Submitter : **Beth Wild Shiring** **Date: 10/10/2006**

Organization : **University of Pittsburgh Medical Center**

Category : **Hospital**

Issue Areas/Comments

OPPS Impact

OPPS Impact

See Attachment

CMS-1506-P-487-Attach-1.DOC

UPMC | University of Pittsburgh Medical Center

October 9, 2006

The Honorable Mark A. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: CMS-1506-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. McClellan:

UPMC Cancer Centers welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule CMS-1506-P, "Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule."

UPMC Cancer Centers encompasses 180 cancer specialists at approximately 40 hospital-based and office-based locations throughout in western Pennsylvania and serves a population of more than 6 million. Treating approximately 30,000 new patients per year, UPMC Cancer Centers is one of the largest cancer care networks in the nation. Our vast network represents the full spectrum of cancer care delivery including: physicians operating sole practices in rural areas; free-standing medical and radiation oncology facilities in rural and suburban areas; and a large group of academic physicians providing hospital-based outpatient care at the flagship Hillman Cancer Center and Magee Women's Hospital in Pittsburgh.

Since our region has one of the highest concentrations of individuals age 65 and over, the age group most at risk of being diagnosed with cancer, we rely heavily on CMS to provide fair and adequate reimbursement for us to care for these patients. We commend CMS for its increased research and analysis into the costs of providing cancer care; however, we do have some concerns regarding the proposed rule that we outline below.

OPPS: New HCPCS and CPT Codes

CMS is proposing to reassign nonmyocardial PET, PET/CT and Steriotactic Radiosurgery (SRS) procedures from new technology to clinically appropriate APC's. We do not believe that there has been sufficient claims data to warrant this change. Many hospitals are still adopting these highly useful, noninvasive diagnostic and treatment tools. Even within the past year CMS has increased the number of allowable diagnoses, which, depending on the severity of the cancer diagnosis, will provide further claims data. We urge CMS to wait two more years until sufficient claims data is collected. If implemented, the impact of these changes would be an estimated PET reduction of $385/scan and a reduction in Cyberknife of $1,200 per SRS fraction.

OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

While we commend CMS for continuing to pay separately for oral and injectable anti-emetics, we do not agree with the proposed rule to increase the drug packaging threshold to $55. Increasing the threshold further limits separate payment for chemotherapy drugs. Eliminating the threshold and paying for all drugs would provide greater equity across provider settings. This would not cause undue burden on hospitals as they have been encouraged to report charges for all drugs, biologicals and radiopharmaceuticals regardless of whether the items are paid separately or packaged.

In CY 2006 CMS adopted the physician fee schedule methodology of ASP +6% for reimbursing separately covered outpatient drugs (SCOD). While we do not believe this payment is sufficient to cover the total cost of drug storage, handling and delivery, this reimbursement methodology was consistent with the used that used by physician offices. CMS is now proposing to cut the ASP further to ASP+5% in the OPPS. There are several problems with the ASP calculation that are further exacerbated by the change to ASP+5%. Some issues include:

- ASP is based on the price that manufacturers charge to distributors, including any prompt pay discounts. These prices and discounts often are not passed along to providers but are included in the calculation of ASP.
- ASP is based on sales to all entities, including group purchasing organizations and large hospital systems on one end of the spectrum and one-physician oncology practices on the other. It means that many hospitals, particularly the smaller ones without purchasing power, will purchase drugs above ASP.
- There currently is a two-quarter lag in the calculation of ASP, meaning that reimbursement is based on prices that are six-months old. Since manufacturers typically raise prices two to three times per year, there is potential for hospitals to suffer losses each time they administer drugs. Even as a large volume buyer, UPMC currently pays greater than ASP for many of our most highly utilized drugs and, in some cases, pay greater than ASP + 6%.

This 1% decrease in reimbursement is compounded with the increase in the packaged threshold. Implementation of ASP+5% would have a negative impact to our net revenue of an additional 3% to our hospital-based locations drug revenue. We recommend that CMS not reduce the already insufficient payment of ASP+6% for drug and consider implementation of the 2% pharmacy handling fee that was discussed in last years proposed rule. We also recommend CMS continue to look for more equitable means of calculating ASP.

OPPS: Drug Administration

In CY 06 CMS adopted 20 of the 33 new CPT codes for drug administration and created six HCPCS codes. While we were able to implement these codes, we strongly agree with CMS's proposal to create six new drug administration APC levels. This will provide for more accurate payment for complex and lengthy drug administration services. We believe that reimbursing for all drug administration services will help to better offset the hospital's costs of providing drug therapies, particularly for the large number of our patients who receive multiple infusions in a single visit or whose infusions take more than one hour to administer. We also recommend that CMS take measures over the next twelve months to evaluate the adequacy of reimbursement for drug administration.

UPMC Cancer Centers would like to thank you for the opportunity to offer our formal comments for your consideration. As always, we are committed to serving the senior citizen population through the Medicare program. We stand ready to work with you to improve that program so that seniors can continue to access the highest quality care.

Sincerely,

Beth Wild Shiring
Chief Operating Officer
UPMC Cancer Centers

Submitter : **Date: 10/10/2006**

Organization : **American Society of Breast Surgeons**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

please see attached

CMS-1506-P-488-Attach-1.DOC

The American Society of Breast Surgeons
5950 Symphony Woods Road, Suite 212
Columbia, MD 20144
Phone: 410-992-5470
Fax: 410-992-5472
Email: jschuster@breastsurgeons.org

October 9, 2006

Administrator Mark McClellan
Center for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Rule: Hospital Outpatient Prospective Payment System (OPPS) (**CMS-1506-P**)

Dear Administrator McClellan:

The American Society of Breast Surgeons (ASoBS) welcomes and appreciates the opportunity to provide comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare Hospital Outpatient Prospective Payment System (HOPPS) proposed rule for calendar year 2007. In particular, we wish to express our concerns regarding CMS's proposed assignments of 19296 and 19297 to new APC's and the impact these proposed reassignments will have on breast conservation therapy.

The ASoBS is a non-profit specialty society with members who are dedicated to treating and caring for patients with breast disease. Additionally, the society encourages the study of breast surgery, promotes research and developments of advanced surgical techniques, improves standards of practice for breast surgery, and serves as a forum for the exchange of ideas. As surgeons devoted to offering surgical and treatment options for our patients with breast cancer, we are very concerned about the proposed reductions in the area of *breast brachytherapy*.

Approximately 80% of women who are diagnosed with breast cancer are detected in the early stages of the disease, when there is a 97% rate of five-year survival. The National Cancer Institute has stated that breast-conservation therapy (lumpectomy followed by radiation therapy) is preferable to mastectomy for most early-stage cancer patients, with comparable long-term recurrence and survival rates. It is the standard of care to provide radiation therapy to the breast following breast conservation surgery.

However, according to the SEER data, up to 19% of women who undergo breast conservation surgery do not proceed to radiation therapy as recommended. The women who forgo radiation have a threefold increase in risk of recurrence of the tumor according to a study published in the Journal of National Cancer Institute in 2004. We know that a majority of local recurrences after breast conserving therapy occur at or near the tumor bed.

For years, whole breast external beam radiation has been the only option for women following breast conservation surgery. A typical treatment course of whole breast external beam radiation requires the patient to visit the radiation oncologist every day, Monday through Friday, for 5-6 weeks.

In the last few years, we have been able to offer women the choice between whole beam radiation and breast brachytherapy. Breast brachytherapy is targeted radiation therapy where the radiation source is placed inside the tumor cavity through a special balloon catheter, and only delivers radiation to the area where cancer is most likely to recur. This technique limits radiation to healthy tissue, lungs and heart, thus reducing possible side effects experienced during whole breast external beam radiation. Unlike whole breast external beam radiation, breast brachytherapy is completed in 5 days. The balloon catheter used to deliver the radiation may be placed in the tumor cavity either at the time of lumpectomy or several days later after the final pathology results become available.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APC's 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APC's to clinical APC's in 2007. The proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007	Balloon catheter Cost
19296 Breast interstitial radiation treatment, delayed	**1524**	**$3,250**	**30**	**$2,508.17**	**($741.83)**	**-22.8%**	**$2750.00**
19297 Breast interstitial radiation treatment, immediate	**1523**	**$2,750**	**29**	**$1,732.69**	**($1,017.31)**	**-37.0%**	**$2750.00**

In addition to the reassignment, CMS changed the status indicator from S to T. For breast surgeons inserting the balloon catheter at time of lumpectomy, the reimbursement the hospital will receive for the entire procedure will be further reduced by the additional 50% reduction applied to the balloon insertion procedure.

Should CMS finalize the proposed APC assignments, it will most certainly limit the ability to offer breast brachytherapy as a treatment option to Medicare beneficiaries since the cost of the device far surpasses the proposed payment rates. We predict that hospitals will no longer authorize the purchase of this device, which is necessary in order to delivery breast brachytherapy.

To prevent hospital cost from limiting access to this valuable treatment option, we suggest CMS maintain 19296 and 19297 in the New Technology APC's 1524 and 1523 respectively. This will allow for collection of additional claims data through calendar year 2006 and permit assignment of these codes to the most appropriate APC for 2008. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or

Formatted: Right: 0.25"

at a separate time. As the relevant CPT codes are device-dependent, the APC to which they are assigned must cover the cost of the device.

Alternatively, CMS could consider assigning breast brachytherapy codes to a breast procedure APC that more accurately reflects the costs of the procedure. Specifically, CPT codes 19296 and 19297 could be assigned to APC 648 which could then be renamed "Breast Level IV". This would result in CPT codes 19296 and 19297 being classified with other device dependent procedures, in which a high cost device is being inserted into the breast.

In summary, the ASBS respectfully requests that CMS implement the following recommendations for the APC assignment for CPT 19296 and 19297 under the OPPS:

- **Consider maintaining CPT 19296 and 19297 in the current APC New Technology codes 1524 and 1523 respectively.**

- **Alternatively, consider assignment of these codes to a more appropriate APC that accurately reflects the costs of the procedure.**

We appreciate CMS's attention to our comments. Should you have any questions or if you would like to discuss our recommendation in greater detail please do not hesitate to contact us at 410-992-5470.

Sincerely,

Helen A. Pass, MD
President
American Society of Breast Surgeons

Richard Fine, D
Co-Chair,
Coding and Reimbursement Committee
The American Society of Breast Surgeons

cc: Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Edith Hambrick, M.D., J.D., CMS Medical Officer; Chair, APC Advisory Panel
Gerald B. Healy, MD, FACS, Chair, Board of Regents, American College of Surgeons
Mark A. Malangoni, MD, FACS, Chair, Board of Governors, American College of Surgeons

Formatted: Right: 0.25"

Submitter : Mrs. Ann-Marie Lynch **Date:** 10/10/2006

Organization : AdvaMed

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1506-P-489-Attach-1.PDF

CMS-1506-P-489-Attach-2.PDF

#484

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

October 10, 2006

Via Electronic Mail and Hand Delivery

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

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List (CMS-1506-P)

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Proposed Hospital Outpatient Prospective Payment System and 2007 Payment Rates and 2007 Update to the Ambulatory Surgical Center Covered Procedures List (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505). AdvaMed is the world's largest association representing manufacturers that produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the proposed 2007 Hospital Outpatient Prospective Payment System

(OPPS) and 2007 Ambulatory Surgical Center (ASC) rules. While we are pleased with some of the proposed changes we remain concerned with other proposals. Our comments will address our concerns and support for provisions within each of the rules.

Part I. Proposed Updates Affecting OPPS Payments for CY 2007

AdvaMed appreciates the opportunity to provide you with comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed 2007 updates to the OPPS payments for Calendar Year 2007. Our comments will address several issues raised in the 2007 update including:

- Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
- Device-Dependent APCs—Use of a Payment Floor in CY 2007
- Charge Compression and APC Relative Weights
- New Technology APCs
- Proposed Movement of Procedures from New Technology APCs to Clinical APCs
- Proposed APC-Specific Policies
- Device –Dependent APCs
- Proposed Brachytherapy Source Payment Changes
- Proposed Payment for Blood and Blood Products
- Drug Administration

A. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

Data Used to Determine APC Rates-- AdvaMed appreciates the significant effort on the part of CMS to stabilize variation in APC payment rates for CY 2007. AdvaMed continues to advocate for the use of external data to validate rates given that the latest available median outpatient claims data is two years old and the Medicare cost reports are older and often inadequate to capture accurate median costs.

Use of Single and Multiple Procedure Claims. AdvaMed commends CMS on their decision to bypass specific codes that do not have significant packaged costs in order to use more data from multiple procedure claims. CMS's new single and "pseudo" single procedure claims rate-setting methodology has yielded data that, on initial analysis, appears to more accurately capture the costs of procedures. We recommend that CMS continue to refine these methodologies to improve the accuracy of estimates for the costs of devices included in multiple procedure claims.

Use of Correctly Coded Claims. AdvaMed is pleased with the CMS decision to use only correctly coded claims that include the appropriate C-code for all device-related APCs in setting payment rates. Use of this methodology results in

payment rates that more appropriately reflect the costs associated with these procedures.

AdvaMed continues to support the mandatory reporting of all C-codes and related incentives to encourage hospitals to remain vigilant in reporting the costs of performing device-related services. Furthermore, we urge CMS to continue educating hospitals on the importance of accurate coding for devices and other technologies. Accurate reporting of device and technology charges will ensure that these items are more appropriately reflected in future payment rates for outpatient services.

Utilizing External Data. AdvaMed continues to have concerns regarding the accuracy of the data used to set rates. Medicare claims and cost report data lag behind advances in technology. This is particularly an issue for high-cost devices. AdvaMed recommends that:

- CMS adopt the 2005 and 2006 Advisory Panel on Ambulatory Payment Classification (APC) recommendations that the agency use external data in setting rates, where the claims data may not accurately reflect device costs
- CMS use external data to validate rates where existing claims data is inadequate and/or outdated
- CMS make adjustments that more accurately represent the cost of performing device and technology-related services, including the incorporation of external data provided by manufacturers and other stakeholders into median cost calculations

B. Device-Dependent APCs—Use of a Payment Floor in CY 2007

AdvaMed appreciates the efforts that CMS has made to improve the rate calculations for some device-related APCs in 2007. In calendar years 2004, 2005, and 2006 CMS implemented a floor to limit the reductions in payment for device dependent APCs whose medians were experiencing significant and unexplained reductions. CMS has not proposed to include a payment floor for CY 2007. We are concerned that the continued reductions in the reimbursement for device dependent APCs will prevent hospitals from covering their costs, translating into significant losses for hospitals that perform these procedures, and leading to access problems for beneficiaries. CMS should continue to use payment floors to avoid future decreases that prevent reimbursement levels from adequately reflecting the costs of the devices and other resources required to perform these procedures.

Cumulative decreases in payment over several years for some APCs have significantly reduced the payment for various procedures. The table below illustrates the continued payment reductions that have been imposed on several device-related procedures since 2002.

APC/Description	2002	2003	2004	2005	*2006*	2007	*Change*
0039 – Implantation of Neurostimulator (Neurostimulator)	$15,489	$11,876 -23.3%	$12,832 8%	$12,532 -2.3%	$11,602 -8%	$10,829 -6.7%	-30%
0222-Implantation of Neurological Device	$15,400	$11,877 -22.9%	$12,669 6.6%	$12,372 -2.3%	$11,455 -7.4%	$10,964 -4.3%	-28.8%
0315, Level II Implantation of Neurostimulator	N/A	N/A	N/A	$20,078	$18,950 -5.6%	$14,500 -23.4%	-27.8%

Improvements are still needed to ensure accuracy in the overall payment for device dependent procedures. **Until CMS has addressed lags in claims and cost data used to calculate the payment rates, AdvaMed urges CMS to set a floor on the 2007 device-related APC rates at no less than 100 percent of the 2006 rates plus the market basket update for all device-related APCs.** Although this change will not alleviate the reductions many devices have experienced over the past several years, it will provide a greater level of continuity.

C. Charge Compression and APC Relative Weights

Under OPPS, payment rates for procedures are based on estimated costs, calculated using Medicare claims and Medicare Hospital Cost Reports. The cost estimation methodology for the CY 2007 OPPS rates relies on CY 2005 hospital claims and FY 2004 or earlier cost reports. Due to the lags in data, recent advances in medical technology are, by definition, omitted from the two data sources. The longer the data lags, the more likely that new technology costs will not be fully reflected in the hospital cost reports and claims data, resulting in inaccurate estimated costs.

Further, studies have found that hospitals typically have a smaller mark-up for higher-cost items compared to other items and services. By using a single cost-to-charge ratio (CCR) for varied items and services in a single hospital department the methodology systematically under-estimates the costs associated with low mark-up items, over-estimates the costs associated with high mark-up items, and does not recognize the variability among hospitals in setting charges. This "charge compression" problem may be particularly problematic when the charge for a device accounts for a high percentage of the total charges associated with an APC.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.[1] The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the researcher also showed that cases with very high device and supply charges significantly impacted the device and supply CCR.

CMS recently announced that it has awarded a one-year contract to RTI International to examine the methods for improving the accuracy of construction of the costs used to develop the weights for inpatient hospitals stays, recognizing that hospitals tend to mark-up high costs items less than low-cost items. Estimated costs under the OPPS methodology reflect similar problems associated with charge compression. Therefore, AdvaMed recommends that CMS:

- make adjustments to the final 2007 OPPS rates to account for charge compression
- implement a payment floor such that the device-related rates do not decrease below their 2006 level
- study methodologies to account for charge compression so as to appropriately adjust payment rates under the OPPS

D. New Technology APCs

AdvaMed recommends that CMS examine the criteria and process for moving procedures from New Technology APCs to clinical APCs and consider measures that would prevent excessive reductions in payment-- including moving procedures to different APCs, utilizing external data for rate-setting purposes, and/or allowing procedures to maintain their New Technology APC designation for a period of time sufficient for the collection of adequate data to substantiate movement to an appropriate clinical APC. **AdvaMed supports the APC Panel's August 2006 recommendation which asks CMS to retain codes that have been assigned to New Technology APCs for at least 2 years until sufficient claims data is collected.**

Inappropriate reductions, which exist under the current system, may not only affect access to new services, but have the potential to negatively affect emerging technology. Therefore, AdvaMed continues to urge CMS to not rely solely on claims data, especially given the potential for errors.

If accurate rates are to be established it is critical that hospitals be educated on the importance of correctly reporting procedures which incorporate a device. AdvaMed also recommends that CMS study the process used by hospitals to report the costs of procedures that are part of New Technology APCs. We are concerned that hospitals may

[1] C. Hogan, Direct Research LLC., March 2006. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data. By accounting for charge compression, Medicare payments will more appropriately reflect use of devices and advanced medical technologies.

only be reporting the device costs instead of reporting all of the costs associated with the New Technology procedures. These reporting errors could explain the reductions in median costs when procedures move from New Technology APCs to Clinical APCs and may also explain why technologies are placed into incorrect clinical APCs.

E. Proposed Movement of Procedures from New Technology APCs to Clinical APCs

AdvaMed would like to comment on two procedures that are proposed to move from New Technology APCs to clinical APCs in 2007:

Ablation, bone tumor(s) -- CMS has proposed to move HCPCS 20982 (Ablation, bone tumor(s) (e.g., Osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomographic guidance) from New Technology APC 1557 with a payment rate of $1,850 to clinical APC 0050 with a payment rate of $1,542. Unlike other tumor ablation procedures in APC 0050, HCPCS 20982 includes imaging guidance which adds additional costs to the procedure. Additionally, the payment for APC 0050 does not cover the CMS median costs for HCPCS 20982.[2] Therefore, AdvaMed recommends that CMS move HCPCS 20982 to APC 0051, a clinical APC with greater resource use similarity.

Nonmyocardial Positron Emission Tomography (PET) and PET/Computed Tomography (CT) Scans-- AdvaMed is concerned with CMS's decision to move PET/CT scans from new technology APC 1514 to new APC 0308. The proposed change does not distinguish between this technology and PET scans. PET/CT scans have emerged as one of the most important technologies used to manage cancer patients. Patients benefit from PET/CT scans through earlier diagnosis, more accurate staging, precise treatment planning, and improved monitoring of therapy. The enhanced images generated by these scans allow physicians to pinpoint tumor position and detect cancer cells often well before they are readily visible.

In 2004, PET/CT was a new technology with no established codes. This technology was granted three separate HCPCS codes by the American Medical Association (AMA) and in March 2005, CMS assigned these codes to New Technology APC 1514. In the 2007 proposed rule, CMS states there is adequate claims data for HCPCS codes 78814, 78815, and 78816 to move from the New Technology APC 1514 (New Technology- Level XIV, $1,200-$1,300) to a "clinically appropriate" APC (proposed APC 0308, $865.30). Moving the procedures to APC 0308 would decrease payment by 30 percent, far below the costs of providing this service.

PET/CT is an enhanced technology that is not comparable to PET or CT scans alone. CMS is required to place HCPCS codes in APCs that are similar clinically, as well as on the basis of resource use. CMS does not appear to have a sufficient amount of accurate

[2] CMS has assigned HCPCS 20982 a 2007 median cost of $1897.59-- based on claims data for January 1, 2005 through December 31, 2005.

claims data to justify movement of these new technologies into an existing clinical APC. In August 2006, the APC Panel recommended that CMS maintain HCPCS codes 78814, 78815 and 78816 in New Technology APC 1514 for CY 2007. AdvaMed agrees with the Panel's recommendation and urges CMS to adopt it in the final rule. Maintaining the PET/CT codes in their existing New Technology category will ensure that they are appropriately reimbursed.

F. Proposed APC-Specific Policies

AdvaMed would like to comment on several procedures that are proposed to move from their current clinical APC to lower paying clinical APCs in 2007:

Percutaneous Renal Cryoablation of Renal Tumor (HCPCS 0135T) -- AdvaMed is pleased that CMS has proposed to adopt the APC Panel recommendation to move Percutaneous Renal Cryoablation of Renal Tumor (HCPCS 0135T) from APC 163 to APC 423 for CY 2007. However, AdvaMed continues to be concerned with the movement of procedures from their existing clinical APCs to lower paying clinical APCs based on inadequate data. While HCPCS 0135T is now grouped with clinically similar percutaneous ablation procedures the rate is not based on timely data and does not adequately reflect the costs incurred by hospitals to perform the renal cryoablation procedure (including the cost of the cryoprobes used in conjunction with the procedure). AdvaMed recommends that CMS review and adjust the payment rate for HCPCS 0135T. We realize the difficulty in pricing new procedures because of the lack of timely and accurate hospital claims and cost report data. In such cases using all available data, including external data in making a determination to move procedures from one clinical APC to another is particularly important.

MRgFUS (HCPCS 0071T and 0072T)-- After reviewing the proposed rule regarding changes to the OPPS payment rates for calendar year 2007 and the APC assignment for the MRgFUS procedure, we are requesting that CMS reconsider the APC assignment of HCPCS codes 0071T and 0072T from APCs 0195 and 0202 respectively to APC 0127 for 2007. Current estimated costs for the MRgFUS procedure are significantly higher than the payment rates for APCs 0195 and 0202. We recommend that CMS place these codes in APC 0127 due to the clinical and cost similarities between MRgFUS and the Stereotactic Radiosurgery (SRS) procedure. Both procedures require treatment planning, continuous monitoring during treatment, use of imaging technology, and a significant amount of time to perform the procedure.

Insertion of Mesh or Other Prosthesis (HCPCS 57567) -- AdvaMed urges CMS to move HCPCS code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site),* to APC 0202 (Level X Female Reproductive Procedures). HCPCS code 57267 is a resource intensive gynecologic procedure requiring the use of a device. CMS has assigned similar gynecology codes to APC 0202, such as endometrial cryoablation (HCPCS code 58356) and hysteroscopic tubal occlusion (HCPCS code 58565).

While CMS analyzed claims for HCPCS code 57267, to better ascertain the costs of this add-on procedure, the analysis inappropriately grouped claims with the C-code for hernia repair (C1781) rather than with the C-codes used to report mesh devices used in pelvic floor reconstruction procedures (C1762 and C1763). When the appropriate C-codes are used, the median costs (after applying the multiple procedure reduction) are closer to APC 0202 (HCPCS 57267 is always performed as an add-on code, and would always be subject to the multiple procedure reduction).

GI Procedures with Stents (APC 0384) -- The payment rate for APC 0384 (GI Procedures with Stents) is proposed to be reduced by 13 percent-- from an APC 2006 rate of $1,601 to $1,395 in 2007. AdvaMed is concerned that the proposed payment rate reduction for APC 0384 may reflect changes in the application of C-code screens rather than actual reductions in costs. In particular three HCPCS codes 43219, 43268 and 43269, accounting for over 90 percent of the single procedures claims, do not require C-code reporting. CMS's application of a C-code screen to all procedures in APC 0384 (including 43219, 43268 and 43269), resulted in a 2006 APC payment rate that better reflected costs. We urge CMS to apply a C-code screen again this year to ensure that device costs are adequately reflected in the payment rate.

G. Device –Dependent APCs

AdvaMed would like to comment on the issues discussed in section IV(A)(4) of the proposed OPPS rule regarding proposed payment policies when devices are replaced without cost or where credit for a replaced device is furnished to the hospital.

Payment for Replaced Devices-- For services furnished on or after January 1, 2007, CMS proposes to reduce the hospital payment and beneficiary co-payment for select APCs in cases where a replacement device is provided at no cost or with full credit for the cost of the replaced device. AdvaMed agrees that neither the Medicare program nor the Medicare beneficiary should be required to pay for devices provided to the hospital at no cost.

However, in proposing to uniformly reduce the amount of the APC payment rates by the amount of the pass through offset, CMS fails to recognize that a patient's current medical condition and diagnosis at the time of replacement may require the implant of a more advanced or different type of device, which often may be, more expensive. AdvaMed recommends that CMS should reduce the offset amount to ensure that the hospital is not held financially responsible for these residual costs.

As mentioned, depending on a patient's diagnosis, upgrades may even result in the need for a different type of technology and the purchase of an additional device (or devices) as a patient's disease progresses and their device indications change. In the case of "same device type" upgrades, a reduced offset percentage would result in more accurate payments to the hospital and ensure that beneficiaries have access to devices that are

appropriate to treat their current medical condition. Cases involving "different device type" upgrades should be exempt from any reduction. Both approaches are in keeping with the principle behind the CMS proposal. AdvaMed is willing to work with CMS and other stakeholders to identify a reduced percentage offset that is appropriate for these cases.

CMS proposes to utilize the presence of the –FB modifier to trigger the offset adjustment to the APC payment rate. Because the current -FB modifier ("Item furnished without cost to provider, supplier or practitioner") as currently defined is not appropriate to identify the cases involving same device type upgrades, AdvaMed recommends that CMS create an additional modifier to facilitate the application of the reduced offset amount. The creation of this new modifier would allow for the appropriate adjustment to the hospital payment rate for the residual costs of an upgraded device and identify those claims to ensure appropriate rate setting in future years.

Impact of Residual Costs of Upgrades on Median Costs for APCs 0107 and 0108--

Currently, when a device is furnished without cost to the hospital, CMS instructs hospitals to charge less than $1.01. In the development of the proposed rates, CMS went to great lengths to exclude claims with these token charges to ensure that only claims that contain the full costs of devices were used in 2007 rate setting. As a result, the median costs for some APCs were significantly increased. We applaud CMS for implementing this change to improve the accuracy of the data used to develop the payments.

As described above, there are circumstances where the hospital may receive only a partial credit for a replacement device. In these instances, the hospital incurs residual costs and bills the difference between its usual charge for the replaced device and its usual charge for the upgraded replacement device. These residual costs, although not insignificant to the hospital, would result in charges that are well below the full cost of a device, which may, in turn, result in depressed median values that would under-represent the cost of the complete procedure. To account for this issue, Advamed believes it is important that CMS exclude claims with charges representing these residual costs from the median used for APC payment rate setting.

An analysis of the median costs for APCs 0107 and 0108 shows that the median costs are increased when claims carrying residual charges were removed from the data set (see chart below).

2007 Proposed Rule File (CY 2005 Claims)				
	From CMS Proposed Rule - the final single-procedure claim medians after device edit.		N of single proc claims FOR APC	Single proc median FOR APC
APC	Table 18 single proc FOR APC	Table 18 Median Cost FOR APC	Claims excluding residual device charges that are less than or equal to $6,000	
	2007	2007	2007	2007
0107	481	$ 17,245	440	$ 18,205
0108	2577	$ 22,887	2440	$ 23,153

Registry Data-- AdvaMed supports evidence-based medicine and the use of sound evidence to support medical practice. As we have stated in comments to CMS in response to the agency's "coverage with evidence development" (CED) guidance document, data collected to improve quality of care and outcomes may provide decision-makers with information on the impact of new technologies and procedures on the Medicare population. Notwithstanding, in matters related to data gathering, we urge CMS to take a "minimum necessary" approach. It is important to consider the significant costs incurred in data gathering. Conducting a "value of information" analysis in consultation with all stakeholders will help to address whether the additional burden and costs of data collection (including the costs incurred by individual hospitals, physicians, and other health care professionals) are warranted. AdvaMed strongly believes that any data collection should occur only to resolve explicit and well-defined appropriateness matters or research questions, and that the questions that need resolution should shape the specific type and manner of data that is collected. Such specificity will create the "stopping rules" for data collection.

Moreover, in CMS's revised CED guidance document, CMS states as a principle governing the application of CED that it "will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices."[3] Furthermore, CMS states that it "will not assume the NIH's role in fostering, managing, or prioritizing clinical trials."[4] We agree with the agency's recognition of the separate and distinct roles and mandates of CMS, FDA, and NIH. We urge the agency to use this approach in both Medicare coverage and payment contexts as CMS considers its role in fostering data collection efforts.

Finally, we note that CMS's statements in the OPPS proposed rule imply that registry data will contribute to the "development of high quality, evidence-based clinical practice guidelines for the care of patients who may receive device-intensive procedures." We agree that, when structured appropriately, registry data may yield hypothesis-generating information that can be used to direct and focus additional research efforts. However, in general, studies need to be performed and yield additional evidence before clinical

[3] Guidance for the Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006, at 9.
[4] *Id.*

guidelines can be developed and formalized. Although registry data may help identify issues related to certain procedures such as the impact of the product on certain sub-populations, clinical practice guidelines should generally be based on more conclusive evidence than the observational data that registries provide.

H. Proposed Brachytherapy Source Payment Changes

CMS should continue the current OPPS payment method for brachytherapy devices provided to Medicare patients in the hospital outpatient setting in 2007. The Medicare Modernization Act required a GAO study, giving CMS and the public 2 full years to analyze the GAO report and make recommendations on payment methods for brachytherapy devices. That GAO study was not published until July 25, 2006 and there has been no reasonable opportunity to assess and incorporate the GAO findings in CMS' proposal. Additionally, an inadequate number of claims exist to determine appropriate payment for many brachytherapy devices. Therefore, the underlying data is not a reliable basis for setting fixed payment levels for brachytherapy devices. AdvaMed encourages CMS to adopt the August 2006 recommendations of the APC Panel and the Practicing Physicians Advisory Council that CMS continue paying for brachytherapy services in 2007 using the cost to charge ratio method. Continuing the current method for CY 2007 will ensure more accurate payments that support high quality care for Medicare patients needing these services.

I. Proposed Payment for Blood and Blood Products

AdvaMed continues to be concerned that low outpatient payments for blood and blood products will continue to challenge hospitals' abilities to assure the availability of safe blood products-- compromising patient safety. Our member companies research, develop and manufacture a broad range of innovative technologies for the collection, testing, safety assurance, processing, storage, and transfusion of blood.

We commend CMS for its efforts, in recent years, to address methodological issues related to the development of APC rates for blood and blood products. Overall, these efforts have resulted in more appropriate APC rates for these products. However, we are concerned that even with these improvements the APC rates continue to be well below actual hospital acquisition costs. We urge CMS to carefully review the blood and blood product APCs and make adjustments to them, particularly focusing on the most commonly used blood products such as leukocyte-reduced red blood cells (APC 0954), that ensure access to the safest possible blood products by Medicare beneficiaries. We also urge CMS to adopt the APC Panel recommendation to reconsider the methodology it uses to develop payment rates for blood and blood products to more accurately reflect the true costs of blood and blood products to hospitals using external and other data.

J. Drug Administration

AdvaMed strongly supports the CMS proposal to create six new drug administration APCs and to provide separate payment for additional hours of drug administration services so as to adequately reimburse hospitals for the staff, supplies, and overhead associated with these services. Currently, payment for second and subsequent hours of drug administration services is packaged into payment for the first hour. We urge CMS to retain these proposed changes in the final rule. Further, we recommend that CMS revise its methods for reimbursing hospitals for hydration and therapeutic infusions administered during the same visit. Under OPPS, both hydration and therapeutic infusions share the same codes. As a result, when a hospital administers both a one-hour hydration infusion and a one-hour therapeutic infusion, the hospital is paid for the first hour of one infusion (under APC 440 *Level VI Drug Administration* with a proposed payment rate of $112.94) and a reduced payment rate for the subsequent hour of the other infusion (under APC 437 *Level II Drug Administration* with a proposed payment rate of $25.49). We recommend that CMS adopt a mechanism to allow for full payment for the first hour of both hydration and therapeutic infusions, similar to the approach used under the physician fee schedule.

Part II: Proposed Policies Affecting Ambulatory Surgical Centers (ASCs) for CY 2007

AdvaMed appreciates the opportunity to provide you with comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed 2007 updates to the list of ASC covered procedures. Our comments will address several issues raised in the 2007 update including:

- Proposed additions for 2007
- Payment determination and group assignment
- Payment for New Technology Intraocular Lenses (NTIOLS)

A. Response to Interim Final Rule Comments

The current list of ASC covered procedures includes services that are: commonly performed on an inpatient basis but may be safely performed in an ASC, are not commonly performed in a physicians' office, require a dedicated operating room or surgery suite and a post-operative recovery room or short-term convalescent room, and are not otherwise excluded from Medicare coverage. Specific ASC standards also require that these procedures not exceed 90 minutes operating or 4 hours recovery/convalescent time, require only local or regional anesthesia (not exceeding 90 minutes), not result in extensive blood loss or prolonged invasion of body cavities that involve major blood vessels, and not be emergency or generally life-threatening. CMS will continue to apply these standards to the 2007 updates.

Procedures Proposed for Addition to the ASC List-- CMS has proposed to add 14 surgical procedures to the ASC list for 2007. These procedures are required to meet existing CMS safety criteria and are performed in an inpatient department more than 20 percent of the time and/or in a physician's office less than 50 percent of the time.

Implantation of Peripheral Stents (CPT codes 37205 and 37206)-- AdvaMed is concerned that several of the proposed additions to the 2007 list of ASC approved procedures cannot be safely performed in that setting. Of particular concern are procedures related to the implantation of peripheral stents, CPT codes 37205 and 37206. These procedures involve major blood vessels— specifically femoral arteries of the pelvic and lower limbs. Pursuant to 42 C.F.R. section 416.65(b)(3(iii) of the ASC standards, procedures that directly involve major blood vessels may not be performed in an ASC. The surgical procedures used in conjunction with CPT codes 37205 and 37206 directly involve major blood vessels/arteries and therefore do not meet the criteria for inclusion on the list of ASC approved procedures. Therefore, to ensure that these services are performed in the appropriate setting, AdvaMed requests that CPT codes 37205 and 37206 not be added to the list of ASC covered procedures for 2007.[5]

Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (CPT code 57267)-- AdvaMed recommends that CMS add CPT 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach to the list of ASC approved procedures for 2007. This code is equivalent in intent and function to CPT 49568 – Implantation of mesh or other prosthesis for incisional or ventral hernia repair. CPT code 49568 crosswalks to Payment Group 7. Because of the similarities between the codes we ask that CMS add CPT 57267 to the approved ASC list and assign it to payment Group 7.

Procedures Involving Medical Devices and Other Technologies for which the Costs Are Not Captured by the Payment Group Rate-- The ASC covered procedure list includes procedures that involve the utilization or implantation of medical devices or other technologies for which the cost may exceed the payment group rate, thereby discouraging ASCs from making these procedures available. These payment issues not only impede the transition of procedures associated with devices or other technologies to the ASC setting, but may also limit patient access to needed procedures. Because of this trend, AdvaMed has previously recommended that CMS move procedures from lower to higher payment groups, allow separate payment for medical devices or other technologies, and delay inclusion of certain CPT codes on the covered procedure list. AdvaMed is pleased that in this proposed rule, CMS has adopted several of the recommendations we made in response to the May 2005 Interim Final ASC Rule. However, we remain concerned with CMS's decision to not include several items discussed in detail below.

---

[5] It is interesting to note that while CMS has proposed to add CPT code 37206 to the list of ASC approved procedures in 2007 that same procedure is not covered in the ASC setting effective 2008.

Separate Payment for Medical Devices or Other Technologies. In our comments on the 2005 Interim Final ASC rule AdvaMed asked CMS to consider allowing medical devices or other technologies to be reimbursed separately in order to adequately cover device costs. The 2007 ASC update rule adopts some of our recommendations regarding payment for these services, including moving HCPCS codes 36475 and 36476 to higher payment groups. However, we are still concerned that CMS has not adequately addressed payment for supply costs, specifically probes and catheters, not covered by the new payment group assignments.

In our 2005 comments AdvaMed recommended that radiofrequency ablation of venous reflux procedures (RFA)(CPT codes 36475 and 36476) be removed from the list of covered procedures due to insufficient data and because the procedures use considerably more facility resources than other procedures assigned to payment group 3. In response to our comments CMS is proposing to keep the procedures on the list, citing their appropriateness for performance in an ASC, while reassigning them to payment group 9 effective January 2007. AdvaMed is pleased with the CMS proposal to move these procedure codes from payment group 3 to payment group 9 for calendar year 2007.[6]

The 2007 ASC update proposes moving HCPCS code 19298, placement of breast radiotherapy tube/catheters, from payment group 1 to payment group 9. AdvaMed commends CMS for making this change which will more appropriately cover some of the facility costs for this procedure. Moving this code to payment group 9 will reduce the gap in payment between the ASC and hospital outpatient departments for this procedure and allow patients to receive the treatment in both settings. While reassignment to a higher payment group represents a positive change, AdvaMed remains concerned with the reimbursement of supply costs associated with this procedure. In the proposed rule, CMS states that the cost of the implant catheters used with this procedure cannot be paid separately because their cost is packaged into the procedure costs. AdvaMed recommends that CMS consider an add-on payment to cover the cost of these supplies.

Reassignment of Procedures to Higher Payment Groups. AdvaMed also asked CMS to move HCPCS 57288 (repair bladder defect) from payment group 5 ($717) to payment group 9 ($1,339). Under the hospital outpatient prospective payment system ("OPPS"), HCPCS 57288 is assigned to APC 202 with a payment of $2,639. In the ASC setting, payment group 5 does not adequately cover the device costs associated with this procedure or the facility costs. CMS has proposed to keep this code in payment group 5 for 2007. AdvaMed renews its request that HCPCS code 57288 be reassigned to payment group 9 in order to cover the associated device and facility costs.

[6] While the text is correct, Addendum AA mistakenly lists the code in payment group 8.

AdvaMed appreciates CMS' efforts to reclassify procedures to other payment groups when appropriate. Toward that end, we urge CMS to reassign the following endometrial ablation procedures (CPT codes 58563 & 58353) from ASC Group 4 to ASC Group 9, effective January 1, 2007.

- *58563 - Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)* and
- *58353 - Endometrial ablation, thermal, without hysteroscopic guidance*

For 2007, CMS has proposed to reclassify CPT code 58565 (hysteroscopic tubal occlusion) to payment group 9, citing the fact that the procedure is significantly more resource-intensive other procedures in ASC payment group 4. Endometrial ablation is a procedure similar to hysteroscopic tubal occlusion, with similar OPPS median costs. Given the similarity of these procedures, we strongly urge CMS to assign CPT codes 58563 and 58353 to ASC payment group 9 for 2007.

The 2007 ASC update proposes moving HCPCS code 61885 (Implant neuroelectrode) from payment group 2 ($446) to payment group 9 ($1,339) and 64573 (Insertion/redo neurostim 1 array), from payment group 1 ($333) to payment group 9 ($1,339). The current ASC payments for these procedures represent less than 20 percent of the proposed 2007 hospital outpatient department costs. Moving these procedures into payment group 9 will more appropriately cover some facility costs and will reduce the gap in payment between the ASC and hospital outpatient departments for these procedures. While reassignment to the higher payment group represents a positive change, AdvaMed remains concerned with the reimbursement of supply costs associated with these procedures. In the proposed rule, CMS states that the cost of the implantable neuroelectrodes and neurostimulators used with these procedures cannot be paid separately because it is packaged into the procedure costs. The supplies associated with these procedures represent a significant potion of the total procedure cost. For this reason, AdvaMed recommends that CMS consider an add-on payment to cover the cost of the supplies used in conjunction with CPT codes 61885 and 64573.

B. NTIOL

Since the inception of the ASC payment process there had been a system for reimbursing Intra Ocular Lenses (IOLs) supplied concurrent with or following cataract surgery. In 1999 CMS began making an additional payment adjustment of $50 for lenses that it determined were New Technology Intraocular Lenses (NTIOLs). These lenses receive NTIOL status, lasting 5 years, following completion of an application process and satisfaction of CMS criteria. In the current ASC update rule, CMS is proposing to significantly change the NTIOL process by making several modifications to the process for notifying the public regarding NTIOLs and revising the content of an NTIOL request.

CMS has historically received and reviewed applications for NTIOLs throughout the year. AdvaMed supports CMS's proposal to fully integrate the NTIOL-related notifications into the annual notice and comment rulemaking for updating the ASC payment rates . In addition, AdvaMed also agrees that requiring additional information in the NTIOL application will allow CMS's medical advisors to complete a more comprehensive evaluation of new NTIOLs, ensuring appropriate payment adjustments.

The NTIOL submission requirements have always been published in the Code of Federal Regulations at § 416.195(a). AdvaMed is concerned by the proposal to post information regarding the revised NTIOL application criteria on the CMS website only. While we support CMS's goal of making the information available as soon as possible and the desire to provide ease of access, AdvaMed recommends that any information concerning NTIOLs also be made available for public review and comment.

Part III. Quality Measures Under the OPPS

AdvaMed appreciates the opportunity to provide you with comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed 2007 changes to the OPPS system regarding quality measures. Our comments will address several issues raised in the 2007 proposal including:

- Hospital Quality Data
- Health Information Technology
- Transparency of health care information

A. Hospital Quality Data

CMS proposes to implement an outpatient prospective payment system (OPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program effective for payments beginning in January 2007. CMS proposes to reduce the OPPS conversion factor update in CY 2007 by 2.0 percentage points if a hospital does not meet requirements for the full FY 2007 inpatient PPS payment update. Thus, CMS will base outpatient payments on hospitals' reporting of quality measures for inpatient care. CMS describes the CY 2007 OPPS proposal as the initial phase of a broader, long-term effort by Medicare to develop quality measures for the care provided to patients in hospital outpatient departments.

While AdvaMed supports steps to improve the quality of hospital care, we are concerned about the specific OPPS proposal that CMS has put forward and the seeming lack of statutory authority to do so. In the proposed rule's preamble, CMS notes that the IPPS quality measures rest on detailed and explicit statutory authorizations. Social Security Act sections 1886(b)(3)(B)(viii)(I)-(VII) states that hospitals are required to submit inpatient quality data to the HHS Secretary and that the Secretary is required to use this data in the computation of IPPS rates. CMS is proposing to apply these same

requirements to OPPS, even though the statutory provisions applicable to OPPS provide no such authority. The agency purports to base its OPPS proposal on very general statutory language concerning "equitable payments," or, as a potential alternative, on equally general language concerning "controlling unnecessary increases in the volume" of services. Neither of these provisions authorizes CMS to apply prescriptive data reporting requirements and conversion factor adjustments to OPPS.

Improvement in the quality of care provided in hospital outpatient departments represents a significant policy goal. Achieving this goal will be particularly challenging given the quality of the information reported on hospitals' claims data (missing codes, multiple procedures on a single claim, etc.) and will require the broad support of stakeholders . Also, a successful value-based purchasing program must include a robust risk adjustment mechanism, and too little attention has been paid to this issue to date. All of the efforts underway toward identifying quality measures will be wasted if the result is to create a disincentive for physicians to treat the most complicated and/or noncompliant cases. AdvaMed would welcome the opportunity to work with CMS, Congress, and other stakeholders to foster thoughtful steps for measuring and improving the quality of hospital outpatient care.

CMS requested comments on ideal measures and value-based purchasing. AdvaMed believes that both quality and cost of care measures, in all settings, should conform to standards of clinically appropriate care as established by peer-reviewed literature or professional consensus. Furthermore, we believe that financial incentives to encourage providers to meet standards based on quality measures are appropriate. Financial incentives should provide for flexibility in meeting the unique needs of individual patients and not encourage providers to avoid the most difficult cases. Examples of costs of care measures that meet these standards are those that accurately calculate the savings from reductions in: medical errors, surgical complications, preventable hospitalizations, inappropriate use of emergency rooms, unnecessary and harmful services, and duplicative procedures.

AdvaMed strongly believes that costs of care measures should not be used to compare the "efficiency" of providers who do not deliver the same quality of care.

AdvaMed believes that quality measures should be flexible enough to allow access to new, improved technology and devices, and should be reviewed and updated periodically to reflect new benchmarks and standards of care. Furthermore, quality measures should not specify a particular brand or model of device and when all providers satisfy a particular measure, it should be removed to reduce the burden of reporting.

If CMS were to adopt a quality measure that assesses whether or not a provider uses a particular medical device or technology, it should allow exceptions. Providers who use a different new device or technology should be excluded from measurement on this indicator, by exclusion from both the numerator and denominator for the measure, or required to report this use through a separate measure. As use of new devices or

technologies often begins in a particular locality, CMS should allow for variation in measures across the country to capture this variability. If CMS does not recognize use of new devices or technologies when evaluating providers, it runs the risk of freezing medical treatment in place, even after it has become outdated. Medical innovation and successful patient outcomes would be inhibited by such limits.

A value-based purchasing program is based on measures of efficiency, which consider both quality and cost of care over an appropriate time period, such as an episode of care. AdvaMed agrees with the Institute of Medicine (IOM) criteria that measures of quality of care should focus on effectiveness, safety, patient-centeredness and timeliness. We believe that the two other IOM criteria – efficiency and equity – can only be determined for a high level of quality. We also believe that efficiency measures must be based on robust measures of the patient's outcome of care.

The measures and the incentive structure in a value-based purchasing program should address the potential conflict between appropriate treatment and less cost. AdvaMed does not support a value-based purchasing program based on efficiency measures that ultimately encourage the provision of low cost care. For this reason, AdvaMed opposes using process measures to assess quality in the context of efficiency and supports using patient outcome measures instead. Reliance on process measures of quality when assessing efficiency could inhibit access to new technologies. Incentives should be aligned such that physicians and other providers are encouraged to deliver high quality care with patient access to advanced medical technologies. In addition, physicians who participate in clinical trials should not have the data from those trials included in their ratings. This would allow for the development of new procedures and other innovations.

As development of additional measures and revision of existing measures occurs, we urge CMS to consider appropriate episodes of care for assessment of quality, cost and equity. For example, some Medicare patients are very active and have life expectancies that may challenge some of the older device designs. When comparing the value of treatment with a new device versus an older device, CMS must consider the long-term benefits and costs. A one-year period would be insufficient to assess the benefits to patients of many new technologies.

AdvaMed supports an open process to develop quality and cost of care measures. The goals of this process should include routinely updated performance measures based on appropriate evidence, effectively related to desired outcomes, and derived through a fully transparent process involving all relevant stakeholders. We encourage CMS to collaborate with consensus-building organizations that allow input from all stakeholders, including manufacturers of medical technology and patients who benefit from this technology, and guarantee transparency when developing, selecting and updating performance measures.

B. Health Information Technology

AdvaMed supports widespread, rapid adoption of health information technology (HIT) throughout the health care system, including universal adoption of electronic health records. We believe that any value-based purchasing system should include incentives for adoption and use of HIT. In addition, we support removal of barriers to the dissemination of resources (financial, equipment or otherwise) to physicians to allow for the use and adoption of interoperable HIT.

AdvaMed supports incentives to reward new modes of providing services that result in quality improvement or cost reduction at the same or improved level of quality for patient care, such as remote patient monitoring, computer-assisted surgery, imaging, telemedicine, and virtual physician visits.

C. Transparency of Health Care Information

AdvaMed supports dissemination of accurate information on the value of health care services. We urge CMS to use caution when releasing such information to ensure that the care being measured is appropriate, that all costs and benefits are included, and that the episode of care examined spans the full period over which benefits and costs accrue.

AdvaMed urges CMS to consider the time-frame over which quality and costs are assessed. If an episode of care encompasses too-short of a time frame, costs and quality may be inaccurately determined. For example, use of an implant for total joint replacement may have to be assessed over the lifetime of the patient, or implant, which may extend over a period considerably longer than one year.

AdvaMed applauds CMS's efforts to increase the quality of care provided to Medicare beneficiaries. We believe that hospital reporting on the expanded set of quality measures is appropriate. Furthermore, we concur that CMS should develop a comprehensive plan for a hospital value-based purchasing program with input from the public and for increasing transparency of health care information. Our overarching concern is that information on costs of care not be reported, or used as a basis for payment, without consideration of the quality of care provided. Low cost, low quality care is not our goal. We strive to provide patients access to advanced medical technology to improve their health.

Conclusion

AdvaMed greatly appreciates the opportunity to comment on the 2007 OPPS, ASC Update, and OPPS quality measure proposed rules and urges CMS to consider and incorporate our recommendations into the final rules for these payment systems. We also urge CMS to give consideration to comments from our members and others who will be providing detailed recommendations on both of these rules.

We would be pleased to answer any questions regarding these comments. Please contact DeChane L. Dorsey, Esq., Associate Vice President, Payment and Policy, at 202/434-7218, if we can be of further assistance.

Sincerely,

Ann-Marie Lynch
Executive Vice President,
Payment and Health Care Delivery

cc: Leslie Norwalk
Herb Kuhn
Liz Richter
Joan Sanow
Carol Bazell, M.D.

Submitter : Mr. Michael Becker **Date:** 10/10/2006

Organization : GE Healthcare

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-490-Attach-1.PDF

#470

GE Healthcare

Michael S. Becker
General Manager, Reimbursement

3000 N. Grandview Blvd., W-400
Waukesha, WI 53188

T 262-548-2088
F 262-544-3573
michael.becker@med.ge.com

October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

GE Healthcare (GEHC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year (CY) 2007(*Federal Register*, Vol. 71, No. 163, August 23, 2006).

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

GE Healthcare is a $15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

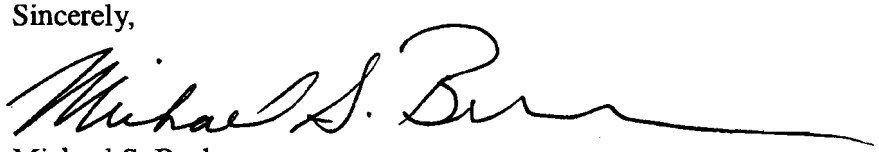
APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

Thank you for providing the opportunity to comment on this important issue. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,



Michael S. Becker
General Manager, Reimbursement

Submitter : Mrs. Valerie Rinkle **Date:** 10/10/2006

Organization : Asante Health System

Category : Hospital

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

Please see the attached comments on the proposed changes to OPPS.

CMS-1506-P-491-Attach-1.DOC

October 10, 2006

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

Re: File Code CMS-1506-P

Dear CMS:

Asante Health System (Asante) includes two acute care hospitals in Southern Oregon. This letter addresses many specific coding, billing and payment concerns regarding the Outpatient Prospective Payment System (OPPS). These comments are in relation to the changes discussed in the 2007 Proposed Rule.

You may call our Revenue Cycle Director at 541-789-4923 should you have any questions concerning these comments.

Cost to Charge Ratios

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

Asante believes that one of the best means for CMS to provide guidance to hospitals to consistently report charges and costs related to all cost centers is to provide specific examples in the OPPS final rule preamble and in transmittals that explain how provider line item charges on claims and hospital CCRs are used to develop APC payment rates. Claim examples will help illustrate two things to hospitals: (1) the importance of correctly pricing procedures and supplies and drugs and (2) ensuring that the cost center where the cost of the service is reflected in the cost report is the same cost center used by CMS in the revenue center crosswalk. If the cost center or CCR is not the correct CCR, then CMS should encourage hospitals to reclassify expense and revenue whenever appropriate or provide comment to CMS as to why the cost center is not appropriate to use in the crosswalk. In this manner, CMS is not mandating changes in hospital accounting practices, but encouraging hospitals to self-adjust those practices based on the knowledge of how the claims and cost

report data is used. Finally, CMS must also instruct Fiscal Intermediary staff to allow hospitals to reclassify expense and revenue whenever appropriate. Examples should be taken from revenue centers or cost areas where there has been a lot of controversy such as blood and blood products and implants/devices.

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

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

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

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

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

Packaged Services

Asante would like to thank CMS for designating specific CPT codes as "special packaged codes" and for allowing separate payment for them when billed on a date of service without any other OPPS payable service. Asante understands that CMS is clarifying for future claim submission that if a packaged service (status indicator "N") is the sole service performed at a visit and there are no other separately identifiable services to justify a hospital visit code, that the hospital cannot bill a visit code in lieu of the packaged service procedure, even when it is the sole service rendered and there are no other services on the claim, OPPS services or otherwise. Note that packaged OPPS services are packaged only to other OPPS services, not to other fee schedule service such as lab or rehabilitation.

Asante has a data concern with respect to this instruction. While we agree that the situation should be very rare, CMS is now preventing a hospital from even submitting the claim to CMS at all. How will CMS ever obtain the data to determine whether the service may need to be reclassified to a "special packaged code?" Asante believes that it is important for hospitals to be able to report these situations even if they result in no separate OPPS payment at the time. Is it possible for a claim with a single "N" status line item that is "returned to provider" (RTP) to be read into the claims database so that CMS is able to evaluate these claims? If not, isn't it a concern to CMS that a valid outpatient hospital encounter is not reported to CMS, particularly when CMS is concerned about quality of outpatient care? There is a mandatory Part B claim submission requirement – in this case, the hospital is unable to report a claim to CMS. Asante believes that the claims should be able to be resubmitted to CMS with a remark in the remarks field so that CMS can obtain the claims data for future analysis.

Medication Therapy Management Services

Asante agrees that CMS has no need to distinguish MTM services provided specifically by a pharmacist from MTM services provided by other qualified staff, as this would mean providers would have to keep up with differing methods of reporting incident-to services depending on the type of staff providing the service. We appreciate that CMS has validated the fact that these services are already accounted for within the OPPS system.

Asante asks for clarification from CMS regarding the term "component of", as it relates to clinic visits, however. MTM might be performed as a component of emergency visits, procedures, and diagnostic tests, however, MTM is often performed as a stand-alone service in the clinic setting meeting all of the outpatient hospital incident-to and coverage requirements. We ask CMS to specifically state whether a clinic visit may be reported to identify MTA when it is the sole service rendered during an outpatient hospital encounter.

Radiology Procedures

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

Device Dependent APCs

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

Drug Administration Coding and Payment

Asante understands CMS is proposing to continue requiring a combination of HCPCS C-codes and CPT codes for use in 2007. Asante has encountered many difficulties this year due to different reporting requirements for Medicare vs. non-Medicare payers. In addition, we have problems with Oregon Medicaid not accepting the Medicare HCPCS C-codes and have not been paid allowable co-payments and deductibles for these services by Medicaid plans when secondary to Medicare.

Asante has had to make the current CPT codes for drug administration work in the hospital setting even though the codes are not intuitive or easily applicable in the hospital setting. We have already incurred the administrative cost and burden to implement these codes, yet we suffer the financial implications of our Medicaid program rejecting these codes and charges for correct secondary, crossover claim payment. Therefore, we ask CMS to move to the full use of the drug administration CPT codes for 2007; however, we urge CMS to work with the CPT Editorial Panel and the AHA to redefine the CPT code definitions so they are applicable for both physician and hospital use.

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

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

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

CMS states that it no longer needs to give specific drug administration instructions related to the use of modifier -59, and that hospitals should use modifier -59 consistently with coding principles generally used for other OPPS services. We believe that continuing to apply the Physician CCI edits for drug administration services under OPPS is inappropriate as this forces providers to report modifier -59 far too often and unnecessarily resulting in CMS' data being "flooded" with modifier -59, rendering it meaningless with

respect to understanding what is happening with the provision of drug administration services. CMS recognized this to some extent earlier this year and "turned off" some of the CCI edits related to drug administration services, but many inappropriate edits continue to be in place resulting in hospitals being forced to report this modifier on virtually every multiple procedure claim that crosses service departments.

For instance, virtually every radiology service in the CCI edit tables that includes a related injection (whether inherent in the CPT or reported by another distinct code) ends up looking like an "error" even when the injection is truly legitimate, separate and distinct from the radiology procedure, and most often provided in other departments, such as the Emergency Department or Observation. Asante encourages CMS to take one service area (e.g. CT) and run data to look at the use of drug administration codes in the physician office setting along with the CT scan, versus the use of drug administration codes on 2006 hospital claims along with the same CT scan. We believe the data will clearly show a tremendous volume difference between the two settings, illustrating that hospitals provide multiple different services through multiple departments on the same date of service which physicians in their office settings do not and hence the same set of edits are not applicable. They simply result in increased administrative burden for hospitals which we believe can easily be alleviated by CMS by "turning off" the physician drug administration CCI edits.

Drugs, Biologicals, and Radiopharmaceuticals

Asante urges CMS to continue using the same percentage increase over the ASP to set payment rates for separately payable and pass through drugs as physicians are paid and to let this rate cover both acquisition and pharmacy handling costs. We do not want any administrative burden to separately charge handling charges or codes. Asante does not support CMS' proposal to pay for drugs at ASP + 5%. This 1% decrease over how we are paid today is not appropriate and furthermore, results in another site of service differential between the physician and hospital setting given that physicians are still reimbursed at ASP+6%. Asante cannot understand how or why CMS would allow such a differential to exist, particularly since physicians are paid for each and every drug, while hospitals are not due to the existence of the drug packaging threshold. Finally, given that CMS does not allow for multiple APC payments for multiple injections of the same drug/substance, we lose out on the administration payment and also on the drug reimbursement if the drug being injected is packaged. Therefore, Asante urges CMS at a minimum to continue reimbursing separately payable drugs using ASP + 6% as is done today.

Asante strongly believes CMS should eliminate the drug packaging threshold and allow separate payment for all HCPCS coded drugs, biologicals, and radiopharmaceuticals regardless of their median cost – particularly for ED, outpatient visit and infusion services. At a minimum, once a drug has been separately paid, its status should remain separately

payable so that CMS may continue to collect the HCPCS data. Since ASP and median cost data is volatile, CMS should not move a drug from separately paid to packaged from one year to the next. Once separately payable, the status should remain fixed for at least 3 years to allow stabilization of claims, ASP and other date.

With the proposal to apply APCs to Ambulatory Surgery Centers, CMS must consider that ASCs will not be paid extra for drugs used for surgery or paid separately for drug administration. Therefore, Asante asks CMS to consider conditional logic for drug and drug administration payment. If the drug and drug administration is associated with routine or expected pre- or post-op surgical care, then it should not be billed by hospitals or ASCs in a manner to generate additional payment (no HCPCS for the drugs and no CPT codes for drug administration). But if the service is due to a complication or unexpected condition that is not pre- or post-op care, the hospital should be able to bill and be paid both the drug and the appropriate drug administration service. By paying for all HCPCS coded drugs separately (those not associated with surgery), CMS will move closer to aligning payment policy across the physician and hospital settings. CMS should issue very clear instructions in transmittals that drug administration services, both pre- and post-operative that are for routine/expected care of the surgical patient during recovery time, whether PACU, short stay or a bed, are not separately payable under OPPS. However, pre- and post-operative drug administration that is not part of the routine care of the surgical patient should be able to be billed and be paid separately under OPPS. By definition, an ASC would transfer the patient to a hospital if the patient required atypical post-operative care. A hospital does not transfer the patient to a separate facility, but rather continues to care for the patient, perhaps in the same bed, but under updated or revised orders from the physician. CMS must think through how the OCE will recognize these services that should be legitimately paid separately from those services CMS considers packaged and not separately payable.

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

ROGUE VALLEY
MEDICAL CENTER
A part of the Asante® family
2825 E. Barnett Road, Medford, OR 97504 • Phone (541) 789-7000 • *www.asante.org*

IVIG

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

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

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

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

Hospital Coding and Payment for Visits

Asante supports the creation of HCPCS G-codes specific to hospitals for reporting facility levels of care for the emergency room and clinic visits. We have trouble with Medicaid and non-Medicare payers recognizing that hospital reporting of the physician CPT codes does not follow physician E/M guidelines. Having specific codes just for hospital use should help resolve this issue with. However, we are very concerned that Oregon Medicaid will not recognize the new G-codes if made final for 2007, even though we believe they should under HIPAA. And we are concerned we will have the same crossover claim

secondary payment issues with visits that we currently have with drug administration C codes. Therefore, we urge CMS to stress the importance of this code set and its applicability to the hospital setting so we can avoid problems with state Medicaid programs and other local payers if these HCPCS G-codes are made final for 2007.

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

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

We are concerned with CMS' use of time in the description of the new HCPCS G-codes proposed for critical care. CMS issued coding and billing instructions concerning critical care at the outset of the OPPS. On page 17 of Chapter II for Claims Processing System Modification for OPPS (the FI training manual) there is no indication that a time threshold of 30 minutes or more was required before reporting CPT code 99291. In addition, on page 18452 of the April 7, 2000 rule CMS states, *"we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore, we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."*

Given the above information, we cannot understand why CMS is now proposing a time threshold for reporting the newly proposed critical care codes. The 30-minute time threshold for CPT 99291 applies to physician billing for their professional services, but not to hospitals under OPPS. The APC payment covers the hospital staff and facility resources expended when critical care is reported -- these resources are expended immediately, not after 30 minutes. In addition, CMS should continue to recognize what it recognized previously - that it will be burdensome for hospitals to keep track of the number of minutes spent caring for a critical care patient in the Emergency Department.

If new HCPCS G-codes for critical care are finalized for OPPS 2007, CMS should eliminate the reference to time in the definition of HCPCS codes Gccc1 and Gccc2. Asante

believes the inclusion of this new time requirement in the description for the proposed G-codes as stated in the 2007 OPPS proposed rule is inadvertent. Therefore, Asante urges CMS to eliminate the time requirement and to continue with its long-standing OPPS policy concerning billing for critical care services.

We believe it is appropriate to distinguish between critical care with and without trauma activation. Hospitals deploy extensive resources to care for a critically ill or injured patient in the hospital, yet there are two levels of critical care for a hospital. The first level involves a patient who is critically ill or injured and extensive staff and facility resources are expended to evaluate and treat the patient. The second level involves activation of a trauma response team. This level entails even more staff and facility resources to be expended. Because there are specific packaged revenue codes for field-activated trauma response, we believe that it is appropriate to recognize these two levels of critical care with separate APCs. APC 0617 should encompass the first level and the second, higher level that includes the trauma response team should be assigned to a separate new APC 0xxx. Both of these critical care levels include services and resources that are radically different from a high level ED visit 99215 proposed to be reported with HCPCS G-code Gyyy5 in 2007.

With the introduction of new codes, five APC payment levels, and the upcoming release of national hospital ED and clinic visit level guidelines, Asante is concerned with the resulting payments from application of the proposed guidelines and how the payments would not, on their face, reflect relative hospital resource utilization between the two major types of visits – type A ED visits versus hospital clinic visits. Furthermore, we are concerned that the application of the proposed guidelines with the 2007 payment rates also results in beneficiaries paying more in co-payment for the same service in a clinic versus an ED. This does not create appropriate incentives for use of scarce healthcare resources. Beneficiaries should pay less in co-payments when having services rendered in organized clinics versus showing up in a hospital emergency department on an unscheduled basis. Furthermore, co-payments should be a factor to encourage beneficiaries to choose the most appropriate setting for health care services. Under the 2006 payment levels a Level I clinic visit co-payment was almost 50% less than a Level I ED clinic co-payment ($10.47 versus $18.71). With the 5 proposed APC visit payment levels for 2007, the Level I clinic visit co-payment is almost equivalent to a Level I ED visit co-payment ($9.95 versus $10.25).

ROGUE VALLEY
MEDICAL CENTER
A part of the Asante® family
2825 E. Barnett Road, Medford, OR 97504 • Phone (541) 789-7000 • *www.asante.org*

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

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

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

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

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

ROGUE VALLEY
MEDICAL CENTER
A part of the Asante® family
2825 E. Barnett Road, Medford, OR 97504 • Phone (541) 789-7000 • *www.asante.org*

Supplemental Emergency Services RN Chart Form

ROGUE VALLEY
MEDICAL CENTER

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

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

Asante agrees that separately payable interventions should be used as a proxy for increased resource utilization by allowing the inclusion of the interventions into the national visit guidelines. We believe that the resource utilization of multiple separately payable services helps define the resource level of the separate visit itself. We do not believe this would result in attributing the same hospital resources to both the visit and the separately payable services. Asante urges CMS to use the American College of Emergency Room Physician (ACEP) model to identify examples of interventions that can serve as useful proxies. In addition, we provide the following worksheet as an example of interventions that impact the level of care.

☐ Complicated personal hygiene clean-up D/T Urine, feces, emesis, pests

☐ Assist with toileting X _____over_____hrs.

☐ Multiple IV attempts due to: combativeness, poor venous access

☐ Multiple Foley catheter attempts; patient combativeness, difficult anatomy.

☐ Multiple Safety and Welfare checks D/T combativeness, Decreased LOC

☐ Complex wound care X_____ minutes. D/T dirty wounds, large abrasions, burns.

☐ Greater than 2 NG tube attempts D/T combativeness, difficult anatomy

☐ Complex transfer requiring >4 staff more man 2 times

☐ 1:1 Nursing X _____ minutes

☐ 2:1 Nursing X _____ minutes

☐ 3:1 Nursing X _____ minutes

Documentation:

_____
_____
_____
_____
_____

Signature / Title: _____
_____

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

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

The guidelines should reference all resources provided by "qualified hospital staff" rather than being limited to nursing staff. In most instances, multiple professional disciplines are involved to provide the best care for the beneficiary. Hospital do follow state scope of practice rules.

Asante recommends that the outpatient visit guidelines include a mechanism for increasing the visit level if more than 50% of the visit is spent on counseling and coordination of care. It is important for CMS to recognize that patient-specific education is an important component in the patient's quality of care. The patient must understand the procedure to consent to treatment, understand what will happen during a procedure, and understand what the plan of care is upon discharge. Asante believes it is imperative that CMS recognize that, in the outpatient setting, this as a resource that must be recognized as separately "countable" in the outpatient visit/clinic setting. In other words, it is a contributory factor for outpatient visits.

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

Asante also recommends that CMS publish a specific definition of "separately identifiable" visit for the hospital setting (i.e. visit code qualifying for modifier -25). Clinical staff will need more specific guidelines for when to report a level code on the same date of service as a procedure.

For any outpatient visit, hospitals receive physician's orders for the services needed for the individual patient. There are times when the physician may write an order for a service that is not "typical" and could be provided at the physician's office rather than by a hospital outpatient department. The CMS guidelines must be structured in a way that prevents limiting the reporting of legitimate hospital services and allows them to be applied to any and every visit.

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

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

For this reason, Asante emphasizes the need for CMS to consider "time" as a factor to be included in the guideline interventions when "counseling and coordination of care" consume more than 50% of the patient visit. To alleviate CMS' concern about additional financial liability for the beneficiary who takes more time due to special needs or disabilities

and therefore owes more in co-payment, Asante encourages CMS to establish equal co-payment amounts across the five levels of hospital outpatient visit and five levels of Emergency Room APCs. Asante encourages CMS to establish a co-payment for all hospital outpatient levels and a separate co-payment for all emergency room visit levels. Asante believes that, if the co-payment is consistent within the visit guidelines across all levels, it will eliminate any potential violation of the law. This methodology would also eliminate any increased financial liability based on an individual disability or other medical conditions.

Observation services

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

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

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

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

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

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

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

ROGUE VALLEY
MEDICAL CENTER
A part of the Asante® family
2825 E. Barnett Road, Medford, OR 97504 • Phone (541) 789-7000 • *www.asante.org*

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

OPPS Payment Status Indicators and Comment Indicators

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

In the spirit of providing suggestions and ideas for continued refinements, Asante would like to propose that the current SI "B" be split into two different SIs because the current definition of SI "B" means two different things. The current definition is:

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

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

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

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

Inpatient-Only List

Asante asks that CMS post the Inpatient-only List on the physicians' web-page of the CMS web-site and provide background detail on the Inpatient-only List to physicians. We also request that CMS discuss this issue on the Physician Open Door Forum and in the MPFS proposed and final rules. We suggest that CMS require carriers to post the Inpatient-Only list in their educational materials. In this fashion, CMS will help educate physicians and facilitate hospitals' education efforts with physicians.

Interrupted Procedures – Modifiers –52, -73, and -74

Will ASCs be allowed to report interrupted procedures with the above modifiers? If so, how will ASCs report interrupted procedures if the patient is not "taken into the OR/treatment room?" Patients are prepared for surgery in various areas of an ASC or a hospital based on space availability, including pre-operative and holding areas. Preparation in these areas incurs the same costs as if the preparation occurred in the treatment or operating room. The current definition of modifier -73 requires the surgery to be cancelled in the room where the surgery is to occur. Note that our Fiscal Intermediary has allowed us to report a visit code for procedures cancelled prior to taking the patient to the treatment room. An ASC would not be able to report a visit code. CMS should make the ability to report a visit code a national OPPS policy or CMS should work with AMA to change the definition of modifier –73 by eliminating the language "being taken to the room where the procedure is to be performed."

Thank you for this opportunity to comment.

Very truly yours,

Valerie A. Rinkle
Revenue Cycle Director

ROGUE VALLEY
MEDICAL CENTER
A part of the Asante® family
2825 E. Barnett Road, Medford, OR 97504 • Phone (541) 789-7000 • *www.asante.org*

DRAFT Visit Guidelines for Hospital Outpatient Care
Asante Comments/Edits
Date last revised: June 1, 2006

Level 1 ED Interventions At least one item below qualifies for low level. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital ED staff. Three or more of the interventions identified by an asterisk under Level 1 qualify for a Level 2 visit. Each asterisked intervention may only be counted once towards this increase.	
Administration of oral, topical, or sublingual medication(s) or sublingual medication(s)	Move rectal, enteral, or nasogastric to Level II interventions.
* Administration of single-use disposable enema or a soap suds enema	Move to Level II interventions.
* Tracheal suctioning via tracheostomy	Move to Level II interventions. Note that inability to handle one's own secretions is an indicator of a patient needing increased hospital resources.
* Assisting physician with examination(s)	Includes pelvic exam. Nursing documentation must support assistance. This should be a Level II or contributory factor. Note that a pelvic exam is a supply and resource consuming exam.
* Bedside diagnostic testing, unless tests are separately paid	Examples: Dip stick urine testing, capillary blood sugar, occult blood tests. Strep test is not included because it is separately payable.
* First aid procedures	Examples: control minor bleeding, ice, monitor vital signs, external body cooling or warming, remove insect stinger, cleanse and remove secretions.
* Prophylactic flushing of heplock	Do not use for the routine flushing of heplocks following the administration of injections/infusions, as routine flushing is bundled into the injection/infusion charge.
Follow-up visit	Includes patient who ~~returns~~ presents for wound check or suture removal or rabies injection series. Note that patients can present without having initial service in the ED.
Measurement/Assessment of fetal heart tones	

~~Nursing~~ visual acuity assessment (includes wall chart)	Add hearing assessment also. Note that some state scope of practices may allow certified nurse assistants to perform. Services should count as long as performed by qualified staff according to State.
Specimen collection(s), other than venipuncture and separately payable services	Examples: Nursing instruction of patient on proper specimen collection (e.g., mid-stream urine, sputum, throat culture collection). Includes collection of specimen (not the performance of the lab test).
* Oxygen administration—initiation and/or adjustment from baseline oxygen regimen	Includes conversion to hospital-supplied oxygen with rate adjustments, as well as initiation of oxygen administration. This should be a Level II intervention.

EMERGENCY DEPARTMENT VISIT GUIDELINES

Definition of Emergency Department Visit: A patient who presents to the emergency department for services, is registered, has an initial clinical assessment (which includes vital sign(s), chief complaint, and clinical assessment of symptom(s)) and receives one or more of the clinical interventions listed below. All elements of the initial clinical assessment must be present.

Level 2 ED Interventions

An ED visit can qualify as a Level 2 visit if one of the following conditions are met:

1) Three or more Level 1 ED interventions identified with an asterisk are provided. Each asterisked intervention may only be counted once toward this increase.

2) One or more contributory factors to the ED Guidelines are provided, in addition to one or more Level 1 ED interventions.

Level 3 ED Interventions

At least one item below qualifies for mid-level. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital ED staff. Three or more of the interventions identified by an asterisk under Level 3 qualify for a Level 4 visit. Each asterisked intervention may only be counted once towards this increase.

* Assistance with or performance of fecal disimpaction (manual disimpaction or multiple enemas)	
* Cardiac monitoring	Definition: Includes one or more of the following: (1) nursing interpretation or review of strips along with physical assessment by the nurse after initiation of cardiac monitoring; and/or (2) check of integrity of blood flow to extremity.
* Care related to device(s) or catheter(s) (both indwelling and in & out) (vascular and nonvascular) and/or ostomy device(s)—other than insertion or reinsertion	Examples: Irrigation, assessment, adjustment, cleaning, dressing change, or changing of bags. Examples of catheters/devices: Foley, ileal conduit, gastrostomy, ileostomy, colostomy, nephrostomy, tracheostomy, PEG tube, central lines, arterial lines, PICC lines.
Frequent monitoring/assessment as evidenced by three sets of vital sign measurements or assessments (in addition to initial/triage set), integral to current interventions and/or patient's condition.	Examples: Additional vital signs, assessment of cardiovascular, pulmonary or neurological status, or peak flow measurement, excluding orthostatics. Note: One set refers to one or more vital sign measurements taken once. Two sets refer to one or more vital sign measurements taken twice with reasonable time interval between sets. Three sets refer to the same vital sign(s) repeated 3 times, rather than 3 different vital signs taken once.
* Insertion of nasogastric (NG) tube or oral gastric (OT) tube	
* Nasotracheal (NT) or orotracheal (OT) suctioning via endotracheal tube	Does not include nasotracheal or orotracheal aspiration for specimen collection.
* Traction set-up	Application of traction device (includes hair traction, Sager traction) prior to definitive treatment.

Level 4 ED Interventions

An ED visit can qualify as a Level 4 visit if one of the following conditions are met:

1) Three or more Level 3 ED interventions identified with an asterisk are provided. Each asterisked intervention may only be counted once toward this increase.

2) One or more contributory factors to the ED Guidelines are provided, in addition to one or more Level 3 ED interventions.

Level 5 ED Interventions

At least one item below qualifies for high level. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital ED staff.

Assessment, crisis intervention and supervision of imminent behavioral crisis threatening bodily harm to self or others	
Assistance with or performance of sexual assault exam by hospital nursing staff	
Core temperature interventions	Examples: Heated or cooled IV fluids, heated or cooled gastric lavage, heated or cooled peritoneal lavage.
Decontamination of hazardous material threatening life, limb or function by irrigation of organs of special sense, or administration of antidotes	

Frequent monitoring/assessment as evidenced by four or more sets of vital sign measurements or assessments (in addition to initial set), integral to current interventions and/or patient's condition.	Examples: Additional vital signs, assessment of cardiovascular, pulmonary or neurological status, or peak flow measurement, excluding orthostatics. Note: One set refers to one or more vital sign measurements taken once. Two sets refer to one or more vital sign measurements taken twice with reasonable time interval between sets. Three sets refer to the same vital sign(s) repeated 3 times, rather than 3 different vital signs taken once.
Continuous irritation of eye using therapeutic lens (e.g. Morgan lens)	

Contributory Factors to ED Visit Level Determination

Contributory factors are services, or other factors that when present may increase the visit assignment by one level. Only one factor is required. ~~These factors apply only to Levels 1 and 3.~~ If a contributory factor is documented, in the absence of an intervention listed under Levels 1, 3, or 5, this service should be assigned to a Level 1. Items below refer to interventions performed by hospital ED staff. Additional explanations, examples, and clarifications appear in the right-hand column.

Airway insertion (nasal, oral)	Not applicable for increasing a Level 3 visit to a higher level visit.
Reporting to law enforcement or protective services (e.g., potential criminal behavior)	
Control of active, heavy bleeding	Example: Control of active, heavy bleeding or the need to apply pressure to wound for > 10 minutes.
Arrival/transfer via paramedic or advanced life support ambulance (ALS unit)	What about BLS? What about other forms of medical transport?
Isolation	Example: For immunocompromised or potentially infectious patients
Monitoring of moderate or greater sedation	To be used when sedation is not provided to perform a separately payable procedure.

	Severity of patient condition requires ongoing simultaneous clinical involvement of two or more staff, excluding physician or non-physician practitioner	Does not include simple patient transfers, e.g., from chair to stretcher. Includes hospital security staff.
	Patient discharge status other than home or discharge to facility other than originating facility	

Also consider:

- Difficult IV/Venous Access
- Communication impairments
- Ambulation training
- Morgue care

Level 1 Clinic Interventions	
At least one item below qualifies for low level. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital clinic staff. Three or more of the interventions identified by an asterisk under Level 1 qualify for a Level 2 visit. Each asterisked intervention may only be counted once towards this increase.	
Administration of oral, topical, ~~rectal, nasogastric~~ or sublingual medication(s)	Move rectal, enteral, or nasogastric to Level II interventions.
* Bedside diagnostic testing, unless tests are separately paid	Examples: Dip stick urine testing, capillary blood sugar, occult blood tests. Strep test is not included because it is separately payable.
Blood pressure check	Add TB test check.

Clinical staff assessment (excluding physician) or single specialized clinical measurement or assessment	**Examples of clinical staff assessment: Vital signs or clinical assessment of symptoms. Examples of single specialized measurement or assessment: fetal heart tones, positional blood pressure readings, visual acuity assessment, and cardiac monitor rhythm strip performed by ~~nurse~~ qualified staff.** What if there are multiple assessments?
* Prophylactic flushing of heplock	Do not use for the routine flushing of heplocks following the administration of injections/infusions, as routine flushing is bundled into the injection/infusion charge.
Specimen collection(s), other than venipuncture and separately payable services	Examples: Nursing instruction of patient on proper specimen collection (e.g., mid-stream urine, sputum, throat culture collection). Includes collection of specimen (not the performance of the lab test).
* Suture or staple removal with or without dressing application	
Analysis and review of lab results with patient face-to-face	Includes the following face-to-face communications: (a) between physician and patient; and (b) between nurse and patient. Why only between nurse and patient? What about MTM with pharmacists, genetic counselors and other qualified staff according to State scope of practice laws?
Physician counseling of patient requiring use of exam room/facility (~~>60~~ up to 30 minutes in duration)	Does not require the presence of ancillary staff. What about staff counseling exceeding this time?

Level 2 Clinic Interventions

A clinic visit can qualify as a Level 2 visit if one of the following conditions are met:

1) Three or more Level 1 clinic interventions identified with an asterisk are provided. Each asterisked intervention may only be counted once toward this increase.

2) One or more contributory factors to the ~~ED~~ Clinic Guidelines are provided, in addition to one or more Level 1 interventions.

Level 3 Clinic Interventions

At least one item below qualifies for mid-level. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital clinic staff. Three or more of the interventions identified by an asterisk under Level 3 qualify for a Level 4 visit. Each asterisked intervention may only be counted once towards this increase.

* Administration of single-use disposable enema or a soap suds enema	
* Assisting physician with examination(s)	Includes pelvic exam. Nursing documentation must support assistance.
* Care related to device(s) or catheter(s) (both indwelling and in & out) (vascular and nonvascular) and/or ostomy device(s)—other than insertion or reinsertion, and excluding irrigation of an implanted venous access device	Examples: Irrigation, assessment, adjustment, cleaning, dressing change, or changing of bags. Examples of catheters/devices: Foley, ileal conduit, gastrostomy, ileostomy, colostomy, nephrostomy, tracheostomy, PEG tube, central lines, arterial lines, PICC lines.

*** First aid procedures**	Examples: Control of minor bleeding, ice, monitor vital signs, external body cooling or warming, remove insect stinger, cleanse and remove secretions
Frequent monitoring/assessment as evidenced by two sets of vital sign measurements or assessments (in addition to initial set), integral to current interventions and/or patient's condition	Examples: Additional vital signs, assessment of cardiovascular, pulmonary or neurological status, or peak flow measurement, excluding orthostatics. Note: One set refers to one or more vital sign measurements taken once. Two sets refer to one or more vital sign measurements taken twice with reasonable time interval between sets. Three sets refer to the same vital sign(s) repeated 3 times, rather than 3 different vital signs taken once.
*** Tracheal suctioning via tracheostomy**	
*** Oxygen administration—initiation and/or adjustment from baseline oxygen regimen**	Includes conversion to hospital-supplied oxygen with rate adjustments, as well as initiation of oxygen administration
***2 or more qualified staff with patient between 30 to 60 minutes**	

Level 4 Clinic Interventions

A clinic visit can qualify as a Level 4 visit if one of the following conditions are met:

2) Three or more Level 3 clinic interventions identified with an asterisk are provided. Each asterisked intervention may only be counted once toward this increase.

2) One or more contributory factors to the ED Guidelines are provided, in addition to one or more Level 3 interventions.

Level 5 Clinic Interventions

At least one item below qualifies for high level. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital clinic staff.

Assessment, crisis intervention and supervision of imminent behavioral crisis threatening bodily harm to self or others	

Assistance with or performance of fecal disimpaction (manual disimpaction or multiple enemas)	
Cardiac monitoring	Definition: Includes one or more of the following: (1) nursing interpretation or review of strips along with physical assessment by the nurse after initiation of cardiac monitoring; and/or (2) check of integrity of blood flow to extremity.
Frequent monitoring/multiple assessments as evidenced by three or more sets of vital sign measurements or assessments (in addition to initial set), integral to current interventions and/or patient's condition	Examples: Additional vital signs, assessment of cardiovascular, pulmonary or neurological status, or peak flow measurement, excluding orthostatics. Note: One set refers to one or more vital sign measurements taken once. Two sets refer to one or more vital sign measurements taken twice with reasonable time interval between sets. Three sets refer to the same vital sign(s) repeated 3 times, rather than 3 different vital signs taken once.
Nasotracheal (NT) or orotracheal (OT) suctioning via endotracheal tube	Does not include nasotracheal or orotracheal aspiration for specimen collection.
Assistance with or performance of sexual assault exam by clinic nursing staff	
Continuous irritation of eye using therapeutic lens (e.g. Morgan lens)	
* Two or more qualified staff with patient exceeding 60 minutes.	

Contributory Factors to Clinic Guidelines	
Contributory factors are services, or other factors that when present may increase the visit level assignment by one level. Only one factor is required. These factors apply only to Levels 1 and 3. If a contributory factor is documented, in the absence of an intervention listed under Levels 1, 3, or 5, this service should be assigned to a Level 1. Items below refer to interventions performed by hospital clinic staff. Additional explanations, examples, and clarifications appear in the right-hand column.	
Airway insertion (nasal, oral)	Not applicable for increasing a Level 3 visit to a higher level visit.
Arrangements and/or social service intervention (includes required reporting) and reporting to law enforcement or protective services (e.g., potential criminal behavior)	Examples: Arrangements and/or social intervention for child abuse, battery, elder abuse, etc.
Arrival/transfer via paramedic or advanced life support ambulance (ALS unit)	What about BLS and other forms of medical transport?
Isolation	Example: For immunocompromised or potentially infectious patients.
Severity of patient condition requires ongoing simultaneous clinical involvement of two or more staff, excluding physician or non-physician practitioner	Does not include simple patient transfers, e.g., from chair to stretcher.
Control of active, heavy bleeding	Example: Control of active, heavy bleeding or the need to apply pressure to wound for > 10 minutes.
Patient discharge status other than home or discharge to facility other than originating facility	
Scheduling of additional hospital visits, including ancillary/diagnostic tests.	
Altered mental status and other communication problems.	

	Revisions to patient's care plan requiring discussion/coordination with patient's treating physician/non-physician practitioner.	

CRITICAL CARE GUIDELINES	
Interventions/care for critically ill or critically injured patients may include, but are not limited to the following interventions: treatment for cardiopulmonary arrest or near arrest related to primary cardiac or respiratory causes, drug overdose, hyper/hypothermia, trauma (including severe burns), and other shock events such as anaphylaxis, diabetic shock, internal bleeding, sepsis, that may result in central nervous system failure, circulatory failure, shock, renal, hepatic, metabolic, and/or respiratory failure, etc. At least one item below also qualifies for critical care. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital clinic or ED staff. ~~Critical care of less than 30 minutes total duration on a given date should be reported with the appropriate visit code.~~	
Critical Care Interventions At least one item below also qualifies for critical care. Additional explanations, examples and clarifications appear in the right-hand column. Items below refer to interventions performed by hospital clinic or ED staff. ~~Critical care of less than 30 minutes total duration on a given date should be reported with the appropriate visit code.~~	
Assist in induction/monitoring of pharmaceutical-induced coma	Examples: Barbiturate coma for status epileptics

Assist with rapid sequence intubation (with provision/administration of sedative and/or paralytic agents), and/or airway management	Examples: Bagging, frequent endotracheal suctioning, assist physician in performance of emergent cricothyrotomy, tracheostomy, endotracheal intubation, or any other emergency airway.
Code team/crash team/trauma team intervention	Multidisciplinary team approach to life or limb threatening situation.
Control of major hemorrhage	Examples: Control of hemorrhage from major trauma, including monitoring, IV fluids, and emergent administration of multiple concurrent blood products, such as for threatened exsanguination leading to hemodynamic instability etc.
Continuous and on-going reassessment until stabilized, requiring immediate aggressive interventions in an unstable patient with potential for rapid deterioration and demonstrated instability.	Examples: Cooling (ice bags, fans), gastric lavage, rapid warming.