration APCs

The PRT has reviewed CMS' proposed restructuring of the five drug administration APCs, and agrees with all proposed changes with one exception. We do not agree with CMS' proposed movement of HCPCS code C8957 from APC 0440 to APC 0339. This CPT code represents the initiation of a prolonged infusion greater than 8 hours and requires more time and resources than the other services assigned to APC 0339. Specifically, additional time and resources are expended to provide patient education related to using the pump and discuss possible side effects. The PRT recommends that CMS maintain HCPCS code C8957 in APC

440. By doing so, CMS will maintain clinical and resource homogeneity and continue to provide hospitals with adequate reimbursement for this drug administration service.

On a separate note, the PRT would like to request that CMS provide separate payment for two additional drug administration CPT codes; CPT code 96376 and 96368. Hospitals have been reporting these codes (and their predecessor codes) without receiving any separate reimbursement for the last two to three years. We believe CMS has sufficient data upon which to make a separate payment determination for these services. The PRT has previously submitted comments on the resources required to provide multiple IV push injections of the same substance or drug being similar to the initial IV push injection or even the subsequent IV push injection code and asks CMS to assign CPT code 96376 to the same APC as 96374. In addition, we believe CMS must recognize the additional nursing time and resources required during a concurrent infusion and should provide separate reimbursement for CPT code 96368. It is not clear to us what the most appropriate APC would be, however, since CMS does not release median cost data for packaged services. Therefore, we ask CMS to provide a discussion of the median costs for both of these services in the final rule and to begin providing separate reimbursement in 2010.

Pulmonary Rehab, Cardiac Rehab and Intensive Cardiac Rehab

Pulmonary Rehab

The PRT appreciates CMS' decision to handle changes and updates to the Pulmonary Rehab program benefit using the National Coverage Determination (NCD) process, a process with which hospitals are familiar and have included in their operational processes for other coverage information.

We are concerned, however, about the payment level CMS has selected for Pulmonary Rehab services, to be formally recognized beginning in 2010. The new proposed G code will be assigned to a new technology APC that pays \$15. There are HCPCS codes that are currently being reported for these services, however. For several years, CPT code 94620 and HCPCS codes G0237, G0238, and G0239 have been reported for these services and the six-minute walk test. This has provided CMS with substantial claims data for rate setting, which has been used for the calculation of CY 2010 payment for these services.

The table below reflects the CY 2009 and CY 2010 national payment rates for these services, as listed in Addendum B and calculated through CMS' usual rate setting process. It must be noted that G0237, G0238, and G0239 are reported in 15-minute increments per the code definition. CMS proposes to establish payment for an entire session of Pulmonary Rehab reported with Gxx30 at half the payment being provided for a 15-minute increment of service in CY 2009.

HCPCS code	CY 2009 payment rate	CY 2010 payment rate
94620	\$55.00	\$56.00
G0237	\$26.58	\$27.57
G0238	\$26.58	\$27.57
G0239	\$26.58	\$27.57

We believe that CMS should use the claims data available for rate setting but should not assign the new G code to a new technology APC. The PRT notes that this would be the first code that encompasses all of these services into a “lump sum” code and payment, but treating the service as if it has never been reported is unnecessary and inappropriate. CMS should assign the same payment to the “new” pulmonary rehab HCPCS code.

CMS is already paying for the current codes for these services, and hospital resources have not changed for providing the services. It is incomprehensible that CMS believes a comprehensive Pulmonary Rehab service can be provided for \$15. At the very least, CMS should not include the six-minute walk test as part of the 30-day review without using the hospital claims data to establish payment for these services. The PRT proposes that CMS establish an additional G code for pulmonary rehab to include the six-minute walk test, utilizing the claims data for CPT 94620 to be reported once per 30 day period. This code would be reported along with CMS’ proposed G code GXX30 (“*Pulmonary rehabilitation, including aerobic exercise (includes monitoring), per session per day*”) for each exercise rehab session.

Hospital Outpatient Department Quality Measures

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

The PRT again endorses the concept of further selection of measures for the HOP QDRP. Nonetheless, we continue to believe that this should only occur after an analysis has been completed by a national consensus-building entity, such as the National Quality Forum (NQF), and the analysis has been endorsed by the provider community. It is our view that providers should have the opportunity to review and comment on any analysis performed by such entities before measures are implemented. In addition, it is important that CMS provide information concerning how reporting a specific measure will affect the measurement of hospital quality and how facilities can ensure that the data are captured efficiently. Only in this way will providers understand how the proposed standards will specifically measure quality, and how reporting the measures will affect the hospital’s ability to capture the data element efficiently.

HOP QDRP Quality Measures for 2010

The four imaging measures adopted for 2010 are claims-based measures. CMS states that this data method was selected because these measures meet the criteria for quality measure selection and will not impose additional chart abstraction burdens on hospitals.

The PRT appreciates CMS' recognition that additional chart abstraction imposes burdens of both time and labor that increase providers' costs. CMS should consider, however, that for some of the imaging services that are "with contrast", it may not see a separate HCPCS code for contrast media utilized during the imaging procedure. The requirements for reporting contrast media have vacillated over the years between reporting a HCPCS code or including the cost/charge of the contrast media in the cost/charge of the procedure reported as an inclusive part of the procedure HCPCS code. As the HCPCS codes changed from payable to packaged, individuals hospitals decided whether to report the packaged HCPCS code. Therefore, CMS should be aware that the use of contrast media may not be apparent based on the claims data received.

Further, the PRT recommends that any quality measure selected should have an easily identifiable correlation to clinical outcomes.

Publication of HOP QDRP Data

The PRT supports CMS' plan to publish HOP QDRP quality data under the CMS Certification Number (CCN) in alignment with the current practice used for reporting RHQDAPU. This approach is consistent with billing practices when hospitals have only one CCN/provider number. The PRT also supports CMS plan to specify when data from multiple hospitals have been combined.

Data Sources

The PRT supports the use of registries to collect data for future quality measures as alternatives to chart abstraction. Because there are multiple registries available, the PRT recommends that CMS identify the specific *types* of registries from which data would be collected and develop a plan to collect data from facilities that do not participate in the selected registries. We also recommend that CMS define the criteria for participating registries in order to ensure quality and consistent data submission formats.

For example, CMS has already established two registries for reporting quality data on implanted cardioverter defibrillators (ICD) and PET scans based on national coverage determinations (NCDs). These are the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry and the National Oncology PET Registry (NOPR). The PRT believes that any and all registries should be required to obtain CMS' approval and/or sponsorship in order to be considered for gathering data. Further, if registry participation becomes a requirement, hospitals must be given adequate time to implement processes and registrations for registry participation.

The proposed rule indicates that data for several proposed quality measures could be obtained by CMS via the facility's EHR. The PRT does not support CMS having direct access to

a facility's EHR for data abstraction, although we believe that specific data submission from the EHR could be developed in order to provide necessary information electronically without increasing hospital burdens. The PRT recommends that CMS allow hospitals to participate in developing electronic standards for such data submission. CMS should also work with hospitals to create a one-way interface for electronic submission of data to CMS.

When considering future HOP quality measures using claims-based data, the PRT recommends that CMS review data across sites of service, including Ambulatory Surgery Centers (ASC) and physician office settings, rather than focusing only on the hospital outpatient encounter. We expect that CMS is interested in outpatients who are sent to hospitals from ASCs for observation. The addition of a new admission source code that identifies hospital transfers from an ASC would provide another set of useful and important data. Transmittal 1775, CR 6478 implements this point of origin code and will be available for future outpatient quality data collection. The PRT thanks CMS for releasing the admission source code from ASCs; the PRT had requested this code several years ago and is very pleased not only with its creation but also with CMS' adoption of it.

Retirement of HOP QDRP Quality Measures

The PRT supports CMS' proposal to immediately retire any quality measure when evidence demonstrates there is a concern regarding patient safety. We agree with CMS' use of multiple methods of communication, including the Quality Net website, to increase public awareness of these changes. The PRT also agrees that it is appropriate for CMS to communicate about the retirement of measures that have no immediate patient safety concerns through the current rulemaking process.

Possible Measures for 2012

The PRT is concerned that requiring 28 HOP quality measures for CY 2012 may present an additional burden on the hospital community. A review of the 16 proposed measures indicates that several measures appear to be related to physician prescribing and ordering practices, or to care provided outside the hospital outpatient setting.

CMS' own criteria state that the HOP quality measures for 2011 continue to address areas of topical importance regarding the quality of care provided in the HOPD and reflect consensus among affected parties. It is not clear that the same criteria are being used for measures proposed for CY 2012. CMS may believe that the information provided thoroughly defines the indicator and indicates the data collection mechanism, but the PRT does not believe this to be true. For this reason, the PRT requests CMS to provide additional background information and explanation about how these new measures specifically affect quality.

The PRT offers the following comments on the specific proposed measures:

Measure 1: Adjuvant Chemotherapy is considered or administered within 4 months of surgery to patients under age 80 with AJCC III Colon Cancer. The PRT notes that this is a prime example of the need for detailed information from CMS. A hospital provider may provide

chemotherapy to a patient whose surgery was performed at a different facility. It is not clear how CMS intends the hospital to gather this information. CMS may be attempting to explore the complete care of a specific patient population, perhaps by using the Common Working File (CWF) to link the information together. Alternatively, CMS may expect the hospital to abstract all the available information and submit these data to CMS. If CMS is using the CWF to make the connections, the PRT agree that this is claims-based data collection. If CMS is expecting hospitals to abstract that data, however, it would be an immense burden for facilities.

Measure 4: Median time from ED arrival to ED departure for discharged ED patients. The proposed rule notes that the specifications are on the Quality Net website; but a search for this specific information yields no information, however. This measure appears to be a through-put issue and one that does not clearly relate to improving either quality of care or clinical outcomes. The PRT believes that the provider community must be allowed to see the clinical evidence underlying this measure and learn what CMS expects to derive from these data before we can make any comment. The PRT notes that fast care does not equal high-quality care. In the Emergency Department, wait times from arrival to departure may be significant for patients with less emergent clinical presentations than others. For example, a patient who arrives in an ambulance after a car accident takes precedence over a patient with a sore throat. This does not mean that the latter receives better care than the former, just that their need was less dire. The ED's purpose is to care for more emergent and critical patients based on the clinical scenario, rather than the patient's time of arrival. CMS *must* provide more details on this quality measure and allow providers to comment on its intent and specifics.

Measures 5-8: Performance of lab work, eye exams and foot exams. These measures are focused primarily on services provided in a physician's office or physician-based clinic, rather than in a hospital outpatient facility. We do not believe these measures are applicable to the outpatient setting. The PRT reiterates our previous comment that CMS should use additional criteria for quality measures, specifically:

1. Hospital measures should measure services provided in the *hospital outpatient setting* rather than measuring physician services or services controlled by the physician (e.g., prescribing or ordering services).
2. Data collection should not increase hospital operational burden by increasing FTEs to either collect data or improve data collection systems.

Measure 9: Medication reconciliation. It is unclear to the PRT how this measure would be obtained through claims data, or how the measure reflects the quality of hospital care.

Measure 10: Pneumococcal vaccination status; 11: Influenza Vaccination status; and 16: Appropriate surgical site hair removal. It is unclear how data for these measures would be obtained from claims data. Hospitals will be required to conduct chart abstraction to collect the data, necessitating the use of additional hospital staff and causes operational burden. In addition, because these measures affect a large volume of cases, they would greatly increase hospitals' data collection and submission burdens without providing any clear benefit related to patients' clinical outcome.

Administrative Requirements

The PRT appreciates CMS' clear and concise definition of an outpatient episode of care as "care provided to a patient who has not been admitted as an inpatient, but who is registered on the hospital's medical records as an outpatient and receives services (rather than supplies alone) from the hospital."

Sampling and Case Threshold

CMS proposes that hospitals with a sufficiently large number of cases would be able to sample cases and submit data for sampled cases rather than having to submit data for all of their eligible cases. In principle, the PRT supports the concept of sampling and the development of eligible case thresholds. We recommend, however, that CMS distribute sampling criteria when the new measure is implemented. For example, measures proposed for 2012 should include the sampling criteria; both should be made available for comment and review in the proposed OPSS rule for 2011. Any rule proposed after 2012 should include the sampling criteria as part of the OPSS proposed rule.

The PRT is concerned about the determination of population and sample size for quality reporting purposes. We request CMS provide additional specification about these requirements in future proposals regarding HOPD quality measures. CMS states in the proposed rule, "In addition, in order to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, hospitals that have five or fewer claims (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter will not be required to submit patient level data for the entire measure topic for that quarter." The PRT disagrees with CMS' assertion that sampling requirements should apply based on both Medicare and non-Medicare cases. We believe that CMS should focus only on the population of patients for which the agency is responsible.

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

Validation Requirements

The PRT believes that CMS' proposed validation requirements are reasonable and would be acceptable to providers if it were the *only* Federal data submission requirement. We are deeply concerned, however, that these record requests will supplement those already established as part of the Federal integrity audit processes (e.g., RAC, Medicaid Integrity, ZPIC, MAC). While these programs were developed by CMS to serve specific purposes, the end result will be that facilities will receive multiple requests from each contracted entity. These requests will be made concurrently and meeting them will significantly increase hospital providers' labor

investments and costs. The PRT encourages CMS to review the validation process with respect to other data requirements, rather than seeing it as a single request, and to consider the operational impact that receiving multiple audit entity requests will have on any single provider.

Data Publication

Under the RHQDAPU, data submitted by hospitals is publicly reported regardless of whether the data were successfully validated for payment determination purposes. For consistency, CMS proposes the same method for HOP QDRP, beginning in the third quarter of CY 2008. The PRT recommends that CMS collect data for a full year in order to provide hospitals with the needed experience with this process and enable them to work through the learning curve. The PRT supports CMS' proposal to adopt a formal mechanism that allows hospitals to request a reconsideration of payment decisions. We appreciate the clear steps outlined in this reconsideration process.

Reporting ASC Quality Data

As CMS notes in the proposed rule, Ambulatory Surgical Centers (ASCs) are not currently required to submit data for any quality measures. CMS proposes to continue this deferment for CY 2010 and address it in future rule-making.

The PRT is concerned that CMS is applying two different sets of criteria to hospitals and ASCs. This is especially troublesome, given the agency's increasing emphasis on collecting data from submitted claims. The PRT understands the burden that ASCs may experience from abstracting measures from medical records, but we cannot understand why implementing claims-based measures (such as the imaging measures) would be burdensome. The PRT has commented previously on this issue, and we continue to encourage CMS to develop quality indicators that are consistent for hospitals and ASCs. The PRT strongly believes that Medicare beneficiaries should receive the same high quality of care regardless of the site where that service is provided. While CMS has indicated its intent to level the playing field, having two sets of reporting criteria does not seem to further this goal.

Electronic Health Records

CMS states in the proposed rule, *"We have been engaged with health IT standards setting organizations to promote the adoption of the necessary standards regarding data capture to facilitate data collection via EHRs, and have been collaborating with such organizations on standards for a number of quality measures. We encourage hospitals to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from the EHR directly to a CMS data repository. We also encourage hospitals that are implementing, upgrading or developing EHR systems to ensure that such systems conform to standards adopted by HHS."*

The PRT is very concerned about the impact of this proposal on hospitals that are in the process of implementing EHR and which began to implement EHRs before HHS published its standards. Implementing and integrating EHRs is a long and costly process from initiation to completion and necessitates considerable financial investment. Also, as noted earlier, the PRT

opposes CMS having direct access to facilities' EHRs for data abstraction purposes. As an alternative, the PRT recommends that CMS allow hospitals to participate in the development of standards for specific data submission, and allow sufficient time for hospitals to create a one-way interface for electronic submission of selective data to CMS.

Healthcare-Associated Conditions under the OPSS

The PRT agrees with CMS' continued delay in expanding the principles behind the IPPS HAC payment provision to the OPSS through an OP-HAC program. The PRT appreciates CMS' acknowledgement of the operational challenges inherent in this expansion. The PRT commends CMS on continued evaluation of the impact of the HAC and POA indicator reporting on Medicare payment.

We believe that, in the outpatient setting, it is inappropriate to single out hospitals for this type of indicator. Unlike inpatient services, outpatient services are not concentrated in one setting but, rather, cross all care settings. The PRT reiterates that we do not support present on admission (POA) reporting of the hospital-acquired conditions for OPSS services. The PRT strongly believes that reporting a POA in the outpatient setting will be operationally burdensome for hospitals, due to the tremendous volume and nature of outpatient services. For example, a patient may present for an ancillary service such as lab work or a radiology exam. Due to the limited nature of these encounters, it would be rare for a diagnosis not to be "present on admission" in the majority of outpatient visits.

In the limited service areas in which POA may be applicable, the PRT encourages CMS to delay implementation of HAC for hospital outpatients until the adoption of ICD-10, at which time providers can submit more specific claims data through the assigned ICD-10 code set. In the CY 2009 rule, CMS stated that ICD-10-CM and ICD-10-PCS will: "*provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes.*" The PRT agrees with CMS' assumption in this matter and is encouraged that a delay in implementation will allow hospitals to operationalize the process using the new code set.

As CMS continues to evaluate and make decisions about this issue, the agency should work closely with stakeholders to ensure a clear and uniform understanding of the indicators' definitions and how CMS intends to use each measure to gauge beneficiary quality of care. History has shown that there are positive outcomes when hospital providers understand CMS' intent and expectations. The PRT is willing to assist CMS to understand how each mechanism to gather these data impacts providers' operational processes. We are also interested in helping to establish the guidelines for a monitoring and reporting process that can ultimately be operationalized in the hospital outpatient setting, produce quality data for both CMS and the provider community, and minimize data submission burdens.

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. The PRT members are very encouraged by the policy-making

process and appreciate how our input can have an impact on future 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.

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