**Submitter :** **Ms. Bonnie Handke** **Date: 10/10/2006**

**Organization :** **Medtronic, Inc**

**Category :** **Device Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1506-P-470-Attach-1.DOC

CMS-1506-P-470-Attach-2.PDF

#470

1

October 10, 2006

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1506- P
7500 Security Blvd.
Baltimore, MD 21244-1850

ELECTRONICALLY SUBMITTED

**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:

Medtronic, Inc. is one of the world's leading medical technology companies specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high quality products and to support innovative therapies that improve health outcomes. We appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Hospital Outpatient Prospective Payment System and 2007 Payment Rates and 2007 Updates to the Ambulatory Surgical Center Covered Procedure List (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505).

Medtronic appreciates the significant effort you and your staff have put into the Hospital Outpatient Prospective Payment System (OPPS) as well as the Ambulatory Surgical Center rules. We also appreciate your release of the 2005 outpatient hospital claims database and willingness to work with us and other stakeholders to preserve beneficiary access to the full range of treatment options in the outpatient setting.

As in previous years, we have studied the OPPS data and methodologies used to set payment rates for device-dependent procedures. While we are appreciative of the significant efforts that have been undertaken to improve the accuracy of the median cost calculations for device

dependent APCs, we continue to have concerns with some specific items in the rule. In these comments, we make recommendations to address our concerns which we believe will ultimately improve the accuracy of the OPPS payment rates and thereby help to ensure beneficiary access to appropriate care.

We will comment and provide recommendations on the following topics:

- **Improving the Accuracy of "Device-Dependent APC" Payments**
  - CMS' Proposed CY 2007 Payment Policy
  - Charge Compression
  - Bundling
  - Violation of "Two Times Rule"
  - Devices Billed in Absence of an Appropriate Procedure Code (Table 20)
  - Proposed Payment Policy When Devices are Replaced Without Cost or Where Credit for a Replaced Device is Furnished to the Hospital
  - Impact of Residual Costs of Upgrades on the Median Costs for APCs 0107 and 0108
  - Refinement of Neurostimulator C codes

- **Improving the Accuracy of "New Technology APC" Payments**
  - Movement of CPT 91035 from New Technology APC 1506 to Clinical APC 0361

- **Other Issues**
  - "New HCPCS and CPT Codes"
  - "Inpatient Only Procedures"
  - "AAA Screening"

## Improving the Accuracy of "Device-Dependent APC" Payments

- **CMS' Proposed CY 2007 Payment Policy: Medtronic Recommendation to Improve Payment Accuracy**

Medtronic is appreciative of the efforts CMS has made to improve the accuracy of the rate setting process for device-dependent APCs. The use of only those claims with an appropriate device code and claims with nontoken charges for the device is a positive step towards payment accuracy. We note, however, that there are still several device-dependent APCs, especially those including high cost devices such as neurostimulators and ICDs, where the device acquisition costs continue to be underrepresented in the median cost data. These are also the APCs that have experienced continued and significant payment reductions since 2002.

The table below illustrates the repeated payment reductions that have been imposed on several device-related procedures since 2002.

| APC/Description | 2002 | 2003 | 2004 | 2005 | 2006 | *2007* |
|---|---|---|---|---|---|---|
| 0039, Level I Implantation of Neurostimulator | $15,489 | $11,876 | $12,832 | $12,532 | $11,602 | *$10,829* |
| 0222,Implantation of Neurological Device | $15,400 | $11,877 | $12,669 | $12,372 | $11,455 | *$10,964* |
| 0315, Level II Implantation of Neurostimulator | N/A | N/A | N/A | $20,078 | $18,590 | *$14,500* |
| 0107, Insertion of Cardioverter-Defibrillator | $19,428 | $17,013 | $18,394 | $17,963 | $16,632 | *$17,185* |
| 0108, Insertion/Replacement/ Repair of Cardioverter-Defibrillator Leads | $29,360 | $23,131 | $24,700 | $24,122 | $22,334 | *$22,808* |

Over the past six years, Medtronic has presented multiple sources of third party, external data to demonstrate that the CMS median cost data for these device-dependent procedures has been thousands of dollars lower than the actual hospital acquisition costs.

| APC | Proposed Payment 2007 | Device Related %[1] | Device Related Portion | IMS Health Median cost[2] | Difference between CMS Device portion and IMS Data |
|---|---|---|---|---|---|
| 0039 | $10,828.84 | 78.51% | $8,502 | $11,561 | ($3,059) |
| 0222 | $10,964.12 | 78.10% | $8,563 | $11,995 | ($3,432) |
| 0315 | $14,500.02 | 83.52% | $12,110 | $18,278 | ($6,168) |
| 0107 | $17,185.34 | 89.13% | $15,317 | $18,304 | ($2,987) |
| 0108 | $22,807.94 | 89.15% | $20,333 | $24,515 | ($4,182) |

[1] Table 21 Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List [CMS-1506-P]
[2] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005 (includes all devices included in APC payment)

We have done extensive research to understand the reasons why the cost data do not accurately represent the actual costs of these implantable technologies. Our analyses have found that one of the most important shortcomings in the OPPS methodology is that it does not include any mechanism to address the known phenomenon of charge compression.

***Until such time that median cost data for device-dependent APCs reasonably reflects the average acquisition costs of the devices, a floor should be established at no less than 100% of the 2006 rates plus the market basket update to eliminate the continued declines in payment year over year for several device-dependent APCs (APCs 0039, 0222, and 0315)***

- **Charge Compression: Medtronic Recommendation to Improve Payment Accuracy**

As stated above, one of the most important shortcomings in the OPPS methodology is its failure to address charge compression. Charge compression occurs when hospitals use a lower percentage mark-up for higher cost items while CMS uses a single, uniform cost-to-charge ratio (CCR) for the many items and services in a single department or cost center. Methodologies that rely on uniform CCRs underestimate the cost of more expensive items and overestimate the cost of less expensive ones, resulting in a systematic distortion of the estimated costs and of the resulting cost-based prospective payment rates.

Although evidence of the effect of charge compression is not new, research supporting an adjustment to offset charge compression was not previously available. We believe an analysis completed and presented to CMS during the IPPS comment period presents a viable solution. The analysis takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR for supplies and equipment into separate CCRs for each supplies sub-category. The charges by revenue center are broken into five supplies sub-categories: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. In the analysis ICDs were grouped with pacemakers based on the prevalence of those devices found in the pacemaker revenue code. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital.

By pooling the information from all hospitals, a regression analysis yielded a single set of CCR adjustments that reflect national average CCRs for each of the five supplies sub-categories. This national-average set of adjustments was then applied to each hospital (and combined with each hospital's actual supplies CCR), resulting in an adjusted estimate of cost on each MedPAR record.

The analysis found a strong, statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. For example, hospitals with a higher share of charges in the pacemaker and implantable device revenue

centers (0275, 0278) have higher supplies CCRs.

CMS could use the coefficients from this regression model to develop a data-driven adjustment for creating CCRs for sub-categories of supplies. Using the available MedPAR data, only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate, making implementation easy while clearly improving accuracy.

The analysis found, on net after all budget-neutrality adjustments, the average CCRs for the supplies sub-categories which are shown in the table below. The average CCR for all supplies together was 0.35 (top line), but the regression analysis showed substantial variation in CCR by category. The pacemaker category (which also includes hospital charges for a significant portion of defibrillators) has an estimated CCR of 0.47 (or just slightly more than a 100 percent average mark-up, calculated by taking 1/CCR). The category of general supplies, by contrast, has an estimated CCR of 0.27 (or just under a 300 percent average mark-up).

**Estimated CCRs for Supplies Sub-Categories**

| Supplies subcategory | Net average CCR after budget-neutrality adjustment |
|---|---|
| Supplies, Total | 0.35 |
| 0270 (general supplies | 0.27 |
| 0278 (implantables) | 0.45 |
| 0272 (sterile supplies) | 0.29 |
| 0275 (pacemaker (and defibrillator)) | 0.47 |
| All other supplies | 0.34 |

Source: Analysis of 2004 5%standard analytic file and hospital cost report data, applied to 2007 OPPS Proposed Rule (CY2005 OPPS claims) data

The analysis submitted during the IPPS comment period showed that this variation in CCRs across sub-categories has a significant impact on supply-intensive DRG weights. Cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers. Below is a table that shows the impact of the adjusted CCRs on selected device-dependent APCs. Like the inpatient analysis, the median cost for device-dependent APCs display increases as a result of the charge compression adjustment.

| Impact of Charge Compression Adjustment on Selected Device-Dependent APCs | | |
|---|---|---|
| APC | Single Procedure Median Cost (CMS Published, Table 18) | Single Procedure Median Cost Adjusted for Charge Compression |
| 0107, Insertion of ICD (Generator-Only) | $17,245 | $21,024 |
| 0108, Insertion/Replacement Repair of ICD (Full System | $22,888 | $27,058 |
| 0089, Insertion of Pacemaker System | $7,532 | $8,373 |
| 0090, Insertion Pacemaker (Generator-Only) | $6,043 | $7,398 |
| 0222, Implantation of Neurological Device | $11,002 | $13,121 |
| 0039, Level I Implant of Neurostimulator | $10,867 | $13,337 |
| 0315, Level II Implant of Neurostimulator | $14,551 | $17,511 |
| Source: Analysis of 2004 5%standard analytic file and hospital cost report data, applied to 2007 OPPS Proposed Rule (CY2005 OPPS claims) data. | | |

In generating the supplies sub-category CCRs, budget neutrality was maintained in each hospital by first "standardizing" each hospital's CCR. After creation of the sub-category CCRs, total supply/device costs in each hospital were made to match exactly total supply/device costs before any adjustments. The detailed (sub-category) CCR data for each hospital kept the hospital aggregate data unchanged (total supply/device costs matched the existing hospital total).

We believe there is a precedent for adjusting CCRs in OPPS comparable to our proposal for device-dependent APCs. CMS utilizes a simulated CCR for blood products. We have studied the blood methodology and compared it to our proposed decompression factor model and have found several parallels.

- For blood: **First,** CMS developed national average CCR adjusters, reflecting the average relationship between blood CCR and average CCR. CMS calculated the average relationship between blood product CCRs and hospital-wide CCRs, for hospitals that reported blood cost centers. **Second**, CMS applied these national average adjusters to the actual hospital-wide CCR in those hospitals that didn't have a blood cost center. This gave "simulated" blood CCRs in each hospital, based on the hospital's actual hospital-wide CCR and national adjustment factors. **Third,** blood charges were separated by revenue center code, and these "simulated" CCRs were applied based on the revenue center code under which the charges were billed. **Finally,**

CMS did not do any particular budget-neutrality adjustment (e.g., did not net the additional blood costs out of any particular department or set of departments), but instead only recovered the extra payment to blood as part of the overall budget-neutrality process.

- For implantable devices: **First**, we developed national average adjusters based on the statistical relationship between mix of supplies charges by revenue center category, and overall hospital supplies CCR. (Our calculation differs from what CMS did for blood because no hospitals had line-item cost report data for implantable devices.) **Second,** we applied these national average adjusters to each hospitals overall CCR for supplies, to arrive at "simulated" CCRs for the supplies sub-categories. Third, we applied these "simulated" CCRs to claim charges, based on the revenue center under which the supplies were billed. **Finally**, we "standardized" our CCRs in each hospital so that total supplies costs in each hospital were held constant. Thus, we kept more-or-less budget-neutral within supplies costs, rather than spread the costs over other items. (It is not guaranteed to be precisely budget-neutral because the rates are ultimately based on medians, and the medians may not behave in a perfectly budget-neutral manner even though we have held total estimated supply costs constant at each hospital.)

- In summary, even though the approaches are not identical, there are a number of parallels between the CMS simulated blood CCR and our de-compressed supplies CCR. They both:

  - vary in CCR by category. The pacemaker category (which also includes hospital charges for defibrillators) attempts to get a CCR that is specific to the particular product in question (blood or implantable);
  - use each hospital's actual CCR for a broader category (hospital-wide or all supplies);
  - apply a single national average adjustment to each hospital's broader CCR to get at the "simulated" CCR for the products in question;
  - apply that adjustment to claim charges based on revenue center on the claims;
  - and arrive at cost estimates that appear closer to reality based on industry transactions prices.

  The main differences are that:

  - The national adjuster for blood came from the subset of hospitals that had line-item data for blood, whereas the national adjuster for implantables came from a regression analysis, and

- The blood costs were not made budget-neutral within any narrow category, while the additional costs of implantables was netted out of the estimated cost of all other supplies within each hospital.

***Medtronic strongly believes that this adjustment can and should be used to address charge compression in OPPS. CMS should extend the current study of charge compression commissioned from RTI to include the outpatient setting and until such time that a decompression factor is implemented, a floor should be established to eliminate the continued declines in payment year over year for several device-dependent APCs (APCs 0039, 0222, and 0315).***

- **Bundling in APC 0418: Insertion of Left Ventricular Pacing Lead: Medtronic Recommendation to Improve Payment Accuracy**

For CY 2007, CMS is proposing to package the costs of CPT codes 93640 (Electrophysiological evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at the time of initial implantation or replacement) and 93641 (Electrophysiological evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator) into APC 0418 (Insertion of Left Ventricular Pacing Elect). APC 0418 is comprised of two CPT codes:

- 33224: Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal insertion and/or replacement of generator)

- 33225: Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)

CPT 33224 is a stand-alone code that represents the insertion of a left ventricular pacing lead with the attachment to a previously placed pacing or defibrillation device. CPT 33225 is an add-on code that represents the insertion of a left ventricular pacing lead at the time of a cardiac

resynchronization therapy pacing (CRT-P) or cardiac resynchronization therapy defibrillation (CRT-D) system implantation.

As CMS suggests in the proposed rule, CPT codes 93640 and 93641 are always performed during an operative procedure for ICD or CRT-D implantation or replacement or with implantation, revision or replacement of *defibrillation* leads. However, the procedures contained in APC 0418 represent the implantation of a left ventricular *pacing* lead. Pacing leads do not require the type electrophysiologic evaluations represented by CPT codes 93640 and 93641 and therefore, it is not appropriate to package the costs associated with these codes into APC 0418.

The proposed 2007 payment rate for APC 0418 including the packaging of 93640 and 93641 is $16,489, which represents a 64% increase over the 2006 payment rate. Given that the 2005 IMS median cost for the left ventricular lead is $2,494, this level of payment appears to be in excess of the device and procedural costs associated with the service, even after the multiple procedure reduction is applied. According to our calculations, if CMS removes the packaging for 93640 and 93641 and excludes claims without a device c-code and token charges, the median cost for APC 0418 would be reduced to approximately $9,700. This amount appears to be more aligned with the actual costs to perform the left ventricular lead implantation when the device costs, procedural costs, and multiple procedure reduction are taken into consideration.

***Medtronic recommends that CMS remove the packaged costs of CPT codes 93640 and 93641 from APC 0418 as their inclusion is clinically inappropriate and creates a situation where the APC is paid excessively.***

- **Violation of "Two Times Rule" in APC 0106: Insertion/Replacement/Repair of Pacemaker and/or Electrodes: Medtronic Recommendation to Improve Payment Accuracy**

APC 0106 is classified as a device-dependent APC. However, there are two procedures contained in APC 0106 that do not involve the placement of a device. CPT codes 33218 (Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter-defibrillator) and 33220 (Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber pacing cardioverter-defibrillator) represent the repair of an existing lead and do not involve the implantation of a device, making these services clinically different than all other device-dependent services contained in APC 0106.

An analysis of the median costs associated device-dependent and non device-dependent procedures found in APC 0106 shows that there is a significant variance in the costs between the two classes of procedures within this APC. As seen in the chart below, the costs associated with the device-dependent procedures contained in APC 0106 carry median costs that are almost three times the costs associated with the non device-dependent procedures.

**APC 0106: Insertion/Replacement/Repair of Pacemaker and/or Electrodes**

| APC 0106 | Median Costs |
|---|---|
| **33210:** Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)<br><br>**33211:** Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)<br><br>**33216:** Insertion of a transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator<br><br>**33217:** Insertion of a transvenous electrode; dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator | $3,583 |
| **33218:** Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter-defibrillator<br><br>**33220:** Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber cardioverter-defibrillator | $1,290 |

Given the variance in median costs and clinical nature of the procedures involved in APC 0106, Medtronic believes it is important to remove CPT codes 33218 and 33220 from this APC and assign them to a more clinically appropriate, non device-dependent APC. Taking into the consideration the clinical nature and median costs of the procedures represented by CPT codes 33218 and 33220, it seems that these codes would be most appropriately assigned to APC 0105 (Revision/Removal Pacemakers, AICD, or Vascular). APC 0105 is a non device-dependent APC involving a variety of procedures, including the removal and repositioning of pacing and defibrillation leads, which seem to be clinically coherent with the lead repair procedures. In addition, the payment rate for APC 0105 ($1,444.39) is also closely aligned with the median costs for CPT codes 33218 and 33220 ($1,290).

The change in assignment of CPT codes 33218 and 33220 may require a slight revision to the APC descriptions for APCs 0105 and 0106. However, the following revised titles would easily clarify the change in assignment of the lead repair procedures:

APC 0105: Revision/Removal/**Repair** Pacemakers, AICD, or Vascular
APC 0106: Insertion/Replacement/~~Repair~~ of Pacemaker and/or Electrodes

***Medtronic recommends that CMS remove the lead repair codes (CPT codes 33218 and 33220) from APC 0106 and assign them to APC 0105. This APC assignment is more appropriate from a clinical and cost standpoint.***

- **Devices Billed in Absence of an Appropriate Procedure Code (Table 20): Medtronic Recommendation to Improve Payment Accuracy**

We support the proposed recommendation that CMS require the presence of a CPT code and C code on certain device related claims. These claims should ultimately lead to more accurate reporting of costs by hospitals. We have submitted comments to assist CMS in establishing appropriate edits to the email address as requested in the proposed rule.

- **Proposed Payment Policy When Devices are Replaced without Cost or with Credit to the Hospital: Medtronic Recommendation to Improve Payment Accuracy**

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. Medtronic 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 is consequently, more expensive. Medtronic believes that CMS should reduce the offset amount to ensure that the hospital is not held financially responsible for these residual costs. These residual costs may be significant to hospitals, as upgraded device replacements may occur in as many as 10 to 20% of the replacement cases.

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 additional device(s) as a patient's disease progresses and their device indications change For example, a patient with a single chamber ICD may, at the time of replacement, be indicated for a dual or triple (CRT-D) device, requiring not only an upgrade to a more expensive ICD pulse generator, but also, the implant of one or more additional leads, which result in different APC mapping. Similarly, a patient whose pacemaker is being replaced may have developed a life-threatening ventricular arrhythmia, thereby making them now indicated for an ICD. An ICD, as confirmed by its separate APC mapping, is a distinctly different type of technology, which requires defibrillation leads to deliver therapy to the patient. In both cases, if the full offset would be applied to the APC payments for the replacement procedures, the hospital would incur significant losses.

Medtronic believes that 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 medically necessary to treat their current medical condition. We are willing to work with CMS and other stakeholders to identify a reduced percentage offset that is appropriate for these cases.

Medtronic also believe that in the case of upgrades to a different device type, such as pacemaker to ICD change outs, that these upgrades should be exempt from any reduction. Both approaches are in keeping with the principle behind the CMS proposal.

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, Medtronic 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.

**Medtronic recommends CMS reduce the offset percentage to the APC payment rate in instances where same device type upgrades result in residual costs to the hospital. Medtronic also recommends that upgrades to a different device type be exempt from any such reduction. Medtronic further recommends CMS create a new modifier to represent same device type upgrades in the claims data.**

- **Impact of Residual Costs of Upgrades on the Median Costs for APCs 0107 and 0108: Medtronic Recommendation to Improve Payment Accuracy**

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 with the goal of ensuring accurate hospital payment.

As described above, there are circumstances where the hospital may receive only a partial credit for a replacement device involving same device type upgrades. 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, Medtronic believes it is important that CMS exclude claims with charges representing these residual costs from the median used for APC payment rate setting. This approach would provide a more accurate payment to the hospital by ensuring that only claims containing the full costs of the device are included in the 2007 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 | | IMS Median Device Acquisition Cost [1] |
| | 2007 | 2007 | 2007 | 2007 | |
| 0107 | 481 | $ 17,245 | 440 | $ 18,205 | $18,304 |
| 0108 | 2577 | $ 22,887 | 2440 | $ 23,153 | $24,515 |

[1] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005

***Medtronic recommends that CMS exclude claims with charges representing residual costs from the calculation of the median so only claims containing the full costs of the device are included in the 2007 rate setting.***

- **Refinement of C codes for Neurostimulator Technology: Medtronic Recommendation to Improve Payment Accuracy**

One of the key issues in the development of payment rates for APCS 0039, 0222, and 0315 is the fact that each of these APCs involves the implantation of a different type of neurostimulation device – with different levels of functionality, programmability, and cost – yet there is only one C code to identify the full range of products in this category. We understand that many hospitals' chargemasters do not adequately distinguish between the costs of devices covered by this C code and that the resulting claims they submit may not be accurate indicators of the charges for devices under the individual APCs.

We have learned from charge master staff at several large hospital systems in the midwest that the common practice for establishing charges for C codes is to review acquisition costs for all devices within a C code, and populate the charge master with the average. Hospitals have expressed difficulty in tracking different types of neurostimulators from a billing and charging perspective. In the case of APCs 0039, 0222 and 0315, the majority of devices are to be reported using C1767. Based on review of IMS data for calendar year 2005, there are approximately 15 devices that are appropriately reported in category C1767. The median acquisition costs of these devices range from approximately $10,788 to $16,378. The types of devices reflected in this category range from single

channel, single array devices to dual channel, dual array devices. These devices are used to treat disorders such as complex pain, urinary incontinence, Parkinson's disease, essential tremor and dystonia.

***Medtronic recommends that CMS create additional C codes similar to the L HCPCS Level II code series which describe the neurostimulator technology more accurately. Language similar to that of the Level II HCPCS will provide a better mechanism for hospitals to accurately report charges associated with this technology.***

**Improving Accuracy of Payment for "Other New Technology Services" (CPT 91035)**

CPT 91035, Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation, has been assigned to APC 1506, a New Technology APC with a payment of $450. This procedure is performed using the Bravo® pH Monitoring System, commonly referred to as capsule-based pH monitoring. Capsule-based pH monitoring is used to assess gastroesophageal reflux disease (GERD) and replaces monitoring performed with nasal catheter for up to 24 hours. CPT 91035 involves inserting a capsule in the esophagus to measure acid reflux. Data on the presence of acid is transmitted to an external receiver via telemetry for up to 48 hours. Data from the receiver is uploaded to a diagnostic workstation for physician review and analysis.

It is proposed that this procedure be reassigned to APC 0361, Level II Alimentary Tests, with a payment of $242. This payment, which represents a -46% decrease, does not cover all the procedural costs.

Our request is three-fold:

- ***Establish a new APC to include CPT 91035 that more accurately reflects all the procedural costs.***

No other procedure in APC 0361 has significant device-related costs. Using Technical Component Practice Expense (TC PE) RVUs (recently through the AMA's RUC review) as a proxy for resources, the RVU for CPT 91035 is 10.27. The next closest TC PE RVU in the APC is for CPT 91012 (Esophageal motility with acid perfusion) at 5.26 RVUs or 51% of the RVU for CPT 91035.

The capsule-based pH monitoring method is the only procedure in the APC with a TC PE that generates a higher payment for physicians than the proposed APC payment for hospitals. See table below.

| CPT/ HCPCS | APC | Payment | "Single" Frequency | Minimum Cost | Maximum Cost | Mean Cost | "True" Median Cost | CV | TC PE RVUs for 2006 | Payment at $37.8975 |
|---|---|---|---|---|---|---|---|---|---|---|
| 91000 | 0361 | 242.01 | 5 | 20.63 | 220.56 | 127.79 | 176.46 | 76.512 | 0.08 | $3.03 |
| 91010 | 0361 | 242.01 | 9521 | 44.62 | 1,223.46 | 270.79 | 231.29 | 59.079 | 3.98 | $150.83 |
| 91011 | 0361 | 242.01 | 72 | 72.74 | 1,297.65 | 286.82 | 237.40 | 83.931 | 4.71 | $178.50 |
| 91012 | 0361 | 242.01 | 270 | 68.43 | 1,149.28 | 338.08 | 298.28 | 51.242 | 5.26 | $199.34 |
| 91020 | 0361 | 242.01 | 500 | 34.26 | 1,193.36 | 265.48 | 236.53 | 59.686 | 4.04 | $153.11 |
| 91030 | 0361 | 242.01 | 33 | 49.35 | 608.10 | 318.61 | 372.97 | 44.652 | 2.12 | $80.34 |
| 91034 | 0361 | 242.01 | 2774 | 45.29 | 1,520.78 | 295.09 | 267.85 | 59.222 | 4.91 | $186.08 |
| 91035 | 0361 | 242.01 | 1085 | 51.78 | 1,998.84 | 387.62 | 331.40 | 68.807 | 10.27 | $389.21 |
| 91037 | 0361 | 242.01 | 207 | 57.72 | 763.01 | 255.53 | 271.34 | 62.722 | 2.60 | $98.53 |
| 91038 | 0361 | 242.01 | 338 | 57.72 | 1,334.80 | 316.45 | 248.34 | 73.601 | 1.84 | $69.73 |
| 91052 | 0361 | 242.01 | 42 | 30.87 | 5,358.61 | 632.94 | 382.04 | 133.082 | 2.18 | $82.62 |
| 95075 | 0361 | 242.01 | 61 | 39.68 | 1,124.39 | 233.33 | 171.50 | 83.943 | - | |

According to IMS Health, the average sales price (ASP) for Bravo capsules was consistently reported by hospitals each quarter in 2005. The range was $158.84 to $200.78 with a mean of $183.64.

The ASP for the capital equipment is not fully reported to IMS. However, a per procedure estimate of the capital cost for the system (receiver, software, laptop computer, printer, datalink and vacuum pump) was submitted with the New Technology APC application in 2003. With a system price of $18,690, the per procedure cost was estimated to be $83.07 (A total of 225 procedures or 1.5 procedures per week times 50 weeks time three years.) Accordingly, all device-related costs for each procedure are estimated to be $266.71 (capsule at $183.64 and capital equipment at $83.07). The proposed payment level for APC 0361 of $242 is less than the device-related costs. When coupled with nursing, supply and overhead requirements, each procedure will result in a loss to the hospital. The median cost of CPT 91035 was calculated to be $331 (see table above). It appears that hospitals are submitting insufficient charges for this procedure despite numerous educational efforts that have been directed at informing hospitals about submitting correct information.

Of particular note, the proposed move of capsule-based pH to APC 0361 does not capture the significantly different resource costs between the two forms of pH monitoring. Catheter-based pH monitoring (CPT 91034) has been a procedure in APC 0361. Compared to the cost of a capsule ($183.64), transnasal catheters used for pH monitoring sell for $45.40.

A new APC, one that is more homogeneous in terms of resources and recognizes all costs, needs to be designated for CPT 91035.

- ***Establish a C-code to track specific charges for device-related costs.***

Assuming that the definition of device-dependent is that device-related costs equal 50% or more of the payment level, CPT 91035 should be designated as a device-dependent procedure. The capsule alone, at a cost of $183.64, is 76% of the $242 payment for APC 0361 and 55% of the median cost of $331. Designating a C-code will increase the likelihood that hospitals will submit appropriate charges for the non-capital device cost.

- ***Conduct a comparison of costs of single claims with claims that include an endoscopy (for example CPT 43200 and 43235) to assure that all costs are captured.***

According to specialty society guidelines, an endoscopy is recommended when medications fail to control symptoms of abnormal acid reflux in the esophagus. If the findings of the endoscopy are negative or inconclusive, pH monitoring is recommended as an additional diagnostic test to determine the extent of acid reflux. Commonly, Bravo is placed immediately subsequent to endoscopy – the physician has determined that a pH test may provide additional information to accurately diagnose the patient's condition, the patient is prepped and placement of the capsule at this time eliminates the inconvenience of scheduling the procedure at another time. Since only single claims were used to calculate the median cost, the claims information would be based on a less likely scenario in which CPT 91035 is provided as a separate procedure. Evaluating the most common scenario, when an endoscopy and CPT 91035 are performed together, needs to be conducted to assure that all costs are captured.

**Other Issues**

- **"New HCPCS and CPT Codes"**

We note that CMS proposes to map two new Category III codes (0155T and 0156T), related to laparoscopy involving gastric stimulation electrodes placed on the lesser curve of the stomach (i.e., morbid obesity), to APC 0130, Level I Laparoscopy. The AMA CPT Editorial Panel in October 2005 considered a coding request to establish Category I codes for neurostimulation lead procedures for a different form of gastric stimulation. This version, Enterra® Therapy for Gastroparesis, involves placement of stimulating leads in the greater curve (antrum) of the stomach in patients with gastroparesis. Assuming that there was a favorable decision by the CPT Panel, we understand that CMS would be assigning APCs to these new CPT codes in the OPPS final rule. In

September, to help expedite the APC decision process, Medtronic submitted an application to establish a New Technology APC for Enterra Therapy.

- **"Inpatient Only Procedures"**

CMS has proposed to remove CPT code 22851 (apply spine prosthetic device) from the inpatient only list effective January 1, 2007. While it may be appropriate for this code alone to be done in an outpatient setting, all of the eligible primary procedure CPT codes (22325-27, 22533-812) are still limited to the inpatient setting only.

In CY 2003, Medicare removed CPT codes 22612 (arthrodesis, posterior or posterolateral technique, single level, lumbar) and 22614 (each addt'l vertebral segment) from the inpatient list as well. However, these procedures are almost always performed using autologous or allograft bone grafts (20930-38) to create the arthrodesis and many will also include posterior instrumentation (22840-44). These additional codes are also still on the inpatient only list.

***Medtronic recommends that CPT codes 22851, 22612 and 22614 remain on the inpatient only list.***

**CMS has also proposed to remove CPT code 61720** (Creation of lesion by stereotactic method, including burr holes and localizing and recording techniques,single of multiple stages; globus pallidus or thalamus) from the inpatient only list.

The APC panel recommended that CMS consult with the relevant specialty society to confirm appropriateness of removing this code from the inpatient only list. It is unclear in the proposed rule whether or not that confirmation occurred.

Medtronic has received feedback from physicians stating that it would not be clinically appropriate to perform this procedure in an outpatient setting. Thalamotomy and Pallidotomy procedures are associated with brain swelling and the risk of delayed intracranial hemorrhage. An inpatient admission with at least an overnight stay is the standard of care.

***Medtronic recommends that CPT code 61720 remain on the inpatient only list.***

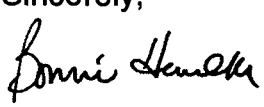
- **"AAA Screening"**

Medtronic supports the proposed creation of a new HCPCS codes GXXXX (Ultrasound, B-scan and or real time with image documentation;

for abdominal aortic aneurysm (AAA) screening) to be used to bill for this new service under both the Medicare Physician Fee Schedule and the OPPS. We are also in agreement that the hospital costs and clinical resources associated with the screening study are similar to limited retroperitoneal ultrasound diagnostic examination and should thus be assigned to the same APC – 266 with a median cost of $98.59 for CY2007.

In closing, outpatient services represent a critical means for patient access to innovative and life-saving medical technology. It is critical that OPPS provide appropriate payment for these services to assure continued Medicare beneficiary access. We appreciate the opportunity to submit these comments. Questions or requests for additional information on these comments should be directed to Bonnie Handke at (763) 505-2748.

Sincerely,



Bonnie J. Handke, RN
Sr. Manager, Health Policy and Payment
Medtronic, Inc

#4 P-2

# Medtronic Comments on Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates [CMS-1506-P]

October 10, 2006

Medtronic, Inc. Meeting with CMS

# Agenda

- Introductions
- Improving the Accuracy of Device-Dependent APC Payment Rates
  - Charge Compression
  - Refining C Codes for Neurostimulator Technology
  - Devices Replaced Without Cost
- Improving the Accuracy of Payment for CPT 91035
- Questions



Medtronic

# Accuracy of Device Dependent APC Payments

| APC/Description | 2002 | 2003 | 2004 | 2005 | 2006 | *2007* |
|---|---|---|---|---|---|---|
| 0039, Level I Implantation of Neurostimulator (Neurostimulator) | $15,489 | $11,876 | $12,832 | $12,532 | $11,602 | *$10,829* |
| 0222,Implantation of Neurological Device | $15,400 | $11,877 | $12,669 | $12,372 | $11,455 | *$10,964* |
| 0315, Level II Implantation of Neurostimulator | N/A | N/A | N/A | $20,078 | $18,590 | *$14,500* |
| 0107, Insertion of Cardioverter-Defibrillator | $19,428 | $17,013 | $18,394 | $17,963 | $16,632 | *$17,185* |
| 0108, Insertion/Replacement/ Repair of Cardioverter-Defibrillator Leads | $29,360 | $23,131 | $24,700 | $24,122 | $22,334 | *$22,808* |

| APC | Proposed Payment 2007 | Device Related %[1] | Device Related Portion | IMS Health Median cost[2] | Difference between CMS Device portion and IMS Data |
|---|---|---|---|---|---|
| 0039 | $10,828.84 | 78.51% | $8,502 | $11,561 | ($3,059) |
| 0222 | $10,964.12 | 78.10% | $8,563 | $11,995 | ($3,432) |
| 0315 | $14,500.02 | 83.52% | $12,110 | $18,278 | ($6,168) |
| 0107 | $17,185.34 | 89.13% | $15,317 | $18,304 | ($2,987) |
| 0108 | $22,807.94 | 89.15% | $20,333 | $24,515 | ($4,182) |

[1]Table 21 Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List [CMS-1506-P]

[2] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005 (includes all devices included in APC payment)



Medtronic

# Longstanding Concerns with Charge Compression

- Medtronic has worked with CMS for 6 years on charge compression in OPPS
  - Inaccurate estimates of costs a key barrier to long-term stability in OPPS
    - Payment rates for defibrillators and neurostimulators thousands of dollars less than acquisition costs
  - CMS has used external data and payment floors in the past
  - Medtronic has proposed a robust charge compression solution
- In the meantime CMS should establish a floor at no less than the 2006 rates plus the market basket update.



Medtronic

# Charge Compression: Issue

- To estimate cost, one CCR is applied to all supplies/devices charges in a hospital.
- But typical markup varies systematically by type of supply. Average markup is lower (true CCR higher) for high-cost devices.
  - Moran Company analysis.
  - CMS external data OPPS adjustments.
  - MedPAC hospital interviews/analysis.
  - Premier data analysis
- So, estimated cost (charge x all-supplies CCR) is too low for high-cost devices, too high for routine supplies.



Medtronic

# Proposed Adjustment: Vary CCR by Supplies Revenue Center Code

- **Revenue centers identify charges in key sub-categories:**
  - Pacemaker/defibrillator, other implantable device.
  - Versus: general supplies, general sterile supplies
- **Create data-driven CCR adjustment for supplies sub-categories.**
  - Regress hospital supplies CCR on hospital supplies mix.
  - Regression results show average CCRs by supplies sub-category.
  - Use regression coefficients to adjust hospital supplies CCR.
  - Sub-category CCR = actual hospital supplies CCR + national average regression-based sub-category adjustment.
  - "Decompressed" cost = subcategory charges x sub-category CCRs.
  - Force budget neut. in each hospital (total supplies cost constant)
  - Re-estimate APC medians with "decompressed" cost.



Medtronic

# Proposed Charge Compression Adjustment Parallels CMS Simulated CCR for Blood

| | **Blood Simulated CCR** | **Proposed Charge Decompression** |
|---|---|---|
| **PROBLEM** | | |
| Cost Reports | Often no CCR for blood. | No CCR for implantable devices |
| Impact on Rates | Blood cost too low, using hospital-wide CCR instead of blood CCR. | Implantables cost too low, using all-supplies CCR instead of implantable device CCR |
| **SOLUTION** | | |
| One national adjustment | Average ratio: Blood CCR / hospital wide CCR | Average difference, implantable device CCR - other supplies CCR |
| Data source? | Cost rpts, hosps w/ blood CCR | Regression analysis, all hospitals |
| New CCR? | Hospital-wide CCR x ratio | Hospital supplies CCR + adjstmnt |
| New Costs? | New CCR x chgs by rev center | New CCR x chgs by rev center |
| Budget neutral? | Subsumed in national calculation | Hold supplies cost constant by hosp. |



Medtronic

# Regression Analysis

- Sum hospital supplies chgs. by rev. center (5% SAF, inpatient and outpatient combined).
- Supplies mix: % of supplies chgs in 4 largest rev ctrs.
- Match to cost report to get supplies CCRs.
- Regress hospital supplies CCR on supplies mix variables plus control variable (CCR for ancillaries excl. supplies).
- Find large, stable, robust impact of charge mix on CCR.
- Best specification combines inpatient and outpatient charges (coincidentally matches data in cost reports).



Medtronic

# Regression Results

| Supplies CCR as Function of % of Supplies Charges by Sub-Category | | | | |
|---|---|---|---|---|
| Variable | Coeff | Std Error | T-value | P-value |
| Intercept | 0.108 | 0.027 | 3.91 | <.0001 |
| CCR, ancill. excl supplies | 0.717 | 0.031 | 23.07 | <.0001 |
| pct_0270 (general supplies) | -0.049 | 0.027 | -1.81 | 0.07 |
| pct_0278 (implantables) | 0.133 | 0.029 | 4.56 | <.0001 |
| pct_0272 (sterile supplies) | -0.025 | 0.032 | -0.78 | 0.44 |
| pct_0275 (pacemaker) | 0.160 | 0.040 | 4.02 | <.0001 |

Source: Analysis of 5% SAF 2004 inpatient and outpatient files matched to 2003 hospital cost reports.

Notes: Dependent variable mean is 0.33. Adjusted R-squared = 0.19. Number of observations is roughly 3,000. Regressions were weighted by supplies charges.



Medtronic

# Average CCRs After Budget-Neutrality Adjustment

| Estimated CCRs for Supplies Sub-Categories | |
|---|---|
| | |
| Supplies subcategory | Net average CCR after budget-neutrality adjustment |
| | |
| Supplies, Total | 0.35 |
| 0270 (general supplies) | 0.27 |
| 0278 (implantables) | 0.45 |
| 0272 (sterile supplies) | 0.29 |
| 0275 (pacemaker (and defibrillator)) | 0.47 |
| all other supplies | 0.34 |
| Source: Analysis of 2004 5% standard analytic file and hospital cost report data, applied to 2007 OPPS Proposed Rule (CY 2005 OPPS claims) data | |



Medtronic

# Impact on Medians: Prop. Rule 2007 Table 18 APCs With >1000 Single-Procedure Claims, Calculated Medians from Claims File.

| 2007 APC | Description | Single-Procedure Claims | Median Cost | Median Cost, De-Compressed | % change |
|---|---|---|---|---|---|
| 0674 | Prostate Cryoablation | 1,447 | $ 6,701 | $ 6,100 | -9% |
| 0656 | Coronary stent | 2,443 | $ 6,544 | $ 6,760 | 3% |
| 0654 | Pacemaker | 1,024 | $ 6,926 | $ 8,371 | 21% |
| 0652 | Intraperitoneal Catheters | 3,178 | $ 1,833 | $ 1,766 | -4% |
| 0623 | Level III Vascular Access Proc. | 19,549 | $ 1,746 | $ 1,788 | 2% |
| 0622 | Level II Vascular Access Proc. | 21,186 | $ 1,398 | $ 1,387 | -1% |
| 0427 | Level III Tube Changes and Repos. | 1,597 | $ 710 | $ 675 | -5% |
| 0386 | Level II Prosthetic Urological Proc. | 1,442 | $ 8,342 | $ 9,586 | 15% |
| 0384 | GI Procedures with Stents | 5,916 | $ 1,390 | $ 1,346 | -3% |
| 0222 | Implantation of Neurological Device | 1,686 | $ 10,975 | $ 13,121 | 20% |
| 0202 | Level X Female Reproductive Proc | 3,659 | $ 2,632 | $ 2,748 | 4% |
| 0115 | Cannula/Access Device Procedures | 1,230 | $ 1,819 | $ 1,769 | -3% |
| 0108 | Defibrillator system | 2,473 | $ 23,101 | $ 27,058 | 17% |
| 0085 | Level II Electrophysiologic Evaluation | 1,257 | $ 2,133 | $ 1,981 | -7% |
| 0081 | Non-Coronary Angioplasty or Ather. | 1,910 | $ 2,654 | $ 2,449 | -8% |
| 0040 | Neurostimulator Electrodes | 1,108 | $ 3,478 | $ 3,785 | 9% |



Medtronic

# Summary

- Use statistical analysis to estimate average CCRs for supplies sub-categories
  - Hospital-level, predict supplies CCR as function of supplies mix.
  - Relies on hospital coding of charges by revenue center
  - Relies on strong average relationship between supply mix and CCR.
  - Statistical (regression) analysis appears robust
  - Size of adjustment appears reasonable (vis-à-vis IMS data).
- Calculate costs for supplies sub-categories, force budget-neutrality.
  - Sub-category CCR = supplies CCR + sub-cat. factor from regression.
  - Sub-category cost = sub-category charges x sub-category CCR.
  - Make budget-neutral within each hospital (total supplies cost constant).
- Raises weights for several device-intensive APCs
- Only works for some major supplies categories.
  - E.g. IOLs are too small as % of supplies charges.
- Actively under consideration for CMS IPPS (RTI to study it.)
- Could be further refined
  - Cardiac versus orthopedic implantables (split by APC group)
  - Sub-categories of cardiac (stent versus pacemaker/ICD), split by APC group



Medtronic

# Decompression factor creates median values that are more closely aligned with hospital acquisition costs

- The data used in 2007 rate setting have been greatly improved by including only claims with the appropriate device codes and non-token charges
- However, charge compression still remains an issue for high cost devices, creating an underestimation of hospital costs
- When the decompression factor is applied, the median values for APCs involving high cost devices are more closely aligned with true device acquisition costs found in external data

| (1) APC (2007 Proposed APC Payment Rate) | (2) 2007 Median with Decompression Applied | (3) Device Related Percentage[1] | (4) Median with Decompression Applied (Device Related Portion) | (5) IMS Health Median Device Acquisition Cost [2] |
|---|---|---|---|---|
| 107 ($17,185) | $21,024 | 89.13% | $18,739 | $18,304 |
| 108 ($22,808) | $27,058 | 89.15% | $24,122 | $24,515 |

[1] *Table 21 Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List [CMS-1506-P]*
[2] *IMS Health, Hospital Suppl.y Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005*



Medtronic

# Recommendations

- Include outpatient adjustment in charge compression study commissioned from RTI
- For device-dependent APCs, CMS should establish a floor at no less than the 2006 rates plus the market basket update



Medtronic

# Payment Levels for Neurostimulators APCs 0039, 0222, 0315

Medtronic

# APCs Impacted

- APC 0039 - Level I Implantation of Neurostimulator
  - Typical device: Single-array neurostimulator for use in deep-brain stimulation or vagus nerve stimulation
- APC 0222 - Implantation of Neurological Device
  - Typical device: Spinal cord neurostimulator for treatment of chronic, intractable pain, single or dual array
- APC 0315 - Level II Implantation of Neurostimulator
  - Typical device: Dual-array neurostimulator for use in deep-brain stimulation



Medtronic
Alleviating Pain. Restoring Health. Extending Life.

# Device Description: Neurostimulators

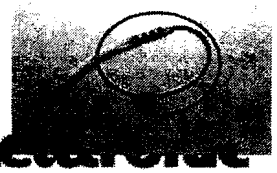
There are four basic devices used in a neurostimulator system, three implanted and one external. The devices are used to treat Parkinson's disease, essential tremor, dystonia, complex pain, and urinary incontinence

❶**Lead** (electrode or electrode array): carries the electric impulse, implanted and connected to the generator via a subcutaneously tunneled extension.

❷ **Generator**: power source that provides the electric impulse, implanted (includes single channel/array, dual channel/array neurostimulators).

❸ **Patient Programmer**: "talks" to generator to adjust stimulation within physician-set parameters, external device.

❹ **Extensions**: connects lead(s) to generator, implanted.



# Description of the Issue

- Common C code prevents accurate reflection of acquisition costs of neurostimulator generator device.
  - Majority of neurostimulator generator devices in APCs 0039, 0222, and 0315 are reported under C1767
  - Devices range from single channel, single array neurostimulators to dual channel, dual array neurostimulators
  - There are 15 different neurostimulator devices reported under C1767



Medtronic

# Description of Issue

- Hospital acquisition cost used to establish charges for C codes typically based on average of all devices within a C code
  - Logical if acquisition costs were similar and all C codes mapped to the same APC
- Median acquisition costs of neurostimulator generators range from $10,778[1] to $16,378[1]

| APC | Median[1] | Mean[1] |
|---|---|---|
| 0039 | $10,778 | $10,561 |
| 0222 | $11,561 | $10,439 |
| 0315 | $16,378 | $16,378 |

[1]IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005.

- Device components of a neurostimulator generator implant
  - Neurostimulator Generator – acquisition costs as indicated above
  - Patient Programmer – acquisition cost $688*
  - Extension(s) – acquisition costs $598 each*

*** Cost of these devices not included in table above.**



Medtronic

# Recommendation and Rationale

- Create additional C codes similar to the L HCPCS Level II code series to describe the technology more accurately which will result in more accurate payment rates (creation of 3 new codes, eliminate C1767)
- Example
  - Cxxxx - Implantable neurostimulator pulse generator, single array,rechargeable, includes extension
  - Cxxxx - Implantable neurostimulator pulse generator, single array, non-rechargeable,includes extension
  - C1820 - Implantable neurostimulator pulse generator, dual array,rechargeable, includes extension
  - Cxxxx - Implantable neurostimulator pulse generator, dual array, non-rechargeable,includes extension
- APCs 0039, 0222 and 0315 should be paid at 100% of 2006 payment rates plus market basket update for calendar year 2007.

# Devices Replaced Without Cost

- CMS initiated removal of no-cost devices from OPPS median calculation
- Upgrades remain a concern
  - 10 to 20% of replacements
  - Hospital disincentive - current clinical indications
  - Additional median protection
- Changes in therapy/device type should be exempted



Medtronic

# CPT 91035 – Capsule-based pH Test for GERD

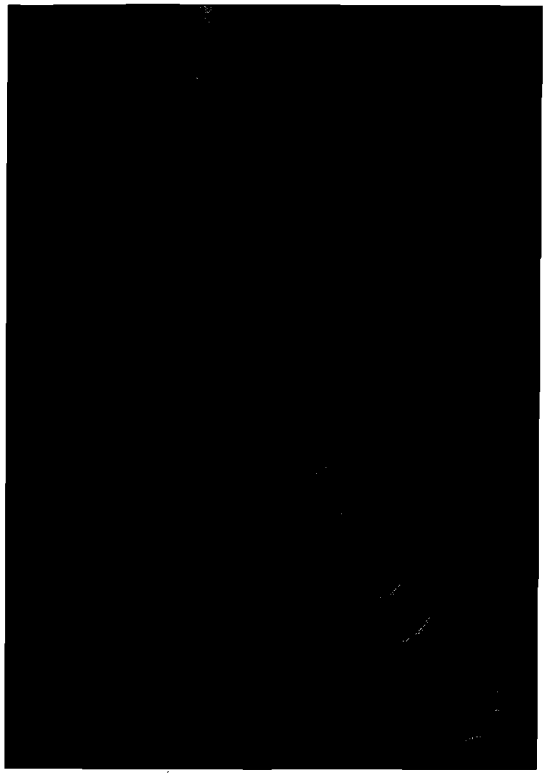
- In 2004, New Technology APC designated for capsule-based pH with payment of $450
- Proposed to move to APC 0361, Level II Alimentary Tests with payment of $242
- Request:
  - Establish new APC to include CPT 91035 that reflects costs – no other procedure in APC 0316 has significant device costs
  - Establish a C-code to track device costs
  - Conduct a comparison of claims including endoscopy



Medtronic

# Clinical Description

- Capsule-based pH monitoring to assess gastroesophageal reflux disease (GERD)
- Replaces monitoring performed with nasal catheter over 24 hours
- Uses implanted capsule attached to the esophageal wall at the GE junction
- Transmits data on presence of acid to external receiver via radiofrequency telemetry for up to 48 hours
- Uploads data to diagnostic workstation for physician analysis and review

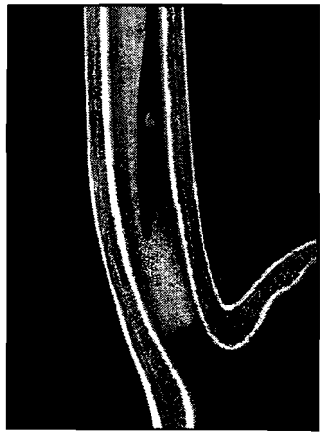




Medtronic

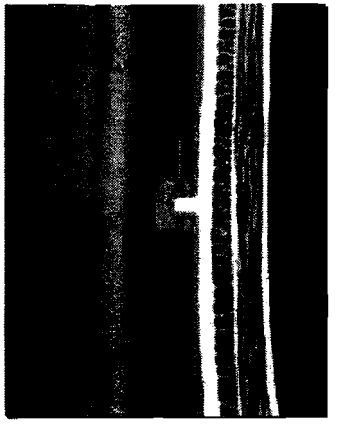
# Bravo® pH System

## *Capsule Insertion*



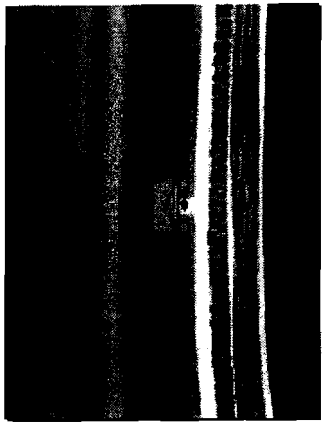
**Step 1**

**Position Bravo Capsule**



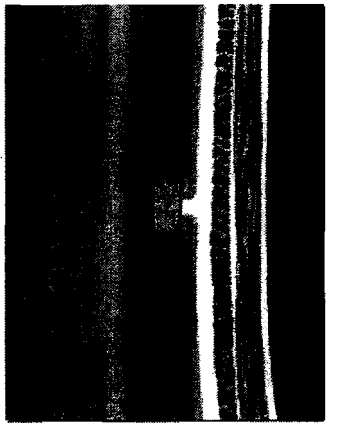
**Step 2**

**Apply Suction**



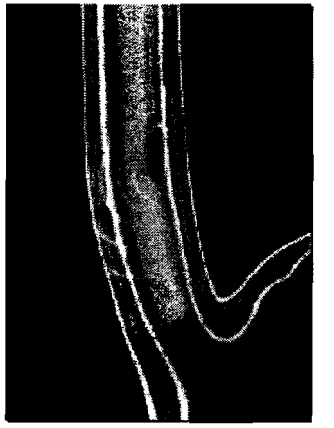
**Step 3**

**Advance Trocar Incising Tissue**



**Step 4**

**Release Capsule**



**Step 5**

**Begin pH Recording**

Endoscopy is not required for capsule insertion, but is often performed prior to insertion for diagnostic purposes.



Medtronic

# Establish APC to Recognize Costs

Technical Component PE

- CPT 91035 has RVU of 10.27 or $389.21 (2006)
- Next closest is CPT 91012 with RVU of 5.26 ($199.34 (2006)) or 51% of value of CPT 91035

CPT 91035 is only procedure in APC with higher payment for physicians than proposed payment of $242

In 2005, capsule ASP of $183.64 (IMS Health)

Capital estimated to be $83.07 per procedure

(System at $18,690 – 225 procedures or 1.5/week X 50 weeks for 3 years)

Total device-related costs = $266.71/procedure

Proposed APC less than device-related costs



Medtronic

# Establish APC to Recognize Costs

- Appears that hospitals have been submitting insufficient charges
- Catheter-based pH monitoring in same APC. Moving capsule-based monitoring to APC 0361 does not capture significantly different resources compared to catheter-based monitoring
- Catheters sell for $45.40; capsule ASP is $183.64



Medtronic

# Technical Component Proxy for Resources

| CPT/ HCPCS | APC | Payment | "Single" Frequency | Minimum Cost | Maximum Cost | Mean Cost | "True" Median Cost | CV | TC PE RVUs for 2006 | Payment at $37.8975 |
|---|---|---|---|---|---|---|---|---|---|---|
| 91000 | 0361 | 242.01 | 5 | 20.63 | 220.56 | 127.79 | 176.46 | 76.512 | 0.08 | $3.03 |
| 91010 | 0361 | 242.01 | 9521 | 44.62 | 1,223.46 | 270.79 | 231.29 | 59.079 | 3.98 | $150.83 |
| 91011 | 0361 | 242.01 | 72 | 72.74 | 1,297.65 | 286.82 | 237.40 | 83.931 | 4.71 | $178.50 |
| 91012 | 0361 | 242.01 | 270 | 68.43 | 1,149.28 | 338.08 | 298.28 | 51.242 | 5.26 | $199.34 |
| 91020 | 0361 | 242.01 | 500 | 34.26 | 1,193.36 | 265.48 | 236.53 | 59.686 | 4.04 | $153.11 |
| 91030 | 0361 | 242.01 | 33 | 49.35 | 608.10 | 318.61 | 372.97 | 44.652 | 2.12 | $80.34 |
| 91034 | 0361 | 242.01 | 2774 | 45.29 | 1,520.78 | 295.09 | 267.85 | 59.222 | 4.91 | $186.08 |
| 91035 | 0361 | 242.01 | 1085 | 51.78 | 1,998.84 | 387.62 | 331.40 | 68.807 | 10.27 | $389.21 |
| 91037 | 0361 | 242.01 | 207 | 57.72 | 763.01 | 255.53 | 271.34 | 62.722 | 2.60 | $98.53 |
| 91038 | 0361 | 242.01 | 338 | 57.72 | 1,334.80 | 316.45 | 248.34 | 73.601 | 1.84 | $69.73 |
| 91052 | 0361 | 242.01 | 42 | 30.87 | 5,358.61 | 632.94 | 382.04 | 133.082 | 2.18 | $82.62 |
| 95075 | 0361 | 242.01 | 61 | 39.68 | 1,124.39 | 233.33 | 171.50 | 83.943 | - | |



Medtronic

# Establish a C-code to Track Costs

Request that CPT 91035 be designated as a device-dependent procedure

Capsule ASP of $183.64 is:

- 76% of APC payment of $242
- 55% of the median cost $331

Designating a C-code will increase the likelihood that hospitals will submit appropriate charges



Medtronic

# Conduct Comparison with Endoscopy Claims

- Capsule-based pH most commonly used immediately subsequent to endoscopy

(Society guidelines recommend endoscopy when medications fail to control symptoms of GERD. If endoscopy findings are negative or inconclusive, pH monitoring is recommended to provide additional information. Placement of capsule while patient is prepped, eliminates scheduling another procedure. Can be placed again at a later time using existing measurement.)

- Median cost calculated using single claims - the less likely placement scenario
- Conduct a comparison when endoscopy and capsule-pH are performed, which is the most likely scenario, to assure that all costs are captured



Medtronic

# Thank You!

Medtronic
Alleviating Pain · Restoring Health · Extending Life

**Submitter :** Mr. Glenn Hackbarth **Date:** 10/10/2006

**Organization :** Medicare Payment Advisory Commission

**Category :** Federal Government

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment.

CMS-1506-P-471-Attach-1.DOC

#471

MEDPAC Medicare Payment Advisory Commission

601 New Jersey Avenue, N.W. • Suite 9000
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

October 10, 2006

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Box 8011
Baltimore, Maryland 21244-1850

*RE: file code CMS-1506-P*

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates* [CMS-1506-P], Federal Register, August 23, 2006. We appreciate your staff's ongoing efforts to administer and improve the payment system for hospital outpatient departments and ambulatory surgical centers, particularly considering the agency's competing demands.

As you know, the outpatient prospective payment system (OPPS) classifies services provided in outpatient departments into ambulatory payment classification (APC) groups. Each APC group has a relative weight, and the OPPS determines payments as the product of the relative weights and a conversion factor. This proposed rule is similar to its predecessors in the sense that it documents changes in the composition of some APC groups and proposes changes to the relative weights based on an analysis of claims and cost report data. Also, the rule estimates the calendar year 2007 update to the conversion factor.

This proposed rule also includes a major proposed restructuring of the payment system for services provided in ambulatory surgical centers (ASCs) as well as proposals that affect the OPPS. In regard to the OPPS, the proposed rule discusses important changes to payments for separately paid drugs and a program for collecting hospital quality data that would affect OPPS payments for individual hospitals.

Our comments on the proposed rule center on five issues:

- payments for separately paid nonpass-through drugs,
- collection of hospital quality data,
- payments for multiple imaging procedures,
- expanding the number of procedures that Medicare covers in ASCs, and
- the method for setting payment rates for ASC procedures.

## Payments for nonpass-through drugs, biologicals, and radiopharmiceuticals

CMS has proposed to pay for specified covered outpatient drugs and other separately paid drugs that are not pass-through drugs at a rate of 105 percent of average sales price (ASP). CMS intends for these payments to cover both the acquisition and pharmacy overhead costs of each drug.

We are concerned that this method could result in inaccurate payments for individual drugs because it does not effectively account for large differences in pharmacy overhead costs among drugs. This proportional method ties total reimbursement for each drug to the drug's ASP. For a drug that has high overhead costs in relation to its ASP, paying for the drug at 105 percent of ASP could result in reimbursements well below the drug's combined acquisition and overhead costs. Conversely, this payment method could over-reimburse for a drug that has low overhead costs in relation to its ASP.

We believe that reimbursements for pharmacy overhead costs should largely reflect methods we recommended in our June 2005 Report to the Congress and that CMS proposed in last year's rule. Both methods collect drugs into APC groups based on attributes that affect overhead costs. Both use hospital charges adjusted to cost to establish payment rates for the pharmacy overhead costs in each APC. CMS's proposed method has fewer APC groups than ours, but the methods are quite similar.

CMS decided not to make its proposed method final, in response to concerns over collecting the data necessary to set payment rates in the APCs. However, we believe it is preferable to pay pharmacy overhead costs using payment tiers because we have found that some classes of drugs—such as cytotoxic agents—have much higher overhead costs than other classes of drugs—such as those taken orally. Therefore, we encourage CMS to revisit this issue and develop a method that recognizes large differences in pharmacy overhead costs between different classes of drugs and reimburses hospitals accordingly.

## Hospital quality data

CMS proposes to link updates in the OPPS to the collection of hospital quality measures. At this time, all of the measures of hospital quality that CMS intends to use are derived from surveys that hospitals initially had to submit to receive full payment updates in the inpatient

PPS. CMS has asked for suggestions on quality measures that are applicable to hospital outpatient departments. We believe that many of the questions in the hospital component of the Consumer Assessment of Health Providers and Systems (HCAHPS) are applicable to hospital outpatient care. These include:

- For nurse care
  - How often did nurses treat you with courtesy and respect?
  - How often did nurses listen carefully to you?
  - How often did nurses explain things in a way you could understand?

- For doctor care
  - How often did doctors treat you with courtesy and respect?
  - How often did doctors listen carefully to you?
  - How often did doctors explain things in a way you could understand?

- When you left the hospital
  - After you left the hospital, did you go directly to your own home, to someone else's home, or to another facility?
  - During this hospital stay, did doctors, nurses, or other hospital staff talk with you about whether you would have the help you needed when you left the hospital?
  - During this hospital stay, did you get information in writing about what symptoms or health problems to look out for after you left the hospital?

- Overall rating
  - Rate this hospital during your stay, from 1 to 10.
  - Would you recommend this hospital to you friends and family?

- About you
  - How would you rate your health?
  - What is the highest grade you have completed?
  - Are you Spanish, Hispanic, or Latino origin or descent?
  - What is your race?
  - What language do you mainly speak at home?

In addition, the surgical care improvement project (SCIP) includes several process-based measures—such as giving aspirin at arrival (e.g. in the emergency department) to a patient with acute myocardial infarction—that conceptually could be useful for evaluating outpatient quality. However, before any process-based measures for evaluating quality are used, some additional analysis may be needed to assure that these measures apply to the outpatient department setting.

MedPAC is a strong supporter of collecting measures of hospital quality, and we commend CMS for expanding the collection of quality data. However, your proposal links updates in the OPPS to the collection of quality measures. We prefer that CMS seek the authority to move

beyond pay-for-reporting toward pay-for-performance so that payment updates depend on empirical results from the quality data, not on whether the data are submitted.

## Other outpatient issues

Under the OPPS, hospitals receive full APC rates for each diagnostic imaging service on a claim, even though hospitals may save costs when they perform multiple services using the same imaging modality on contiguous body parts in the same session. In the proposed outpatient rule for 2006 (*Federal Register*, July 25, 2005), CMS cited an analysis which showed that many costs incurred for an initial imaging service are not incurred in subsequent services. The agency proposed reducing by 50 percent the OPPS payments for multiple imaging services within the same family of codes performed in the same session. Full payment would be made for the service with the highest APC rate, and the 50 percent discount would be applied to the APC rate for each additional service in the same family performed in the same session. We supported this policy in our comment letter on the proposed rule (submitted on September 16, 2005), based on a recommendation from our March 2005 Report to the Congress.

In the final outpatient rule for 2006, CMS deferred implementing a payment reduction for multiple imaging studies subject to further study (*Federal Register*, November 10, 2005). Some commenters on the proposed policy argued that any efficiencies related to providing multiple imaging services in the same session are already reflected in hospitals' costs, which are the basis for the APC rates. Based upon initial analyses that failed to disprove this contention, CMS decided to defer the policy while it further examined ways to improve the accuracy of imaging payments, such as changing the median cost calculation for imaging services or discounting payments for multiple imaging studies. CMS did not revisit this issue in this proposed rule. We encourage CMS to continue its examination of ways to improve payment accuracy for imaging services, including a multiple procedure reduction.

## ASC payable procedures

When CMS implements a revised ASC payment system in 2008, the agency proposes to expand the list of surgical services payable in an ASC by including all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay. The Commission supports paying for procedures in ASCs that meet clinical safety standards and do not require an overnight stay, including services that are primarily performed in physician offices. However, we encourage CMS to seek Congressional authority to replace the current inclusionary list of ASC services with an exclusionary list, as the Commission recommended to the Congress. We agree with CMS that expanding the list of services payable in an ASC would benefit ASCs by allowing these facilities to receive payment for a much broader range of services than is now allowed.

In our March 2004 report, the Commission recommended that after the ASC payment system is revised, the Congress should direct the Secretary to replace the current list of approved ASC

procedures with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay. CMS is currently required by law to establish and update a list of services that may be safely performed in ASCs. Only procedures on the list are eligible for Medicare facility payment when provided in ASCs. CMS is required to update this list every two years, although there was no update between 1995 and 2003. Under this approach, if a new procedure is developed that can be safely performed in ASCs, Medicare will not pay for it in an ASC until the ASC list is updated and the procedure is included. This could create a time lag between the introduction of new services and their availability in ASCs. Thus, we recommended that the Congress authorize CMS to create a list of services that are specifically excluded from payment in ASCs, which is a similar concept to the list of procedures excluded from payment in hospital outpatient departments. If CMS were allowed to create an exclusionary list, Medicare could begin paying ASCs for new procedures at the same time it started paying for the procedures in other settings. CMS would have to keep an exclusionary list up to date to prevent ASCs from performing services that are not clinically safe in that setting. We support CMS's proposal to add procedures that are primarily performed in physician offices to the ASC list. Even though physicians can safely perform many surgical services on healthy beneficiaries in their offices, sicker patients may require the additional infrastructure and safeguards of an ASC or outpatient department. Physicians and patients should have the discretion to decide which setting is most clinically appropriate.

## ASC ratesetting

CMS proposes to revise the ASC payment system in 2008 using the OPPS's procedure groups (APCs) and relative weights. The conversion factor, or average payment amount for each service, would be based on a budget neutrality adjustment designed to keep total payments under the new ASC payment system equal to total payments under the old system. Payments for services added to the ASC list in 2008 that are primarily provided in physician offices would be capped at the physician fee schedule nonfacility practice expense rate. The Commission supports aligning the ASC payment system with the OPPS, but we have recommended that the conversion factor should be based on the costs of ASCs. We have also recommended that ASC rates should not exceed OPPS rates for the same procedures, accounting for differences in the bundle of services covered by the base payment rate in each setting.

The current ASC payment system is outdated and should be replaced by a system based on the OPPS. The current system classifies services into only nine payment groups of clinically-unrelated procedures and sets rates based on 1986 cost data. Because these rates are based on

old cost data, they are probably no longer consistent with ASCs' costs. The broad ASC payment groups make it difficult for CMS to classify new services and increases the likelihood that many services are over- or underpaid. In addition, the ASC rates are not aligned with rates for surgical procedures provided in other ambulatory settings. If payment variations among settings are unrelated to differences in underlying costs, there could be financial incentives to shift services to the most profitable setting.

To remedy these problems, in our March 2004 report to the Congress, we recommended that the Secretary revise the ASC payment system so that its relative weights and procedure groups are aligned with those in the OPPS. This change would accomplish three objectives:

- Using a greater number of payment groups could enhance the accuracy of payments for individual ASC services.
- Linking the two payment systems would make it administratively easier for CMS to update ASC procedure groups and relative weights.
- Aligning the ASC and outpatient payment systems could minimize financial incentives to shift services between settings.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS implement a revised ASC payment system no later than January 2008, taking into account the recommendations of a Government Accountability Office (GAO) report. The MMA required that GAO study the relative costs of services in ASCs and hospital outpatient departments and examine whether CMS should use the OPPS's procedure groups and relative weights as the basis for the ASC payment system; this report has not yet been completed. In this regulation, CMS outlines its proposal to base the ASC system on the OPPS's groups and relative weights, along with policies for which services should be packaged into the base rate and how to set the ASC conversion factor. We comment on these issues below.

The ASC and outpatient payment systems have different packaging policies for which devices and services are included in the base rate for surgical services and which are paid separately. CMS proposes to increase the size of the ASC payment bundle but to maintain the current outpatient bundle. In both payment systems, the facility fee includes the costs of the operating and recovery rooms, nursing and other staff, most surgical supplies and equipment, and anesthesia materials. Medicare also packages other services related to the procedure, such as drugs, biologicals, and diagnostic services, in the ASC payment. However, ASCs may bill separately for prosthetic implants and implantable durable medical equipment (DME) that are inserted during a procedure. Under the OPPS, CMS packages payments for prosthetic implants and implantable DME into the base rate, but pays separately for some items and services provided in conjunction with a surgical procedure. In addition to the base payment, for example, hospital outpatient departments can receive separate pass-through payments for

certain new drugs and devices used in the delivery of services. They may also bill separately for ancillary services, such as imaging, that are provided during a procedure. In order to promote more efficient use of services, CMS proposes to expand the ASC payment bundle to include payments for prosthetic implants and implantable DME. However, the outpatient payment bundle would remain the same.

We support CMS's proposal to expand the ASC payment bundle but encourage the agency to make the payment bundles in the ASC and hospital outpatient settings even more comparable. We agree with CMS that prospective payment systems should package all items related to a service to encourage providers to use resources efficiently. However, the OPPS excludes some items and services from the payment bundle for surgical procedures. Establishing broader payment bundles in both the ASC and hospital outpatient payment systems would promote efficient resource use and better align the two payment systems, which is important if the ASC relative weights are to be based on the OPPS weights. Different bundling policies may lead to different relative payment amounts in each setting, even if the base payment rates share the same relative values in both settings.

The MMA mandates that total payments under the new ASC payment system must be equal to total payments under the old system. To ensure that the new system is budget neutral relative to the old system, CMS proposes to multiply the OPPS conversion factor by a budget neutrality adjustment of 0.62. CMS's current estimate of the 2008 ASC conversion factor is $39.69 (the product of 0.62 and $64.01 (the current estimate of the 2008 OPPS conversion factor)). The budget neutrality adjustment is derived by dividing projected ASC spending under the current payment system by projected ASC spending under a system that uses OPPS procedure groups and relative weights.

Ideally, the ASC conversion factor would be based on either ASCs' costs or the lowest-cost safe alternative setting for ambulatory surgical procedures. Because CMS has not collected recent ASC cost data, we are not able to estimate ASCs' costs or determine which surgical setting has the lowest costs. Thus, the Commission is unable to judge whether an ASC conversion factor that equals 62 percent of the OPPS conversion factor is appropriate. The GAO study mandated by the MMA may shed light on the relative costs of services in ASCs and hospital outpatient departments.

In the Commission's March 2004 report to the Congress, we recommended that the conversion factor under a new ASC payment system be based on the costs of ASCs. We encourage CMS to seek the statutory authority to base the conversion factor on ASCs' costs. The Commission has expressed concern that current ASC rates are based on ASC cost and charge data from 1986 and are thus probably no longer consistent with ASCs' actual costs.

In our March 2004 report, we suggested two alternatives for CMS to collect ASC cost data at the procedure level:

- CMS could periodically survey a sample of ASCs, or
- CMS could require that ASCs submit annual cost reports.

Although either approach would impose administrative burdens on CMS and ASCs, policymakers need timely data to set ASC rates that approximate the costs of efficient providers. In addition to setting the ASC conversion factor, CMS could also use cost data to monitor the overall adequacy of ASC payments.

If CMS decides to adopt its proposed method for setting the ASC conversion factor, the agency should ensure that the calculation of projected ASC spending under the current system includes payments for prosthetic implants and implantable DME, which may be billed separately under current policy.

The Commission has also recommended that ASC rates should not exceed OPPS rates for the same procedures, accounting for differences in the bundle of services covered by the base payment rate in each setting. Based on our analysis of two indirect measures of relative costliness (patient mix and regulatory burden), it does not appear that ASCs incur higher costs than outpatient departments for the same procedures (MedPAC, Report to the Congress, March 2004). We compared risk scores for patients who received similar procedures in each setting and found that outpatient department patients have higher average risk scores, which indicates that these patients are more medically complex than ASC patients (risk scores represent beneficiaries' expected costliness based on their age, sex, and diagnoses). We also found that outpatient departments are subject to additional regulatory requirements, such as the Emergency Medical Treatment and Active Labor Act, which are likely to increase their overhead costs.

## CY 2007 ASC impact

The introduction to this section states that "adding the 14 procedures we are proposing in section XVII of this preamble and implementing the Pub. L. 109-171 mandate would result in a savings to the Medicare program of approximately $150 million in CY 2007." The conclusion to this section states that "the Office of the Actuary estimates that the Medicare program would realize a $35 million savings as a result of implementing the changes proposed for CY 2007." These two statements appear to be contradictory and should be clarified in the final rule.

## Other ASC issues

As CMS prepares to implement a revised ASC payment system and to significantly expand the list of services payable in ASCs, we suggest that the agency update the Medicare conditions of coverage (COCs) for ASCs. To receive payment from Medicare, ASCs must meet the COCs,

which specify minimum standards for administration of anesthesia, quality evaluation, operating and recovery rooms, medical staff, and other areas. These standards have not been revised since 1982. By contrast, Medicare's conditions of participation for hospitals were updated in 2003 with the requirement that hospitals adopt quality assessment and performance improvement programs. In April 2006, CMS announced its intention to issue proposed revisions to the ASC COCs this fall (*Federal Register*, April 24, 2006). We encourage CMS to publish this proposed rule soon.

## Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

GMH/aw/w