CMS-1392-P-803 **Medicare**

Submitter : **09/12/2007**

Organization :
Hospital

Category :

Issue Areas/Comments

Quality Data

Quality Data

see attached document concerning Quality Data

CMS-1392-P-803-Attach-1.DOC

#803

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

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

Quality Data

The Provider Roundtable (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 provides medical assessments, diagnostic studies, treatments, and evaluations to determine if admission is warranted. Thus, information required by CMS on quality indicators must be very specific and related to the patient's current visit.

The PRT agrees that the five proposed ED-AMI indicators should be reported by the transferring facility. PRT members that represent smaller facilities note that their facilities have the mechanisms and resources to provide care for ED-AMI patients pertaining to these indicators, but that they may not have the resources required for data collection and reporting on these indicators. While CMS did not specifically state that the reporting mandate is applicable to CAHs, the PRT strongly recommends that this information should be included in the data submission for the ED-AMI indicators.

The PRT believes that CMS has not clearly explained how the five proposed PQRI indicators will be captured. Given the proposed rule's definition of an "outpatient encounter", we anticipate that the volume related to these five PQIs will be nearly unmanageable. We request that CMS clarify several areas, including the type of services or conditions to be included and, given the tremendous volume of outpatients, whether hospitals would be allowed to provide a sampling of patients.

The PRT also asks CMS to clarify whether it expects facilities to report on outpatient services that include diagnostic studies. For example, a patient who has a diagnosis of CHF and presents to the hospital with a physician order for CXR would be an outpatient service. If the presenting problem is a secondary condition rather than CHF, would CMS require data reporting? In addition, CMS should clarify the expectations for data reporting on patients with CHF who frequently recur and return to the outpatient clinic. Further, if these patients are on an ACE inhibitor, CMS should clarify if this is to be reported for *each* encounter.

As another example, peri-operative care and timing of antibiotics are currently captured for inpatients and would be a reporting indicator that could be considered for surgical cases. The proposed rule is unclear concerning whether these indicators are for specific surgical procedures, or if interventional procedures are also to be included. Likewise, clarification is needed concerning whether specific types of prophylactic antibiotics are to be identified and if sampling will be allowed. We believe that the population related to these two indicators will be overwhelmingly large to manage without sampling.

The pneumonia PQRI appears to be a logical condition for measuring quality related to antibiotic administration in the Emergency Room and observation status. PQRI for A1C would not be measured in an acute care facility, in the ED, or in observation status. The A1C test is frequently ordered on newly diagnosed diabetics in order to help determine how elevated their uncontrolled blood glucose levels have been. The test may be ordered several times while control is being achieved, and then several times a year after that time, in order to verify maintenance of good control. This indicator applies primarily to a provider-based diabetic clinic or a physician's office, not a facility.

AMI patients who present to smaller hospital Emergency Rooms are treated and then transferred to other acute care facilities for continued care. At the moment, quality indicators for these transferred patients are not included in the reporting structure in the receiving facility, since the initial treatment was not provided by the receiving facility. The PRT understands and supports CMS initiative to obtain this missing information for these transferred patients.

The PRT reviewed the remaining 30 proposed quality indicators and concurred that their focus is primarily for physician offices or a physician-based clinic -- rather than for hospital outpatient facilities. The PRT urges CMS not to implement these indicators until they have been further refined and made more specific to the hospital outpatient setting.

The proposed rule indicates that the CY 2009 payment reduction will be based on outpatient data validation as of January 2008 discharges. The PRT would like CMS to clarify if the proposed payment reduction would apply for all services reported in CY 2009. We feel there should be a

grace period of data collection not directly tied to the next year's payments, which would be more closely allied to how IPPS indicators were collected and validated. CMS should remain mindful of the timeframe for implementation to train staff, and allow vendors to set up their products.

If CMS staff has questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052

CMS-1392-P-804 **Medicare**

Submitter : **09/12/2007**

Organization :
Hospital

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

See attached document concerning OPPS: Packaged Services

CMS-1392-P-804-Attach-1.DOC

#804

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

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

OPPS: Packaged Services

The Provider Roundtable (PRT) generally endorses the concept of CMS' expanded packaging proposal, but has reservations about the manner in which CMS selected services to package and what these services were specifically packaged into. We are fundamentally concerned with this since CMS' proposal will result in providers losing separate APC reimbursement for over 200 codes which currently generate separate payment. Therefore, we need to be certain that the costs associated with these proposed packaged services have been appropriately accounted for in the OPPS system. Specifically, our review of the APC proposed payment rates for a number of procedures which presumably would now include packaged charges are simply lower, and in some cases much lower, than the payment we receive today for all of the services through separate APC payment. We are deeply concerned that CMS may have understated some of the median costs, and in other cases, the packaged services may not have been accounted for at all if they were not present on the claim or if they were present on multiple procedure claims. Despite our concerns, we support CMS' implementation of the general packaging concept for 2008, but to a limited extent as we describe below.

On a separate note, the PRT is disappointed with the overarching tone and theme of this proposed rule, which implies that hospitals provide whatever services they wish at whatever cost, with their only concern being reimbursement for the service, and that reimbursement would motivate hospitals to report services on separate claims just to be paid more. We further note that existing requirements found at 42 CFR 411.15 (m) provide that hospitals must furnish and bill for services necessary to complete an outpatient hospital encounter. Therefore, repetitive language throughout the proposed rule stating that hospitals would potentially respond to packaging proposals by delivering part of the service at one hospital and the remainder of the service at another hospital would be a violation of existing CMS regulations.

CMS has identified seven service areas for packaging for CY 2008. The PRT recommends that CMS delay implementing packaging relating to some of these areas as outlined below. We strongly encourage CMS to conduct further analysis in these service areas to ensure that the rate-setting logic accurately accounts for the packaged dollars associated with these tests and procedures before it proceeds to package them.

We further note that CMS' assumption that this packaging initiative will "*create enhanced incentives for hospitals to provide only necessary, high quality care and to provide that care as efficiently as possible*" and that the packaging "*would create incentives for efficiency and volume control, while providing hospitals with flexibility to provide care in the most appropriate way for each Medicare beneficiary*" is incorrect and invalid. Hospitals provide services only upon order of a physician. Therefore, it is the physician community that drives the volume and selection of tests, as well as deciding the most appropriate care for patients. Hospitals must provide resources to complete the ordered tests based on the direction of the physician or refer the patient to another facility that can provide the ordered services. Hospitals may make suggestions to a physician regarding the reasonableness of one particular modality vs. another; however, the ultimate decision for the ordered service remains under the purview of the physician. Physicians and the community in general expect hospitals to keep abreast of advances in medical practice and to provide services that are ordered. Innovation and best practices definitely have associated increased costs. To base packaging policy on the frequency of service and to suppress payments to hospitals because CMS suspects that hospitals are "*over-providing*" services contributes to the further deterioration of hospitals' abilities to provide state-of-the-art care to Medicare beneficiaries.

If CMS' intent to expand the packaging concept is to succeed without causing huge financial risk for hospitals and beneficiary access to care problems, then the PRT believes CMS must strive to use correctly coded claims for rate setting, even if those claims are multiple procedure claims. Furthermore, CMS should discard incorrectly coded claims even if those claims are single procedure claims. In order to calculate accurate payment rates for what CMS characterizes as the "independent procedure or service," CMS must use only correctly coded claims for rate setting. Without accounting for the presence or absence of a packaged service on a claim, CMS will underestimate the median cost for the independent procedure or service and thereby reduce hospital APC payments. Based on CMS' existing rate-setting methodology it is clear that only single or pseudo single claims were utilized and where packaged services could be packaged they were packaged, without any regard to the appropriateness of the packaging. In addition, we are concerned about the distribution of packaged charges on multiple procedure claims since these claims are not

used for setting APC payment rates. We understand that CMS believes that packaged services appear with relatively equal frequency and quantity on single versus multiple procedure claims; however that still does not mean that CMS has appropriately allocated the packaged services, if at all, on multiple procedure claims. We believe CMS needs to work towards refining its packaging logic to allow for more packaged charges to be included in the rate-setting process and to allocate those packaged dollars using specific logic so that providers have a greater comfort level of what services are packaged into other services. We ask CMS to release additional data shedding light on the percentage of packaged services/dollars allocated to each separately payable APC and a listing of the codes and their frequency so we can better understand where the packaged dollars were assigned. We cannot fully support what appears to be a hasty decision on CMS' part to drastically change the OPPS system without additional data and analyses from CMS. Packaging for the sake of packaging or to introduce what CMS believes to be a set of efficiency and flexibility incentives for hospitals is irresponsible and to a large extent unfair to providers if packaging has only been marginally done. Furthermore, CMS has not addressed what the PRT believes will be a significant down stream effect of more packaging, which is a deterioration in the quality of future claims data, which in turn will impact 2010 APC payment rates.

As providers, we need a greater level of proof that currently paid services now proposed to be packaged have in fact been packaged to the most appropriate services and that these charges have not been lost altogether from the OPPS system. We are not confident that this is the case for all of the service areas CMS proposes to package in 2008 and strongly recommend that CMS further evaluate its data. The PRT urges CMS to proceed with caution to prevent negatively impacting hospital service lines that are integral to providing high quality patient care. We offer our specific thoughts by service area below.

GUIDANCE SERVICES

The PRT acknowledges that based on CMS' definition, guidance services are dependent services as they are not performed alone but as an adjunct to another procedure that can be performed independently. Because the other procedure can be performed alone, it is appropriate to package the guidance service into that individual procedure based on the manner in which the claims data reflect the dependent procedure having occurred with the independent procedure. For example, we agree that ultrasound guidance for a biopsy can be packaged, but we ask CMS to review whether it was appropriately packaged into a biopsy procedure or whether it was also packaged to other procedures that it should never be packaged to simply because of how the claim was submitted. In other words, does CMS use only those claims containing the biopsy CPT code and the guidance CPT code for rate setting? Another example is fluoroscopic guidance for inserting a tunneled central venous catheter. We agree that this can be appropriately packaged into the insertion procedure, but again ask CMS to review how many times it was packaged into this appropriate procedure versus another random procedure where the packaged dollars should never be assigned. We believe that CMS' existing rate-setting logic allows inappropriate packaging to occur. We understand from the rule that there is no assurance that the guidance would ONLY be packaged into the specific procedure(s) that require guidance and this is the significant issue that concerns us. If the packaging of a dependent procedure is not directed to one or more specific independent procedures, then we

believe CMS will underestimate the median cost for the independent APC services, and potentially overestimate others (those that received packaged dollars but should not have). Once CMS appropriately matches dependent guidance services with only the appropriate independent procedures (and we believe that the claims data was likely reported more accurately than not), the PRT will then support the packaging of guidance services for the majority of modalities.

IMAGE PROCESSING SERVICES

The PRT agrees with the proposal to package image processing services with one hesitation. The fact that CMS states "*Resource cost was not a factor we considered when proposing to package supportive image processing services*" is troublesome. Many facilities do not have the resources to provide image processing "in house" and must contract with an outside provider. Excluding resource cost in making this decision is irresponsible on CMS' part and goes against the principles upon which this prospective payment system is predicated. The PRT strongly urges CMS to revisit the resource cost associated with these services in order to ensure appropriate payment for these services under OPPS but more important to assure that hospitals can continue to provide these services to beneficiaries. These services provide very important data in the care and diagnosis of all patients and not considering the cost to hospitals will result in these services being less available.

INTRA-OPERATIVE SERVICES

The PRT agrees with the packaging of the majority of codes listed in table 12 of the proposed rule. However, two of the codes are unlisted procedures and could be reported as independent procedures and therefore cannot be considered dependent. CPT codes 92999 (Unlisted neurological or neuromuscular diagnostic procedure) and 37299 (unlisted [eye] procedure, posterior segment) should not be packaged. Under CPT rules, unlisted codes are reported when a specific CPT code does not exist for a procedure. Based on this rationale coupled with the fact that these codes are not designated as add-on codes, they are not candidates for packaging as there is no indication that all procedures reported with these codes are dependent in nature. These are the only unlisted codes on the proposed packaging list for intraoperative services and should be removed and separate APC payment continues. The PRT supports the APC Advisory Panel's recommendation to assign CPT code 96020 (functional brain mapping) to status indicator Q. The PRT wishes to commend CMS on excluding diagnostic services that are independent themselves, but are sometimes provided in association with other independent procedures. Once again, however, the PRT is concerned that CMS did not, but should, consider resource costs involved when making the decision to package certain intra-operative services.

IMAGING SUPERVISION AND INTERPRETATION SERVICES

The PRT adamantly opposes CMS proposal for packaging imaging supervision and interpretation services, as we do not believe that CMS conducted a thorough enough analysis of the many ways that CPT codes can be reported for multi-faceted services, that is services where there could be

more than just one surgical CPT and one radiology S&I CPT. For instance, there is great variety in coding for Interventional Radiology services, and the current CPT coding system is set up on a "component" basis (S&I plus surgical) for this very reason. Otherwise, it would require hundreds of additional unique CPT codes to cover all the potential combinations of procedures that could be performed.

Furthermore, this is an area where the current cost center to revenue coding mapping is problematic. Hospitals report the surgical CPT component for most Interventional Radiology services under revenue code 0361 and this revenue code is mapped to the surgery cost center. Most of these procedures are performed in the radiology department or the heart catheterization laboratory, therefore, CMS' median cost calculation using the surgery CCR is highly suspect.

Also, based on current status indicators assigned to non-S&I procedures and CMS' packaging proposal, there will be times when two services are reported together and both are packaged services. If one service has a status indicator of Q, this is the service that will be reimbursed, which indicates that no consideration was given to an appropriate packaging methodology, but just packaging because of the code descriptor. There will be other instances when none of the codes on a claim are classified as a significant procedure, but only status indicator T which triggers reduced payment depending on the status indicator of the other procedures on the claim. In addition, it could result in a claim with packaged services only thereby resulting in no payment for a particular service that was rendered.
As an alternative to Table 13 in the proposed rule, where CMS shows a positive payment outcome for a simplistic CT/myelogram case, we would like to provide a scenario for CMS to consider involving an extensive angiography case (including only the procedure charges) as follows:

CPT CODE	CODE DESCRIP	2007 SI	2007 APC PAYMENT	2008 SI	2008 APC PAYMENT
	DX ANGIOGRAPHY W/ PTA SFA				
75625	ABDOMINAL AORTOGRAPHY	S	1,279.92	Q	
75716	ANGIOGRAPHY EXTREMITY BILATERAL	S	1,279.92	Q	
75774	SELECTIVE ANGIOGRAPHY EA ADDL VESSEL	S	584.32	N	
75774	SELECTIVE ANGIOGRAPHY EA ADDL VESSEL	S	584.32	N	
36247	3RD ORDER SELECTIVE CATHETER PLACEMENT	N		N	
35474	ANGIOPLASTY FEM-POP EA VESSEL	T	2,639.19	T	2,934.24
35474	ANGIOPLASTY FEM-POP EA VESSEL	T	1,319.60	T	1,467.12
75962	ANGIOPLASTY FEM-POP S&I	S	383.95	Q	
75964	ANGIOPLASTY FEM-POP EA ADDL VESSEL S&I	S	383.95	N	
	TOTAL APC PAYMENT		**8,455.17**		**4,401.36**

As evidenced in the example above, it is not conceivable that the S&I codes have been properly accounted for within the surgical codes. The proposed packaging concept for S&I codes will result in excessive and extreme decreases in reimbursement that will be detrimental to hospitals. The PRT agrees with the APC Advisory Panel's recommendations that CMS delay the packaging of these services and study the impact of this proposal in greater detail; ensure that services are not packaged

into other services that are already packaged; and review alternative packaging options for these services. We also urge CMS to study the impact of the cost center to revenue code center mapping and charge compression in relation to these services.

CONTRAST MEDIA

The PRT notes that in the past, some of the items proposed for packaging have been packaged and unpackaged and then packaged again. For example, contrast media was separately reportable, then included in the procedure being performed; at which time some hospitals included the charge for the contrast in the charge for the procedure. Later, contrast media again was designated as separately reportable and separately payable, and some hospitals may have broken out the contrast charge and reported it separately while others may have left it packaged into the procedure charge despite the fact that separate payment was at stake and likely lost to the provider if they did not report the contrast HCPCS code separately. This is just one example of how frequent status indicator changes from packaged to separately payable and back to packaged again can cause provider billing problems, all of which can result in poor and inconsistent data being reported to CMS. Additionally, such frequent short-lived changes cause an enormous operational burden for providers.

Despite the above, the PRT does support CMS' proposal and the APC Advisory Panel's recommendation to package contrast media in 2008. As noted previously, we believe CMS should develop some claims logic or parameters for establishing into which procedures the contrast media is packaged and only use procedure line items for median cost calculation that have contrast packaged into them. Not doing so will undervalue the overall median cost for the procedure line item. For example, we agree that it is appropriate to package contrast into the procedure code for a cardiac catheterization and radiology procedures that indicate they are performed with contrast, but if a CT scan of the brain with contrast and a chest x-ray are reported on the same claim. We believe CMS should use logic that assigns the contrast to the CT scan rather than allowing this to remain as a multiple procedure claim which is how we understand CMS treats it today.

DIAGNOSTIC RADIOPHARMACEUTICALS

These have been packaged and unpackaged over time and the reported line item codes and charges are likely to be susceptible to the same issues described above under contrast agents. CMS states that most of the single procedure nuclear medicine claims had a radiopharmaceutical present, but cannot comment on the appropriateness of the billed radiopharmaceutical with the particular nuclear medicine procedure. We believe CMS should have performed some sort of clinical and resource homogeneity analysis before simply deciding to package all diagnostic radiopharmaceuticals as we do not believe this is appropriate.

Radiopharmaceuticals have a short half-life and are administered based on the specific patient's disease and situation. These products, which are considered drugs rather than supplies by our hospitals, are not ordered in bulk and do not sit on a shelf waiting to be used. Neither are they

interchangeable despite CMS' assertion that packaging these will give providers flexibility in selecting the most efficient products, services, care delivery, etc. For example, a patient that 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 as a substitute for a more expensive one – unless of course we stop seeing certain types of patients altogether. The incentive CMS is attempting to create is misguided and inappropriate and could result in serious access to care problems. Additionally, if a patient does not show up for the scheduled test or service, the hospital must absorb the cost for the radiopharmaceutical that was ordered for that study. These agents are very costly to the hospital and again, patient specific.

For the reasons cited above, the PRT recommends that CMS delay its proposal to package radiopharmaceuticals for at least one year. It may be possible for CMS to create groupings of radiopharmaceuticals rather than paying for each one separately as an attempt to move closer to packaging but without tying non-substitutable radiopharmaceuticals to procedures. Therefore, CMS should continue to provide separate reimbursement under the current reimbursement methodology for all radiopharmaceutical HCPCS codes.

Finally, the PRT supports the APC Advisory Panel's recommendation that CMS provide data on the percentage of diagnostic nuclear medicine study claims that were reported with and without a corresponding radiopharmaceutical. We believe this data will provide vital information concerning hospital reporting trends for these services and agents. Based on the analysis, it can be determined whether an edit is indicated for reporting these services either on the front-end through the Outpatient Code Editor or on the back-end in CMS' rate-setting logic. For diagnostic radiopharmaceuticals, an OCE edit could be added that would require the reporting of a radiopharmaceutical when a nuclear medicine test is reported. This edit could be constructed at the revenue code level since diagnostic radiopharmaceuticals should be reported under revenue code 0343 and diagnostic nuclear medicine procedures are reported under revenue code 0340 or 0341. This edit would support CMS' packaging initiative by improving the available cost data for these services. It would also demonstrate to CMS that radiopharmaceuticals are not interchangeable; services being interchangeable and providing the same result regardless of the modality is a basic, recurring concept in CMS' packaging methodology stated throughout this proposed rule, yet we disagree with it with respect to radiopharmaceutical use in nuclear medicine studies.

OBSERVATION SERVICES

The Provider Roundtable (PRT) believes that based on CMS' own definition, observation is not a dependent service. CMS has defined observation care as "*a well defined set of specific, clinically appropriate services which include ongoing, short-term treatment, assessment and reassessment, that are furnished while a decision is being made regarding whether a patient will require further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital.*" The ongoing assessment and monitoring is an active process that occurs during the observation stay. The medical monitoring itself becomes the primary independent service, and the other ancillary services become dependent to this active ongoing assessment.

The PRT realizes that CMS is alarmed by the rapid increase of separately payable observation service claims. However, we believe that this is directly related to the positive changes CMS made to the reporting system in response to work done by the APC Panel and other provider groups over the past several years. CMS listened to the operational burdens facing hospitals and responded with a simplified reporting and payment system. The PRT and the APC Panel reported to CMS that hospitals were likely under-reporting observation care in the past due to the complexity of billing rules prior to the changes made in 2006. We believe that the claims data generated under the simplified reporting and payment system support this information and is the primary reason CMS has seen an increase in the frequency of the separately payable observation APC. The PRT believes that claims data will stabilize and the upward trend will vanish with 2007 and later claims data.

Another contributing factor to the increased volume of claims is related to CMS' policies aimed at reducing the occurrence of one-day stays in the inpatient setting. Therefore, the PRT recommends that CMS compare the increase in the number of claims containing HCPCS code G0378 (observation per hour) with the decrease in one-day inpatient stays. The PRT further recommends that CMS continue the current policy for reporting observation cases and strongly advocates that CMS delay any changes until the 2007 claims data is available for review.

CMS states in the proposed rule: "*We are also concerned that the current criteria for separate payment for observation services may provide disincentives for efficiency. In order for observation services to be separately payable, they must last at least 8 hours. While this criterion was put in place to ensure that separate payment is made only for observation services of a substantial duration, it may create a financial disincentive for an HOPD to make a timely determination regarding a patient's safe disposition after observation care ends. By packaging payment for all observation services, regardless of their duration, we would provide incentives for more efficient delivery of services and timely decision making.....To the extent that hospitals could change their behavior and cease providing observation services, refer patients elsewhere for that care, or increase the frequency of observation services, the data would show such a change in practice in future years and that change would be reflected in future budget neutrality adjustment.....We believe it is unlikely that hospitals would cease providing medically necessary observation care or refer patients elsewhere for that care if they were unable to reach a decision that the patient could be safely discharged from the outpatient department.*"

The PRT would like to remind CMS that it is incumbent upon the physician, not the hospital, to make the determination regarding the order for observation, the length of the observation stay, and the patient's safe discharge once the observation period ends. We do not see how increased packaging provides an incentive for hospitals to make a resource decision related to either selection of observation status or time spent in observation as both are determined by the physician.

The PRT also questions whether observation dollars are truly being packaged into other separately payable services. We believe that most observation charges, currently packaged or separately payable through APC 0339, are only claims that also contain other separately payable supportive services such as an outpatient visit, various lab and ancillary diagnostic studies, and/or other procedures or tests. By definition, claims that contain such services along with observation hours will be multiple-procedure claims that cannot be used in the APC rate-setting process. Hospitals

need proof that the majority of observation charges are in fact being packaged under CMS' proposed packaging proposal. In addition, CMS should more fully disclose where the observation packaged charges reside.

The PRT concurs with the Observation subcommittee and full APC Advisory Panel's recommendation for a delay in the implementation of observation packaging and the need for further data analysis. We agree with and expand upon the APC Panel's recommendations:

1. To continue separate payment for the current conditions until future claims data beyond 2006 are analyzed for trends of either stabilization or continued exceptional growth.
2. Request that CMS provide a detailed analysis of the distribution of separately payable observation charges for APC 0339 present on single vs. multiple procedure claims so that the APC Advisory Panel and providers can analyze and understand what amount of observation dollars would be used for packaging and into which services these dollars would be packaged.
3. That observation services would be ideal for CMS to study for Composite APC payment. At the September 2007 meeting, the APC Advisory Panel recommended investigation of a composite APC regarding ED/Clinic services and observation status with separate payment made when a visit code and observation are reported together, regardless of the medical condition. The PRT further recommends inclusion of HCPCS code G0379 (direct admit to observation) in addition to the Emergency Department and Clinic E/M visit codes recommended by the APC Advisory Panel. While it was suggested that the volume of these claims was low, the PRT offers that a direct admit situation requires the same significant resource utilization since there is no difference in the services. Even if the patient was seen in the physician's office, the admission assessment and care provided is no different than the patient who was seen in the ED or in an outpatient clinic. This code should be included in the group of services included in a composite APC.

While CMS has made many positive strides to decrease the reporting burden for observation services, some FIs and MACs have increased the operational burden on hospitals by adding other requirements. Within the PRT membership, there are several providers who have FIs and MACs requiring the time related to diagnostic procedures to be carved out and disallowing the reporting of observation stays that are less than 8 hours. The PRT believes that these additional restrictions are contrary to the guidelines published by CMS and are resulting in inaccurate and incomplete data reported to CMS. The PRT requests that CMS issue further directives requiring its FIs and MACs to adhere to and not deviate from the explicit guidance issued by CMS as found in the IOM.

SUMMARY

In summary, the PRT strongly encourages the APC Advisory Panel and CMS to further evaluate non-specific packaging of services and ensure the use of correctly coded claims while discarding incorrectly coded claims (i.e., those where a packaged service would be expected to be reported but is missing) when calculating the independent procedure median costs. Without this level of specificity, if the associated packaged service is missing, an inappropriate allocation will occur and may ultimately compromise the integrity of the future APC rate-setting process. We agree with and support the majority of the APC Advisory Panel's recommendations as we also believe that

sweeping changes of this magnitude require detailed analysis prior to broad-scale implementation and this level of analysis simply cannot be thoroughly accomplished during one regulatory cycle. If CMS proceeds with making such radical changes, it may place hospitals and beneficiaries at risk for very important services. We cannot state strongly enough that it is absolutely essential that CMS conduct an analysis regarding which independent services should have dependent services packaged into them.

If CMS staff has questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052

CMS-1392-P-805 **Medicare**

Submitter : **09/12/2007**

Organization :
Hospital

Category :

Issue Areas/Comments

Drug Administration

Drug Administration

See attached document concerning Proposed Hospital Coding and Payment for Visits which is listed under this section of the proposed rule.

CMS-1392-P-805-Attach-1.DOC

#805

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

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

Proposed Hospital Coding and Payment for Visits

Clinic Visits: New and Established Patient Visits

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

The original definition in 2000 did not specify the three-year time frame; this was added in the 2006 OPPS final rule. This time frame is operationally difficult to apply for hospital providers. A

hospital medical record number is created for the individual patient the first time that services are provided; this may be upon birth or the first time a patient seeks services from a specific provider. This unique number is utilized each time the patient presents for services and is never assigned to any other patient. A multi-hospital system can choose to use the same medical record number at all of their facilities regardless to which campus the patient presents.

To the extent that hospitals expend additional resources evaluating and managing a new patient, these resources can be accounted for in each hospital's internal visit guidelines as is the case with consultation codes.

The PRT acknowledges that CMS' claims data indicates a new patient visit involves more resources than an established patient visit. However, we strongly believe this data may be flawed since it is almost impossible for hospitals to operationalize CMS' definition of a new patient and therefore the new patient visit codes may simply be reported as a matter of course, rather than through some thoughtful charging practice. In addition, we believe providers have reported new patient visits even when less than 3 years have transpired since the patient was last treated at the hospital, again contributing to the cost differences CMS is seeing. Simply put, we do not trust the data providers have reported to CMS given our own experiences and challenges in utilizing these codes and knowing that we do not report them very often. Despite the fact that keeping these codes in place and reporting them would result in better payment rates for some providers, the PRT members and its hospitals would prefer to take a reduction in APC payment rates by using only the established visit codes and having the median costs for new and established patients blended, rather than having to adhere to CMS' required definition of new patient. We truly believe that we are representative of all hospitals when we propose that CMS change its policy so that hospitals are only required to report the five established visit codes and CMS should continue to map these to five separate APC payment rates. Therefore, for 2008 and 2009 payment, the PRT proposes that CMS blend the median cost data for new and established visit codes and create five distinct levels of APC payment for these visit codes. We are willing to live with reduced payments over the next two years while reporting five visit codes but fully expect that CMS will receive much more accurate and robust cost data after two years at which time we believe APC payment rates for visits will stabilize and be more reflective of our resource consumption.

If CMS chooses to continue reporting both new and established visit codes, the PRT strongly urges CMS to change the definition of an established patient by removing the verbiage "created within the past 3 years" and return to the original definition published in 2000: "*If the patient has a hospital medical record, that patient is considered an established patient to the hospital.*"

Type A and Type B Emergency Departments

CMS has specifically requested comments on the clarification needed to assist hospitals in determining whether an ED is a Type A or Type B, and on how this policy can be further clarified in light of hospitals' operational responsibilities to efficiently provide emergency services.

Providers are in full agreement and understanding of the application of Type B designation for "Fast Track" areas that are physically separate from the main ED; that have specific staff assigned for care of those patients; and that have specific hours (not 24/7) of operation. The Provider Roundtable (PRT) requests that CMS provide further clarification and specific guidance related to the necessity to "carve out" part of an Emergency Department for reporting as Type B.

Hospitals have an operational responsibility to efficiently provide services, and facilities work very hard to expedite patients through the system without compromising care. CMS notes throughout the proposed 2008 rule that they are specifically encouraging flexibility in resource utilization in order to provide quality care in the most cost effective manner possible. To that end, many hospitals are doing just this by finding a way to cluster patients in a specific set of rooms, identified as "fast track" rooms, which are housed within the main ED area. These rooms are used to treat both critical and non-critical patients. The staff that treats these patients are ED staff. The rooms used are available 24/7, but may not be used during all hours/days depending upon the census of the ED. The PRT contends that this "fast tracking" of patients is a process improvement initiative, and is not dependent upon the place of service. During peak patient visit hours, it is beneficial for some patients to be clustered in these "fast track" rooms rather than being spread throughout the ED. Facilities usually set specific hours when these rooms are "carved out" for fast tracking patients through the main ED due to historical data on ED census. The rooms may not be used outside these hours if they are not needed, but are functional for any ED patient when needed. Patients in a "fast track" room receive the same level of care as other patients: hospital staff floats between all ED rooms, although a specific nurse may be assigned to the "fast track" rooms during designated hours. As in any other nursing area, nurses receive a patient care assignment but ultimately have responsibility for all patients in that area. This is true for ED patients also, whether those patients are specifically assigned to a "fast track" room or not.

We believe the broad application of the "Type B" designation to include dual-use rooms within the ED walls has the unintended result of financially penalizing providers that utilize these "fast track" processes to improve patient care and reduce wait times. The PRT requests that CMS accept "fast track" as a process in this type of situation and refine the definition of Type B to exclude "carve out" rooms when the entire area as a whole meets the definition of a Type A Emergency Department.

Development of National E/M Guidelines

The Provider Roundtable (PRT) appreciates CMS not releasing national guidelines that are not functional in a hospital setting. We also appreciate CMS' acknowledging that providers have been diligent in creating, refining, and maintaining internal guidelines. We understand CMS' current data indicates that hospitals' internal guidelines have produced stable visit level assignments without great fluctuation from year-to-year. However, we still believe it would be valuable in the future for CMS to move towards standardization and the development of national E/M guidelines. To that end, the PRT supports CMS' work toward the development of national E/M guidelines, but does not believe that there is a pressing need in the immediate future. The PRT provided analyses, modeling, and comments/recommendations to CMS earlier this year concerning development of national

guidelines and hopes that information was useful in CMS' own analysis.

The PRT agrees that the initial six criteria, along with the additional five proposed E/M criteria form an excellent framework for the development of facility specific E/M guidelines. A poll was conducted among the PRT membership and all members note that the criteria proposed are reasonable and expect that most hospital's guidelines already meet these principles. We recommend that CMS define "great frequency" in the proposed criteria: "*The coding guidelines should not change with great frequency.*" The PRT applauds CMS for their continued efforts on this issue.

The PRT encourages CMS to work with and encourage the AMA to include these principles in the E/M section of the CPT book. Doing so would ensure easy access to the guidelines, promote consistency among all providers, and enable other payers to accept that CMS' use of the AMA CPT codes is different in the hospital setting versus physician setting.

The PRT has learned that some FIs are imposing their own unpublished E/M criteria upon providers rather than utilizing the provider's internally developed E/M guidelines during facility audits; these FIs are determining "reasonableness" of services as they relate to placement within various levels. When applied by the FI, these unpublished guidelines are detrimental to the hospital claims data as they are producing lower level calculations than the hospital's internal guidelines and more important, are in direct conflict with CMS' directive that requires providers to develop and use their own internally developed guidelines to report clinic and emergency department E/M visit codes. Hospital internal guidelines must be recognized by the FIs and to that end, the PRT vehemently urges CMS to provide clear direction to its FIs that they must use the individual facility's E/M internal guidelines when conducting a review or audit. CMS should explicitly state that an FI (or MAC) is not allowed to impose its own criteria upon the provider. The PRT asks that CMS make this explicit in instructions to FIs and MACs to be issued as soon as possible.

<u>E&M ED Triage Issue</u>

In the absence of national visit guidelines for Emergency Department services, the Provider Roundtable (PRT) would like clarification from CMS regarding the use of a low-level ED Visit code to cover the facility resources of a patient who is triaged and receives services, but leaves before receiving any physician or non-physician practitioner treatment. This question has been posed several times during the Hospital Open Door Forum calls yet remains unanswered despite the obvious need for clarification from CMS at a national level.

In this context, "triage" includes an initial assessment by a licensed practitioner (who is not a physician or non-physician practitioner) to ascertain whether the situation must be immediately managed (e.g., profuse bleeding, chest pain) or whether the situation is less life threatening (e.g.: sore throat, migraine headache).

Hospitals have an obligation under EMTALA to provide a Medical Screening Evaluation (MSE). However, some patients leave before receiving this MSE from a designated qualified provider (as dictated by state laws and/or hospital by-laws). We are concerned about the resource utilization

associated with assessing patients who present to the hospital ED, but leave before receiving the MSE.

Technically, there is no coverage for the above scenario under the "incident-to" provisions for Hospital OP Therapeutic Services [100-02, Chap. 6, Section 20.4]: *"Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services. To be covered as incident to physicians' services, the services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician."*

Triage is not covered because a) there is no professional service for it to be integral to, nor alternatively b) there is not an order to provide the service. There is, however, an expectation that the service will be provided to ensure that the most critical patients are seen first. However, by nature of the presence of physicians within the ED, the "general assumption of supervision" is met on hospital premises.

However, it is also conceivable for triage services to be considered diagnostic services. Under section 20.3 in the manual [100-02, Chap. 6, Section 20.3] guidance is provided as follows: *"A service is 'diagnostic' if it is an* ***examination*** *or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury."* Additionally, *"Covered diagnostic services to outpatients include the services of nurses..."*

Historically CMS has alluded that the resource associated with a nursing assessment is commensurate with a low level E/M visit. Additionally, the ACEP model includes "triage" in the 99281 list of possible interventions. We believe that CMS recognizes that facility resources are expended for triage and did propose that triage be "payable" (though did not explicitly indicate that it is "covered") when CMS initially proposed HCPCS codes to replace E/M codes in 2002:

"Emergency Visits
Because, our data indicated that, in general, hospitals under the OPPS were reporting emergency visits appropriately, we believed that insofar as hospitals have existing guidelines for determining the level of emergency service, those guidelines reflected facility resource consumption. Therefore, we proposed that GXXX1— Level 1 Facility Emergency Services be reported when facilities deliver, and document, basic emergency department services. These services included registration, triage, initial nursing assessment, minimal monitoring in the emergency department (for example, one

additional set of vital signs), minimal diagnostic and therapeutic services (for example, rapid strep test, urine dipstick), nursing discharge (including brief home instructions), and exam room set up/clean up. We expected that these services would be delivered to patients who present with minor problems of low acuity."

We believe that CMS has the authority to designate 99281 as a "nurse visit" under OPPS just as CMS has treated 99211 under the Medicare Physician's Fee Schedule (historically referred to as a "nurse visit" but listed in the current IOM 100-04, Chap. 12, Section 30.6.4) as follows: *"When evaluation and management services are furnished incident to a physician's service by a nonphysician employee of the physician, not as part of a physician service, the physician bills code 99211 for the service."*

In an environment where utilization of Emergency Room services is increasing annually, it is imperative that CMS define which hospital resource expenditures are reportable if the patient is not seen by the physician. Hospitals are required to accept all patients who present with a possible emergency condition and utilize resources to assess each patient. The PRT asks for clear instructions from CMS that these services are reportable. Providers have broached this question with different FIs and have received contradictory responses resulting in variable data being reported to CMS from providers around the country. The PRT presents several actual Emergency Department scenarios to facilitate answers by CMS. In all of these scenarios, it is given or assumed that the emergency physician is present in the emergency room meeting hospital physician supervision requirements.

1. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. The assessment process indicates the patient may wait in the waiting area until an ED bed becomes available. The patient leaves the hospital before receiving any other service. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines?

2. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. Based on the patient's clinical presentation, Emergency Room protocols allow the nurse to initiate diagnostic tests (for example, a patient presenting with chest pain may meet criteria to initiate a chest pain protocol which would instruct the nurse to draw cardiac enzymes, obtain an EKG, and possibly a CXR. The protocols are reviewed at regular intervals and approved by the ED physicians). The protocol orders are documented on the patient's medical record. The patient leaves without any other service. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines?

3. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. Based on the patient's clinical presentation, Emergency Room protocols allow the nurse to initiate diagnostic tests (for example, a patient presenting with chest pain may meet criteria to initiate a chest pain

protocol which would instruct the nurse to draw cardiac enzymes, obtain an EKG, and possibly a CXR. The protocols are reviewed at regular intervals and approved by the ED physicians). The protocol orders are documented on the patient's medical record. The patient leaves without any other service. The physician does not personally examine the patient, but personally reviews, authenticates and dates the encounter record in the chart. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines??

4. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. Based on the patient's clinical presentation, Emergency Room protocols allow the nurse to initiate diagnostic tests (for example, a patient presenting with chest pain may meet criteria to initiate a chest pain protocol which would instruct the nurse to draw cardiac enzymes, obtain an EKG, and possibly a CXR. The protocols are reviewed at regular intervals and approved by the ED physicians). The protocol orders are documented on the patient's medical record. The physician personally examines the patient, documents a note and authenticates and dates the encounter record in the chart. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines??

If CMS staff has questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052

CMS-1392-P-806 **Medicare**

Submitter : **09/12/2007**

Organization :
Hospital

Category :

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

Please see attached comment regarding "OPPS: Device-Dependent APCs", specifically concerning when devices are replaced with partial credit to the hospital.

CMS-1392-P-806-Attach-1.DOC

#806

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

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

Proposed Payment when Devices are Replaced with Partial Credit to the Hospital

The PRT agrees that beneficiaries should get the benefit of reduced device costs when replaced at full or partial credit to the hospital. However, we have several comments concerning the proposed payment policy, particularly in comparison to the Inpatient Prospective Payment System (IPPS) policy in this area and the operational implications.

On page 371 of the display copy, CMS states "*some hospitals have told us that they do not reduce charges for the device being implanted or used in the procedure in cases in which they receive a partial credit for the device, even in cases in which the credit is as much as 50 percent of the cost of an expensive device.*" The PRT is highly concerned with this statement because we believe such hospitals are already in violation of CMS policy stated at PRRM Section 2204.4 which reads: "*Medicare charges refer to the regular rates for various covered services which are charged to beneficiaries for inpatient or outpatient services. The Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.), must be recorded in the respective income accounts of the facility,* ***and must be***

related to the cost of the service. "[emphasis added]. A charge for a device that has received a credit cannot be related to the cost of the device if it is charged the same amount as a device which received no credit. The PRT believes that CMS merely needs to re-emphasize existing policy with regard to hospital charge practices and instruct hospitals to reduce their charge for devices if there is a manufacturer credit.

CMS states that the median cost for device-dependent APCs used by CMS does not reflect full or partial credits because claims with modifier FB and token device charges were excluded. However, the PRT notes that to the extent the provider's cost of devices in their Medicare cost report reflects reduced costs due to credits, full and partial, the CCR used to reduce charges to cost does include the impact of credits. If the hospital did not reduce their billed charge for a credit, then the CCR for that department will be lower and the median cost calculation lowered. For example, if the hospital used one device and their charge is $200 and their normal cost is $100, then the CCR would be 0.50. If they received a 50% credit on the one device implanted and retained their billed charge of $200.00, then their CCR would drop to 0.25 ($50.00/$200.00). If the hospital does reduce its billed charge, then the CCR will also reflect credits and the median cost calculation using the CCR will reflect the credit.

For OPPS, CMS proposes to reduce the device-dependent APC payment by 50 percent of the offset that would apply if the device were replaced at no cost, but only if the credit is 20% or more of the cost of the new replacement device. Note that the offset percentage is the percentage of the APC payment that is attributable to the cost of the device. Also, note that under PRRM Section 2302.6, hospitals must charge the same amount for the same service to inpatients and outpatients, so this offset amount should appropriately represent the value of the device under both OPPS and IPPS.

Under CMS' proposal, when a hospital receives a credit of 20% or more of the new device, CMS will reduce the payment for that device by 50%, a direct loss to the provider of up to 30% of the cost of the device. The PRT notes that this was the original policy proposed by CMS for the Inpatient Prospective Payment System, but later changed to 50 percent as discussed on page 479 of the display copy of the IPPS Final Rule for 2008. We note that CMS does not explicitly describe the type of DRG payment reduction to apply when a full or partial credit is received by a hospital for a device as evidenced by the presence of condition codes 49 and/or 50 on a claim. Rather, CMS leaves the logistics of this situation up to individual Fiscal Intermediaries and contractors up to and including the hospital having to produce an invoice for the device to the contractor upon request.

Finally, CMS requests that hospitals report a unique modifier if the credit on a replacement device is 20% or more of the cost of the replacement device. CMS states that requiring hospitals to reduce charges may be burdensome. Given that CMS already has policy in place that would require a hospital to reduce charges when its cost is reduced (i.e., PRRM Section 2204.4), it seems administratively burdensome to add an additional modifier when that modifier will not completely provide CMS with the information that it seeks (i.e., the amount of the device credit). Furthermore, adding modifiers is a coding requirement, whereby adjusting charges is a departmental requirement and the value of a credit is known to a department, not necessarily to a coder.

The PRT notes that the IPPS and OPPS policies are inconsistent and operationally untenable and likely to provide poor claims data for CMS to base future policies. Furthermore, CMS has not

published the calculation or amounts of device reductions to apply under IPPS and neither have they published the savings to beneficiaries in their deductible if they are hospitalized as an inpatient and receive a replacement device at full or partial credit. In other words, how will the beneficiary benefit from the DRG payment reduction CMS plans to take?

For these various reasons, the PRT proposes the following to bring consistency to the two payment programs for these devices and which provides CMS with the information it needs in a manner that has the least reporting/administrative burden.

PRT Recommendations	IPPS	OPPS	Needed CMS Action
Provider charges for the device must reflect cost as per PRRM Section 2204.4	Provider charges must be reduced by the percentage of the credit. If 100% replacement, then token charge for the device only.	Provider charges must be reduced by the percentage of the credit. If 100% replacement, then token charge for the device only.	Restate policy per PRRM Section 2204.4 and instruct hospitals to reduce their charges for devices replaced at no or partial credit by the amount of the reduction.
Provider reports condition code 49 and/or 50 for full credit	Provider notes 100% credit in remarks field	Provider notes 100% credit in remarks field	Change policy to require hospitals to report the percentage of the credit in the remarks field on the UB04 claim when condition code 49 or 50 is reported.
Provider reports condition code 49 and/or 50 for partial credit of 50% or more	Provider notes percentage of credit in remarks field	Provider notes percentage of credit in remarks field	Change policy to require hospitals to report the percentage of the credit in the remarks field on the UB04 claim when condition code 49 or 50 is reported.
CMS Payment adjustment for a device with 100% credit	CMS reduces DRG payment by 100% of the applicable OPPS device offset (represented in dollars, not as a percentage) as calculated under OPPS	CMS reduces the APC payment by 100% of the device offset (current 2007 policy)	CMS uses the device cost calculations from OPPS to make payment reductions under both OPPS and IPPS.

CMS Payment adjustment for devices with 50% or more credit to the device	CMS reduces DRG payment by 50% of the applicable OPPS device offset (represented in dollars, not as a percentage) as calculated under OPPS	CMS reduces the APC payment by 50% of the device offset	CMS uses the device cost calculations from OPPS to make payment reductions under both OPPS and IPPS.

The advantages to the PRT recommendations are as follows:

1) The hospital will know ahead of time the amount of the reduction for both OPPS and IPPS.
2) The hospital does not have to report a special modifier under OPPS in addition to modifier FB and also condition code 49 and/or 50
3) The hospital communicates the exact amount of the device credit to CMS to allow CMS to track this issue.
4) The payment reduction for partial credit is consistent between OPPS and IPPS (i.e., 50 percent) and the amount of payment reduction known in advance to the hospital.
5) Fiscal Intermediaries can conduct audits to ensure hospitals are correctly reporting percentage credits, but hospitals do not have to provide invoices before an IPPS claim with a partial credit is processed for payment and this will allow the CMS contractors to process claims more readily.

If CMS staff has questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052

CMS-1392-P-807 **Medicare**

Submitter : **09/12/2007**

Organization :
Hospital

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Please see attached document regarding Specified Covered Oupatient Drugs for OPPS 2008.

CMS-1392-P-807-Attach-1.DOC

#807

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

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

Pharmacy Handling and Separately Payable Drug Payments

The Provider Roundtable (PRT) has significant and grave concerns about the proposed reporting of pharmacy handling. CMS is bound by the statutory language of "average drug acquisition cost" and the PRT acknowledges CMS' directive to pay according to the statutory provision. The PRT suggests that defining pharmacy payment with terminology such as "ASP + X%" does separate drug cost from overhead/handling and meets the statutory requirement. The PRT also understands that CMS is attempting to remove the discrepancy between payment systems but also suggests that CMS has not factored into the equation the additional requirements that hospital pharmacies face when compared to retail pharmacies and physician's offices. Retail pharmacy systems have the capability of reporting drug acquisition cost separate from handling as retail pharmacies are reimbursed for handling/dispensing. For hospitals, there is no way to quantify handling easily and no way to automate the process. The proposed methodology of reporting pharmacy handling is unreasonable and presents HUGE operational issues for hospitals.

Operational concerns:

While CMS believes the uncoded revenue code is operationally easier than the prior C-code idea, the PRT disagrees and believes the new proposal is even worse in several ways. We understand that for one category of drugs – SCODs - CMS needs to address the statute by paying average acquisition cost and also pay for overhead/handling, but we do not believe the statute dictates separation of these payments. Primarily, the concept of separating overhead/handing from acquisition costs of drugs is an operational nightmare with significant financial risk to hospitals.

The first concern is calculating pharmacy handling consistently because there are many variables that prevent a quick and easy calculation. Each drug will have a different handling charge depending on the route of administration. For example, the same drug may be given orally, IV push or via IV infusion. This creates three separate and unique calculations in order to reflect the accurate handling charge for a single drug with multiple preparations. The PRT asks CMS to imagine the resources required by our pharmacy departments to develop such charges for all of the drugs we currently administer, let alone all of their preparations.

Another issue that CMS should understand is that existing pharmacy systems cannot handle the explosion of charges and billing systems cannot automatically split one line item charge into multiple line items. To accommodate the reporting of a separate handling charge, hospitals will have to double the size of the Charge Description Master (CDM) or add items that can be "edited" so the individual handling charge can be added for each drug. Once this is completed, there is more manual intervention in order to insure that the correct charge is added to the individual claim. EACH account will have to be reviewed in order to know which drugs have been charged. The handling charge must be calculated individually (for editable CDM items) or the specific CDM number for the handling of that INDIVIDUAL drug must be selected. These items then have to be keyed in on the individual account. This process is just to get a claim out the door to Medicare. This will be a manual intervention nightmare for all providers!

Manual intervention correlates to a huge potential for errors. If charge corrections are required, someone has to remember to correct the handling charge also. This whole proposal creates a potential compliance risk for hospitals – if the correct handling charge is not rolled up to the correct drug line item, hospitals will inadvertently report incorrect data to private payers and have potentially billed a different individual drug charge to Medicare than to its private payers.

Most billing systems can combine charges by revenue code, grouping all items together for a single revenue code, but they cannot split line items out. Billing systems will not be able to allocate the handling charge to the individual drug line item charge. Additionally, billing systems are not able to allocate charges on a noncoded revenue line item to multiple revenue code lines. If pharmacy handling is reported under revenue code 259 (for example purposes only), and drugs are reported under revenue codes 636 and 250, it will be impossible for the billing system to know how much of the handling reported in revenue code 259 to allocate to revenue code 636 versus revenue code 250. Billing systems also do not combine HCPCS/CPT coded lines with noncoded lines for payment combination, even when reported under the same revenue code on the same date of service. Because revenue code 636 requires a HCPCS code, and the pharmacy handling will be a noncoded line item charge, there is no way to combine the two drug related charges onto one line item.

This creates a huge concern regarding cross-over claims. Once a hospital submits a claim to the primary payer, the primary payer transmits the claim to the secondary payer in many circumstances. If one of the payers is Medicare, this creates a huge potential for denied claims. Will Medicare's system be able to correctly report the charges to the non-Medicare secondary payer? If Medicare is the secondary payer, will Medicare accept the claim from the primary payer who doesn't accept separated line items and has no concern about what amount should be left on the drug line and what amount should be split out for pharmacy handling? How will each payer administer cross-over claims or will the hospital simply be penalized by delayed or denied payment?

CMS mentions in the proposed rule that *"So long as hospitals provide the same total charge to all payers, it would be acceptable to report that charge as a line item for one payer and two (or more) line items for another payer."* While we don't necessarily disagree with this statement, this will be a reporting burden for providers. Several non-Medicare payers have requirements that medications must be billed at the negotiated rate with no additional fee to cover pharmacy overhead. Many payers and some states require hospitals to submit a complete CDM on an annual basis. There is a high likelihood that these payers and states will see those separate charges for pharmacy overhead and disallow those detailed line items altogether on audit (even if the provider did roll them together on the claim to a single line item), because when a claim is audited, it is audited from the detail bill, not the UB claim form. This structure will create a prime target for third party payer auditors to deny the pharmacy handling line item, and perhaps the entire drug charge since they will not be able to disaggregate the information in any automated manner. That means that providers would still have to maintain the single comprehensive charge in the CDM for the drug which includes the overhead component, and then outside of the CDM (most likely manually) providers will have to manipulate the Medicare claim form. So this reporting requirement could become an entirely back-end manipulative process as noted previously in this comment.

Data Issues from the proposed rule:

From a data collection, or more important from a data integrity standpoint, the PRT is concerned about what will happen with the overhead costs in the larger context of multi-procedure claims as CMS looks to the rate-setting process in future years. First and foremost, we are having a difficult time evaluating specifically what will be required to produce a final claim since CMS' proposal does not name a specific revenue code for all providers to use to report the pharmacy handling charges; coupled with the fact that the rule also does not specify what constitutes pharmacy handling...it is left up to providers to decide.

But in the bigger picture, the concern is that additional lines of uncoded charges within the universe of claims will result in even more data being lost within the packaging hole as we believe CMS will see more and more drug charges, both the separately payable drug and the packaged pharmacy handling drugs charges on multiple procedure claims. Many drug charges already appear on multi-procedure claims and are currently not accounted for in the rate-setting process, therefore this proposal will simply compound CMS' inability to allocate packaged dollars correctly to procedures. CMS even reiterates in this proposed rule that "*we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.*" If

CMS can't use the claim then the packaged dollars for handling fall completely out of the rate-setting process which will result in even lower aggregate drug reimbursement in the future.

By leaving the door open for providers to decide whether or not they want to report the overhead charge on a per drug or per episode basis, claims data will reflect wildly differing charges which bear no relationship whatsoever to the procedure or procedures being performed. The question is: what if there is a multi-procedure claim for drug administration (for instance one that includes both chemo and non-chemo infusion, as well as an injection), and assume the claim could be manipulated in some way to become a pseudo-single---if that provider chooses to report overhead on per-episode basis (which means only one line item), how would the "*per-episode*" overhead be allocated to the individual drug administration procedures or is this irrelevant to CMS or in all likelihood will CMS simply view this as a multiple procedure claim for rate-setting purposes and not include it in future APC rate setting?

Another situation that happens very frequently in the outpatient hospital setting is that drug administration services are not reported on all claims that have pharmacy charges. Where will the pharmacy handling costs be packaged on these claims? Currently, drug administration services are not reported separately with surgery procedures as drug administration is considered to be part of the surgical procedure. Why should hospitals have the administrative burden of separating the two costs just to have them packaged into the procedure where they are going to be packaged anyway? If handling line items are excluded, then CMS' claims data is seriously flawed and will negatively affect future APC payment calculation.

CMS will never get 100% accurate data on separation of acquisition cost and handling. They will get a blend of both costs. Since there is no literally defined information for pharmacy handling, CMS is not going to get real information but only approximations. Many facilities will set a flat fee for handling which will reflect an average which will be overstated for some drugs and understated for others. CMS will also have to reconstruct their use of CCR. If hospitals bill one line based on acquisition cost, CMS cannot apply the current CCR because it is based on claims data and cost report information for a combined charge under this proposal. What was once a one line item charge has been split into at least two separate line items.

If the ultimate intent is to keep overhead packaged, the PRT fails to see the necessity of splitting out the two and reporting them on separate line items. The PRT believes that pharmacy handling is currently packaged in the most appropriate place – the pharmacy and with the drug, and should remain there. So we support CMS' "second" option as presented in the rule, which is to continue to provide a single bundled payment, representing combined acquisition and overhead, and make no changes to the reporting. And, as is mentioned in the proposed rule, this method still is consistent with your broader packaging efforts.

Should CMS move forward with the proposed structure of reporting pharmacy handling, it is absolutely impossible for hospitals to report this by January 1, 2008. This proposal would have to be delayed until such time as time and motion studies can be conducted by our pharmacists to establish appropriate pharmacy handling charges, To that end, CMS must issue a definition of pharmacy handling and manualize this definition; define the revenue code for reporting the handling charge (which should correspond to the pharmacy department so that cost matches expense), obtain

NUBC approval for usage of a revenue code for this purpose, and issue guidance to assist hospitals in convincing the pharmacy and/or billing vendors that this process must be automated. The aforementioned documentation will possibly assist with explaining the charge structure to non-Medicare payers. The delay will have to allow for Medicare, Medicaid and other payers to alter their claims systems that deal with cross-over claims to prevent delays and denials of hospital services because of the differing reporting requirements. The delay will also have to allow for the pharmacy and billing systems vendors to automate this function in their systems.

Separately payable drug APC payments based on ASP + 5%

The PRT cannot stress enough that we recommend CMS continue to use at a minimum ASP +6% as the payment method for average acquisition plus overhead/handling for all separately payable drugs. This formula elegantly covers average acquisition cost because average sales should equal average purchase costs and it retains consistency with payment for the same drug between sites of service (the hospital and the physician office setting), a principle CMS continues to promote. Prior studies by MedPac and data collected directly from hospitals indicates that ASP + 6% does not cover both acquisition and handling cost in the hospital setting. Despite this lack of appropriate reimbursement, the PRT and its member hospitals consider this more palatable than the proposed new reporting structure of carving out pharmacy handling separately from the drug charge. Making hospitals expend resources resulting from huge administrative costs to break out pharmacy overhead/handling with no apparent improvement to the payment system or to the quality of care or safety of medication administration is a direction that appears to be futile, and goes against CMS' stated goals of cost-containment, value-based purchasing, improvements in quality of care, and finally the flexibility it says in the proposed rule that it wants to give providers.

If CMS staff has questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052

CMS-1392-P-808 **Medicare**

Submitter : Dr. Richard Ray **09/12/2007**

Organization : Dr. Richard Ray
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-808-Attach-1.PDF

CMS-1392-P-808-Attach-2.RTF

CMS-1392-P-808-Attach-3.TXT

#808

September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. I believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925

in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current

proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

1 Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
2 Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
3 Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
4 Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

R.Ray MD

Northeast Ohio Center for Pain Management, 60 S. Pleasant St. ,Ste B Oberlin , OH 44074-1633

CMS-1392-P-809 **Medicare**

Submitter : Mr. David Sniff **09/12/2007**

Organization : Sarah D. Culbertson Memorial Hosptial
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

see attachment

CMS-1392-P-809-Attach-1.PDF

CMS-1392-P-809-Attach-2.PDF

#809

Sarah D. CULBERTSON Memorial Hospital

238 South Congress • Rushville, IL 62681

Telephone: (217) 322-4321
Fax 1 : (217) 322-6425
Fax 2 : (217) 322-4246

Website: www.cmhospital.com

September 12, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, D.C. 20201

Delivered Via ON-Line Form: http://www.cms.hhs.gov/eRulemaking

Subject: CMS-1392-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates: Proposed Changes Affecting Necessary Provider Designation of Critical Access Hospitals

Dear Deputy Administrator Kuhn:

I am writing on behalf of Sarah D. Culbertson Memorial Hospital , Rushville, Illinois in reference to proposed changes that will impact the Critical Access Hospital (CAH) program. I respectfully urge you to withdraw the provisions in this rule relating to provider based off-site facilities owned by "necessary provider" Critical Access Hospitals (CAHs).

Of major concern is the provision that would restrict CAHs from operating any offsite facilities after January 1, 2008 unless they meet the 35 mile criteria. All of our Illinois CAHs are "necessary providers." For my hospital, it will be geographically impossible to find a new off-campus location that would meet the 35 mile requirement.

As you well know, physician shortages are one of the most difficult challenges facing our rural hospitals. This will have a serious negative impact on the provision of physician services, especially in our rural designated shortage areas in Illinois.

The CAH program was enacted to help struggling small rural hospitals maintain the financial strength to enable them to care for their communities. The proposed rule changes run counter to this goal and would jeopardize the ability of hospitals like mine to provide essential health care for our seniors.

With these issues in mind, I again, respectfully urge you to withdraw the provisions in this rule relating to off-site clinics owned by CAHs. .

Thank you for your consideration. Please contact me with any questions you may have.

Sincerely,

D. David Sniff
CEO

CMS-1392-P-810 **Medicare**

Submitter : Dr. Willam McRoberts **09/12/2007**

Organization : Holy Cross Hospital
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please print the following attached note thanks

CMS-1392-P-810-Attach-1.DOC

#810

September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. I believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on

the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all

settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

W. Porter McRoberts MD, Chief Pain Medicine and Interventional Spine and Pain Management, Holy Cross Hospital
Sharon Atwood NPAC
Robert Mills MD
Bill Leone MD
Martin Roche MD, Chief, Department of Orthopaedics
Brian Fingado MD
Jose Jackson MD
Jose Diaz MD
Pat Taylor MD, CFO, Holy Cross Hospital
James Desmarteau
Neil McKay RN
Marsha McClung
Denise Daley
Karien Berg
Mark Forinash, RN
Rick Cope MD
John Johnson, President, Holy Cross Hospital, Fort Lauderdale, Florida 33308