MEDICARE HOSPITAL INPATIENT OPERATING AND CAPITAL PAYMENT FISCAL YEAR 2009 PROPOSED RULE

SUMMARY

On April 14, 2008, the Centers for Medicare and Medicaid Services (CMS) released its proposed rule for federal fiscal year (FY) 2009 changes to Medicare's hospital inpatient prospective payment system (IPPS). The payment rates and policies will affect Medicare's operating and capital payments for short-term acute care hospital inpatient services as well as inpatient services provided by certain "IPPS-Exempt" providers. The regulation is scheduled for publication in the *Federal Register* on April 30, 2008 with a 60-day comment period (from the date of public display) closing on June 13, 2008. Most of the new rates and proposed policy changes are effective October 1, 2008.

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I. Impact

CMS estimates that total payments to all hospitals under the IPPS will increase by an average of 4.1 percent in FY 2009, or by $3.967 billion, taking into account all changes in the final rule and CMS' projection that improvements in documentation and coding will increase total payments by 1.8 percent. Without the projected coding-related increase, CMS projects that total payments would increase 2.3 percent combining all changes in the proposed rule.

The major changes in the rule affecting total spending on operating payments are the market basket update of 3.0 percent, an across-the-board reduction of 0.9 percent to maintain budget neutrality (as required by law), and projected growth (including coding-related increases which the 0.9 percent reduction is intended to offset partially). Two proposed policies would reduce spending by about 0.1 percent combined: expansion of the post-acute transfer policy and implementation of payment limitations for preventable hospital-acquired conditions each are projected to save about $50 million. The proposed rule projects that total payments under the capital PPS would increase only about $6 million, or 0.0 percent due to the proposed changes.

CMS' impact analysis shows that the proposed rule would provide a 2.3 percent payment increase, on average, to hospitals before factoring in the projected coding-related increase of 1.8 percent – and 4.1 percent after incorporating this projection. In general, the classes of hospitals which tend to fare better are larger, urban or teaching; hospitals which are small or rural will experience smaller payment increases due largely to completion of the transition to MS-DRGs. Estimates of the impacts are displayed in Table I of the rule (included in the appendix). Note that the last column of this table (column 9) includes CMS' projected 1.8 percent coding-related increase, while column 8 shows the impact of the rule before factoring in this projection. The table below shows the impact on the major categories of hospitals; both the impact of the DRG changes alone and the impact of all changes taken together are displayed.

Hospital Type (no. of hospitals)	Changes in DRG Weight	All Changes (prior to estimated casemix growth)	All Changes (including estimated casemix growth)
All Hospitals (3,528)	0..1	2.3%	4.1%
Large Urban (1,402)	0.5	2.6%	4.4%
Other Urban (1,140)	0.0	2.2%	3.9%
Rural (986)	-1.0	1.5%	3.3%
Major Teaching (238)	0.5	2.5%	4.2%

The differences across hospital types are smaller than for FY 2008, and all categories will see an increase, usually 1.5 percent or more.

II. Proposed IPPS Rate Updates

The rule would provide an FY 2009 market basket update of 3.0 percent, the estimated full market basket increase (as required by current law), for hospitals that report the required quality measures to CMS, while hospitals declining to report would get a 1.0 percent update. According to the rule, an estimated 186 providers may not receive the full market basket increase in FY 2009 because of the failure to report quality measures. (See section V-A below for details of the FY 2009 voluntary quality reporting requirement.) The standardized amounts, which would be effective October 1, 2008 (FY 2009), are:

TABLE 1A.--NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS; LABOR/NONLABOR (69.7 PERCENT LABOR SHARE/30.3 PERCENT NONLABOR SHARE IF WAGE INDEX GREATER THAN 1)

Full Update (3.0 Percent)		Reduced Update (1.0 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,553.98	$1,544.98	$3,484.97	$1,514.98

TABLE 1B.--NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX LESS THAN OR EQUAL TO 1)

Full Update (3.0 Percent)		Reduced Update (1.0 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,161.36	$1,937.60	$3,099.97	$1,899.98

TABLE 1C.--ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR

	Rates if Wage Index Greater Than 1		Rates if Wage Index Less Than or Equal to 1	
	Labor	**Nonlabor**	**Labor**	**Nonlabor**
National	$3,553.98	$1,544.98	$3,161.36	$1,937.60
Puerto Rico	$1,501.82	$920.46	$1,421.88	$1,000.40

TABLE 1D.--CAPITAL STANDARD FEDERAL PAYMENT RATE

	Rate
National	$421.29
Puerto Rico	$197.19

III. Proposed Changes to DRG Classifications and Relative Weights

A. MS-DRGs in FY 2009

In the FY 2008, CMS began a two-year transition to a new patient classification system, Medicare Severity-Diagnosis Related Groups (MS-DRGs). In FY 2008, one-half of the PPS payment was determined using the new MS-DRGs and one-half was based on the previous CMS-DRGs. As expected, the proposed rule for FY 2009 would complete the transition to MS-DRGs and base the payment fully on the new classification system. The classification system would have 746 MS-DRGs in FY 2009, one more than in the current year due to the creation of a new MS-DRG for AICD Lead Procedures (see below). The proposed rule refers readers to the FY 2008 final rule (72 FR 47140 through 47189) for a detailed description of the process used to develop the MS-DRGs.

For this proposed rule, CMS' DRG analysis was based on data from the FY 2007 Medicare Provider Analysis and Review (MedPAR) File, which contains hospital bills for discharges occurring during the period October 1, 2007 through September 30, 2007. The proposed rule analysis included bills from this period which had been received by September 30, 2007.

The proposed rule notes that many of the annual changes to the MS-DRG classifications are the result of specific issues brought to CMS' attention by interested parties. CMS encourages individuals to raise such issues no later than early December for them to be considered for the next annual proposed rule updating the IPPS. The preamble also notes that CMS will consider requests to use non-MedPAR data in the recalibration process according to a process described in the FY 2000 IPPS final rule (64 FR 41500). Under this process, a significant sample of the non-MedPAR data should be submitted by mid-October with final data due in early December. The specific changes proposed for FY 2009 are described in section E below.

B. Adjustment for Coding-Related Increases

CMS expects average casemix to increase under MS-DRGs, especially in the initial years, due to improved documentation in the medical record and more complete and accurate coding. In the FY 2008 proposed and final rules, CMS included a prospective adjustment to the standardized amounts using its broad authority under the Social Security Act. CMS actuaries had projected coding-related casemix increases of about 4.8 percent over the first two years after implementation of MS-DRGs. Based on this projection, the proposed rule included a 2.4 percent reduction in the standardized amounts each year for two years, FY 2008 and FY 2009. Despite a high volume of comments opposing the large offset and questioning its legitimacy, CMS affirmed it in the final rule with these changes:

- The total adjustment was unchanged at 4.8 percent and was applied over three years rather than two years due to the 2-year phase-in of MS-DRGs. CMS

stated that it did not believe that the incentives to improve documentation and coding would be as strong in the first year as it had previously estimated.
- The coding and documentation adjustment was set at -1.2 percent in FY 2008 and -1.8 percent in both FY 2009 and FY 2010. The rule indicated that the FY 2009 and FY 2010 adjustments may be revised based on actual experience.

Subsequent to issuance of the final rule, on September 29, 2007 Congress enacted the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (P. L. 110–90) and included a provision to override the regulation. The law reduced the documentation and coding adjustment from -1.2 percent to -0.6 percent in FY 2008 and from -1.8 percent to -0.9 in FY 2009. CMS implemented the statutory changes and revised the FY 2008 payment rates, factors, and thresholds in a final rule that appeared in the Federal Register on November 27, 2007 (72 FR 66886). The changes are effective retroactive to October 1, 2007.

In the proposed rule for next year, FY 2009, CMS applied a documentation and coding adjustment of -0.9 percent to the national standardized amounts as required by the new law. Because the documentation and coding adjustments established in the FY 2008 IPPS final rule were cumulative, the -0.9 percent adjustment in FY 2009 is in addition to the -0.6 percent adjustment in FY 2008, yielding a combined effect of -1.5 percent.

P. L. 110–90 also specifies that to the extent the documentation and coding adjustments applied in FY 2008 and FY 2009 result in overpayments or underpayments relative to the actual amount of documentation and coding-related increases, the Secretary will make adjustments in fiscal years 2010-1012 to correct the overpayments or underpayments, with interest. The statute states that "…any adjustment...shall reflect the difference between the amount the Secretary estimates that implementation of such Medicare Severity Diagnosis Group (MS-DRG) system resulted in changes in coding and classification that did not reflect real changes in casemix and the prospective documentation and coding adjustments applied under [this provision]."

In the FY 2009 proposed rule, CMS describes its preliminary analysis plans to determine the portion of the casemix increase that is due to changes in documentation and coding. It will conduct a thorough retrospective claims analysis to measure the extent of the overall national average changes in casemix for FY 2008 and FY 2009. Part of the overall national average change would be attributed to underlying changes in actual patient severity and part would be attributed to documentation and coding improvements under the MS-DRG system. In order to separate the two effects, CMS plans to isolate the effect of shifts in cases among base DRGs from the effect of shifts in the types of cases within base DRGs. The proposed rule observes that shifts among base DRGs are the result of changes in principal diagnoses while the shifts within base DRGs are the result of changes in secondary diagnoses. It also notes that CMS expects most of the documentation and coding improvements under MS-DRGs to occur in the secondary diagnoses,

making the shifts among base DRGs less likely to be due to the implementation of MS-DRGs and the shifts within base DRGs more likely to be due to MS-DRGs.

CMS also plans to evaluate data to identify the specific MS-DRGs and diagnoses that contributed significantly to the documentation and coding payment effect and to quantify their impact. This step will entail analysis of the secondary diagnoses driving the shifts in severity within specific base DRGs. Finally, if additional analyses are warranted, CMS may decide, if feasible, to use historical data from the Hospital Payment Monitoring Program (HPMP) to corroborate the within-base DRG shift analysis. The HPMP is supported by the Medicare Clinical Data Abstraction Center (CDAC). From 1999 to 2007, the CDAC obtained medical records for a sample of discharges as part of CMS' hospital monitoring activities, collecting data on a random sample of between 30,000 to 50,000 hospital discharges per year. CMS says that the historical CDAC data could be used to develop "an upper bound estimate" of the trend in real case-mix growth (that is, real change in underlying patient severity) prior to implementation of the MS-DRGs. The proposed rule welcomes public comments on the analysis plans.

The FY 2009 proposed rule also invites public comment on two specific issues pertaining to application of the coding adjustment. After issuing a final FY 2008 regulation that applied the adjustment to the hospital-specific portion of the IPPS payment made to sole community hospitals and Medicare-dependent small rural hospitals, CMS rescinded the application of the adjustment to the hospital-specific rates retroactive to October 1, 2007 in a final rule that appeared in the *Federal Register* on November 27, 2007 (72 FR 66886). That final rule noted that CMS still believed it would be appropriate to apply the documentation and coding adjustment to the hospital-specific rates, but upon further review it had decided that application of the adjustment to the hospital-specific rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting "the standardized amount" and does not mention adjusting the hospital-specific rates.

CMS now believes that it has the authority to apply the documentation and coding adjustment to the hospital-specific rates using the special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment authority authorizes "… such other exceptions and adjustments to [IPPS] payment amounts…as the Secretary deems appropriate." CMS will examine the FY 2008 claims data for hospitals paid based on the hospital-specific rate for evidence of significant increases in case-mix for patients treated in these hospitals. If significant increases are found, CMS will consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates using the above authority. Because the documentation and coding adjustments are cumulative, if CMS were to propose to apply the adjustment to the FY 2010 hospital-specific rates, it may involve applying the FY 2008 and FY 2009 documentation and coding adjustments (-1.5 percent combined) plus the FY 2010 documentation and coding adjustment (-1.8 percent), discussed in the FY 2008 IPPS final rule to the FY 2010 hospital-specific rates.

CMS also seeks comment about whether to apply the coding adjustment to the 25 percent Puerto Rico-specific portion of the PPS payment for hospitals in Puerto Rico. In calculating the FY 2008 payment rates, CMS erroneously applied the -0.6 percent documentation and coding adjustment to the Puerto Rico-specific standardized amount for FY 2008, relying on its authority under section 1886(d)(3)(A)(vi) of the Act. CMS currently is in the process of developing a Federal Register notice to correct that error in the Puerto Rico-specific standardized amount for FY 2008 retroactive to October 1, 2007. Similar to the question of applying the adjustment to the hospital-specific rate, CMS believes it could apply the adjustment to the Puerto Rico-specific standardized amount using its special exception authority. It will evaluate FY 2008 claims data and consider application of the adjustment to the Puerto Rico standardized amount in FY 2010.

C. Refinement of the MS-DRG Relative Weight Calculation

In the FY 2007 final rule, CMS changed the basis for calculating the DRG relative weights from billed charges to hospital costs, where costs are determined by calculating cost-to-charge ratios (CCRs) from hospital cost reports and using the CCRs to convert billed charges to costs. The FY 2007 and FY 2008 final IPPS rules describe the details of the cost-based weight calculation methodology. As specified in the FY 2007 final rule, the move to cost-based relative weights occurred over a 3-year transition period, making FY 2009 the first year in which the weights will be based fully on cost data. The FY 2009 proposed rule confirms the completion of this transition.

In the FY 2007 and FY 2008 final rules, CMS decided not to implement either hospital-specific relative value (HSRV) MS-DRG weights or an adjustment to correct for charge compression. HSRV was one of the original MedPAC recommendations made in its March 2005 report on specialty hospitals and the FY 2007 proposed rule included it as part of the switch to cost-based weights. After significant opposition to HSRV in public comments, however, CMS chose not to adopt the methodology and to commission further analysis of the methodology by RAND. Similarly, CMS acknowledged the issue of charge compression but decided not to implement a regression-based adjustment to the supply center CCR as had been suggested by many commenters, including the Medicare Payment Advisory Commission (MedPAC). Such a change also was recommended in research conducted by RTI under a contract with CMS. In the FY 2008 final IPPS rule, and also the CY 2008 final hospital outpatient PPS (OPPS) rule in the case of charge compression, CMS announced that RAND and RTI were conducting additional analyses of these methodological issues. The FY 2009 proposed rule indicates that CMS received their reports late in its preparation of the regulation leaving insufficient time to include specific proposals in the rule. CMS says that both reports will be made available on the CMS website in the near future and it invites public comments on them and on its decision “not to adopt regression-based CCRs or an HSRV methodology at this time or in the future.”

RTI's initial report in March 2007 included short, medium and long-term recommendations to improve the accuracy of cost report data used for calculation of the relative weights. Its short-term recommendations included expanding the distinct hospital CCRs to 19 by disaggregating the "Emergency Room" and "Blood and Blood Products" from the Other Services cost center and by estimating regression-based CCRs to disaggregate Medical Supplies, Drugs, and Radiology cost centers. For the medium-term, RTI recommended expanding the MedPAR file to include separate fields to disaggregate several existing charge departments. In addition, RTI recommended improving hospital cost reporting instructions so that hospitals can properly report costs in the appropriate cost centers. RTI's long-term recommendations included adding new cost centers to the Medicare cost report, such as adding a "Devices, Implants and Prosthetics" line under "Medical Supplies Charged to Patients" and a "CT Scanning and MRI" subscripted line under "Radiology-Diagnostics".

In response to these recommendations, CMS:

- expanded the number of distinct hospital department CCRs from 13 to 15 by disaggregating "Emergency Room" and "Blood and Blood Products" from the Other Services cost center (note that these lines already existed on the hospital cost report;
- moved the costs for cases involving electroencephalography (EEG) from the Cardiology cost center to the Laboratory cost center group which corresponds with the EEG MedPAR claims categorized under the Laboratory charges; this change improves consistency between costs and their corresponding charges in the MedPAR file; and
- agreed with RTI's recommendations to revise the Medicare cost report and the MedPAR file as a long-term solution for charge compression. CMS stated that it would consider additional lines to the cost report and additional revenue codes for the MedPAR file in developing proposals for FY 2009.

In the FY 2008 final rule, CMS did not adopt RTI's short-term recommendation to create four additional CCRs using a regression-based methodology. The preamble of the FY 2009 proposed rule reiterates the issues a year ago: 1) how would the short-term adjustments interact with the proposed MS-DRGs (the proposed severity-adjusted DRGs were not available for the initial RTI analysis; 2) how would the adjustments change if they were based on both inpatient and outpatient charges (the RTI analysis had considered only inpatient DRGs); and 3) how would the adjustments interact with the HSRV methodology which remains under consideration for FY 2009. The recently completed and soon-to-be-posted RTI and RAND reports were designed to address these issues.

In the FY 2008 rulemaking process, some public comments expressed concern about the accuracy of using regression-based CCR estimates to determine the relative

weights rather than the data actually reported on the cost report. They noted that regression-based CCRs would not fix the underlying mismatch of hospital reporting of costs and charges. Instead, the commenters suggested that the impact of charge compression might be mitigated through an educational initiative that would encourage hospitals to improve their cost reporting. CMS reports that hospital associations have launched an educational campaign to encourage consistent reporting, which would result in consistent groupings of the cost centers used to establish the cost-based relative weights. In response to the educational initiative:

- On February 29, 2008, CMS issued Transmittal 321, Change Request 5928, to inform the fiscal intermediaries/Medicare Administrative Contractors (MACs) of the hospital associations' initiative to encourage hospitals to modify their cost reporting practices with respect to costs and charges in a manner that is consistent with how charges are grouped in the MedPAR file.
- In responding to comments in the CY 2008 OPPS/Ambulatory Surgery Center (ASC) final rule with comment period and repeated in the FY 2009 IPPS proposed rule, CMS emphasized that it "fully support[s]" the educational initiatives of the industry and that it would "examine whether the educational activities being undertaken by the hospital community to improve cost reporting accuracy under the IPPS would help to mitigate charge compression under the OPPS, either as an adjunct to the application of regression-based CCRs or in lieu of such an adjustment" (72 FR 66601).

D. Proposed Changes to the Cost Report

As a long-term solution to the problem of charge compression, the FY 2009 proposed rule includes a modification of the cost report to have one cost center for Medical Supplies Charged to Patients and one cost center for Implantable Devices Charged to Patients. CMS proposes to instruct hospitals to report only devices that meet the four criteria listed below in the cost center for Implantable Devices Charged to Patients. All other devices and non-chargeable supplies would be reported in the Medical Supplies cost center. This change would allow for two distinct CCRs, one for medical supplies and one for implantable devices and durable medical equipment (DME) rented and DME sold. The four criteria proposed for implantable devices are:

- The device has satisfied the Federal Drug Administration (FDA) regulatory approval.
- The device is "reasonable and necessary" for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part.
- The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, is surgically implanted or inserted through a natural or surgically created orifice or surgical incision in the body, and remains in the patient when the patient is discharged from the hospital.

- The device is not any of the following:
  - Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).
  - A material or supply furnished incident to a service (for example, a surgical staple, a suture, customized surgical kit, or clip, other than a radiological site marker).
  - Material that may be used to replace human skin (for example, a biological or synthetic material).
  - A medical device that is used during a procedure or service and does not remain in the patient when the patient is released from the hospital.

CMS believes that these criteria would capture most costly implantable devices (for example, implantable cardioverter defibrillators (ICDs), pacemakers, and cochlear implants) for which charge compression is a significant concern, but it invites public comment on the criteria. The agency also seeks comments on how surgical kits which combine a high-cost implantable device with other lower cost supplies (some of which may not be an integral or necessary part of the implantation procedure) should be handled. For example, how should component pricing be identified for individual items in surgical kits to ensure that charges for the high-cost device and the lower cost medical supplies are allocated to the appropriate cost center? Finally, CMS identifies two options for defining the new implantable device cost center and seeks comments on these alternatives as well as others which commenters might suggest. The two alternatives are:

- Alternative 1: Distinguish between high-cost and low-cost items based on a cost threshold. Under this methodology, CMS also would have one cost center for Medical Supplies and one cost center for Devices, but it would instruct hospitals to report items that are not movable equipment or a capital expense but are above a certain cost threshold in the cost center for Devices. Items costing below that threshold would be reported in the cost center for Medical Supplies.
- Alternative 2: Divide the Medical Supplies cost center based on markup policies by placing items with lower than average markups in a separate cost center. This approach would center on documentation requirements for differential charging practices that would lead hospitals to distinguish between the reporting of supplies and devices on different cost report lines. If requested by the fiscal intermediaries/MACs at audit, hospitals could be required to submit documentation of their markup policies to justify the way they have reported relatively inexpensive supplies on one line and more expensive devices on the other line.

The cost report changes are part of a CMS initiative to update and revise the hospital cost report to eliminate outdated requirements in conjunction with the Paperwork Reduction Act. The proposed rule states that CMS will propose the actual changes

to the cost reporting form, the attending cost reporting software, and the cost report instructions in Chapter 36 of the Medicare Provider Reimbursement Manual (PRM), Part II "after publication of this IPPS proposed rule." If CMS adopts the proposal to create one cost center for Medical Supplies Charged to Patients and one cost center for Implantable Devices Charged to Patients in the FY 2009 IPPS final rule, the cost report forms and instructions would reflect those changes. CMS expects the revised cost report would be available for hospitals to use when submitting cost reports during FY 2009 (that is, for cost reporting periods beginning on or after October 1, 2008). Because there is approximately a 3-year lag between the availability of cost report data for IPPS and OPPS rate-setting purposes and a given fiscal year, use of the two distinct CCRs, one for medical supplies and one for devices, would first be available for calculating the FY 2012 IPPS relative weights and the CY 2012 OPPS relative weights.

MedPAR Revenue Codes: In its March 2007 report, RTI found inconsistent reporting between the cost reports and the claims data for charges in several ancillary departments (Medical Supplies, Operating Room, Cardiology, and Radiology). For example, the data suggested that some hospitals often include costs and charges for devices and other medical supplies within the Medicare cost report cost centers for Operating Room, Radiology, or Cardiology, while other hospitals include them in the Medical Supplies Charged to Patients cost center. The proposed rule notes that the educational initiative undertaken by the national hospital associations is encouraging hospitals to consistently report costs and charges for devices and other medical supplies only in the Medical Supplies Charged to Patients cost center, but adds that equal attention must be paid to the way in which charges are grouped by hospitals in the MedPAR file.

The proposed rule recommends that certain revenue codes be used for items reported in the proposed Medical Supplies Charged to Patients cost center and the proposed Implantable Devices Charged to Patients cost center, respectively. In general, if an item is reported as an implantable device on the cost report, the associated charges should be recorded in the MedPAR file with either revenue codes 0275 (Pacemaker), 0276 (Intraocular Lens), or 0278 (Other Implants). Likewise, items reported as Medical Supplies should receive an appropriate revenue code indicative of supplies. CMS acknowledges that additional instructions relating to the appropriate use of these revenue codes may need to be issued and that CMS or the hospital associations may need to request new revenue codes from the National Uniform Billing Committee (NUBC). CMS is soliciting comments on how the existing revenue codes or additional revenue codes could best be used in conjunction with the revised cost centers on the cost report.

E. Preventable Hospital-Acquired Conditions (HACs), Including Infections

1. Background

Medicare's IPPS encourages hospitals to treat patients efficiently. However, complications, such as infections, acquired in the hospital can trigger higher payments in two ways. First, the treatment of complications can increase the cost of hospital stays enough to generate outlier payments. Second, if a condition acquired during the beneficiary's hospital stay is one of the conditions on the complications and comorbidity (CC) list, the result may be a higher payment to the hospital under a CC DRG.

Section 5001(c) of Pub. L. 109-171 (The Deficit Reduction Act of 2005) required the Secretary to select, by October 1, 2007, at least two conditions that are (1) high cost or high volume or both, (2) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence based guidelines. Beginning October 1, 2007, CMS required hospitals to begin submitting information on Medicare claims specifying whether diagnoses were present on admission (POA). For discharges occurring on or after October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to a higher paying MS-DRG if a selected HAC was not present on admission. That is, the case will be paid as though the secondary diagnosis was not present.

CMS evaluates candidate conditions against the following criteria:

- Coding: Does the condition have a unique ICD-9-CM code that clearly describes the condition?
- Burden (High Cost/High Volume): Is the condition high cost or high volume, or both?
- Prevention guidelines: Are there evidence-based guidelines available for hospitals to follow to prevent the condition from occurring?
- Complication or comorbidity: Is the condition a major CC (MCC) or a CC that would result in assignment to a higher paying DRG?
- Additional Considerations: Are there any potential administrative difficulties that CMS would face if the condition were selected?

2. Current Preventable HACs

In the FY 2008 IPPS final rule, CMS selected the following eight conditions to which the HAC provision will initially apply:

- foreign object retained after surgery;
- air embolism;
- blood incompatibility;
- stage III & IV pressure ulcers;
- falls and trauma
- catheter-associated urinary tract infection;

- vascular catheter-associated infection; and,
- surgical site infection (limited to mediastinitis after coronary artery bypass graft).

3. Proposed Refinements of Current Preventable HACs

For FY 2009, CMS proposes two refinements of the previously selected HACs:

a. Foreign object retained after surgery: CMS proposes to make ICD-9-CM diagnosis code 998.7 (Acute reaction to foreign substance accidentally left during a procedure) subject to this HAC payment provision.
b. Pressure ulcers: The following new ICD-9-CM diagnosis codes have been established to capture the stage of pressure ulcers:
    - 707.20 (Pressure ulcer, unspecified stage)
    - 707.21 (Pressure ulcer stage I)
    - 707.22 (Pressure ulcer stage II)
    - 707.23 (Pressure ulcer stage III)
    - 707.24 (Pressure ulcer stage IV)

CMS proposes to classify ICD-9-CM codes 707.23 and 707.24 as MCCs and codes 707.20, 707.21, and 707.22 as non-CCs. CMS also proposes to remove the CC/MCC classifications from the current pressure ulcer codes that show the site of the ulcer (ICD-9-CM codes 707.00 through 707.09).

4. Proposed Preventable HACs for FY 2009

For FY 2009, CMS seeks comment on the following 9 HAC candidates, taking into account the CMS criteria listed above. For each of the candidates, the proposed rule includes Medicare data, specific ICD-9-CM codes, links to selected evidence-based guidelines and specific issues for which CMS particularly seeks comments.

a. Surgical Site Infections Following Elective Surgeries: CMS is considering adding the following surgical procedures to the surgical site infection HAC: 1) total knee replacement (81.54); 2) laparoscopic gastric bypass (44.38); 3) laparoscopic gastroenterostomy (44.39); and, 4) ligation and stripping of varicose veins (38.50 through 38.53, 38.55, 38.57, and 38.59).
b. Legionnaires' Disease
c. Glycemic Control: CMS is considering whether the following forms of extreme glucose derangement should be subject to the HAC payment provision:
    - Diabetic Ketoacidosis: ICD-9-CM codes 250.10 – 250.13 (CC)
    - Nonketotic Hyperosmolar Coma: ICD-9-CM code 251.0 (CC)
    - Diabetic Coma: ICD-9-CM codes 250.30 - 250.33 (CC)
    - Hypoglycemic Coma: ICD-9-CM codes 250.30 – 251.0 (CC)
d. Iatrogenic Pneumothorax
e. Delirium
f. Ventilator-Associated Pneumonia (VAP): The lack of a specific code was one of the barriers to including VAP as an HAC in the FY 2008 IPPS final

rule. A new ICD-9-CM code (997.31) has now been created to identify VAP.

g. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)
h. Staphylococcus Aureus Septicemia
i. Clostridium Difficile-Associated Disease (CDAD)

The proposed rule includes a discussion of Methicillin-Resistant Staphylococcus Aureus (MRSA) but CMS does not propose MRSA as an HAC because MRSA as a bacterium does not meet two of the statutory criteria, codeable CC/MCC and reasonably preventable through evidence-based guidelines. However, CMS acknowledges the significant public health concerns that have been raised and expresses a commitment to reducing the spread of multi-drug resistant organisms, such as MRSA.

5. Present on Admission (POA) Indicator Reporting

Specific instructions on how to select the correct POA indicator for each diagnosis code are included in the ICD-9-CM Official Guidelines for Coding and Reporting, available at the Web site: http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/icdguide07.pdf . The definitions of the POA indicators and the CMS proposals are summarized in the table below.

POA Indicator	Definition	CMS Proposal
"Y"	condition was present on admission	Pay the CC/MCC MS-DRGs
"W"	provider has determined, based on data and clinical judgment that it is not possible to document when the onset of the condition occurred	Pay the CC/MCC MS-DRGs
"N"	condition was not present on admission	Do not pay the CC/MCC MS-DRGs
"U"	documentation is insufficient to determine whether condition was present at the time of admission	Do not pay the CC/MCC MS-DRGs. However, CMS seeks comments on possible exceptions, e.g., patient left against medical advice

6. Potential Enhancements of Preventable HAC Payment Policy

CMS seeks comments on potential enhancements of the preventable HAC payment policy. CMS makes no specific proposals and notes that some of the enhancements listed below may require new statutory authority.

- Apply risk adjustment to make the HAC payment provision more precise.

- Collect data on rates of HACs to obtain a more robust longitudinal measure of a hospital's incidence of these conditions.
- Use POA information in various ways to decrease the incidence of preventable HACs.
- Adopt ICD-10-PCS to facilitate more precise identification of HACs.
- Apply the principle behind the HAC payment provision (Medicare not paying more for preventable HACs) to Medicare payments in settings of care other than the IPPS.
- Use CMS' authority other than the HAC payment provision to address other events on the National Quality Forum's (NQF's) list of Serious Reportable Adverse Events.

F. Changes to Specific DRG Classifications

1. Pre-MDCs: Artificial Heart Devices

On February 1, 2008, CMS published a proposed coverage decision memorandum for artificial hearts which stated, in part, that while the evidence is inadequate to conclude that the use of an artificial heart is reasonable and necessary for Medicare beneficiaries, the evidence is promising for the uses of artificial heart devices. CMS supports additional research for these devices, and therefore proposed that the artificial heart will be covered by Medicare when performed under the auspices of a clinical study. Following consideration of the public comments received, CMS expects to make a final decision on or about May 1, 2008.

As a result of discussion and comment from September 2007 ICD-9-CM Coordination and Maintenance Committee meeting, the title of procedure code 37.52 for artificial hearts has been revised to read "Implantation of internal biventricular heart replacement system." In addition, the Committee created new code 37.55 (Removal of internal biventricular heart replacement system) to identify explantation of the artificial heart prior to heart transplantation. To make conforming changes to the IPPS system with regard to the proposed revision to the coverage decision for artificial hearts, CMS proposes the following:

- Remove procedure code 37.52 from MS-DRG 215 (Other Heart Assist System Implant) and assign it to MS-DRG 001 (Heart Transplant or Implant of Heart Assist System with Major Comorbidity or Complication (MCC)) and MS-DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC).
- Remove procedure code 37.52 from the Medicare Code Editior (MCE) "Non-Covered Procedure" edit and assign it to the "Limited Coverage" edit.
- Include in this proposed edit the requirement that ICD-9-CM diagnosis code V70.7 (Examination of participant in clinical trial) also be present on the claim.

2. MDC 1 (Diseases and Disorders of the Nervous System)

a. Transferred Stroke Patients Receiving Tissue Plasminogen Activator (tPA)

The American Society of Interventional and Therapeutic Neuroradiology (ASITN) informed CMS that in some instances, patients suffering an embolytic or thrombolytic stroke are evaluated and given tPA in a community hospital's emergency department, and then are transferred to a larger facility's stroke center that is able to provide the level of services required by the increased severity of these cases. The facility providing the administration of tPA in its emergency department does not realize increased reimbursement, as the patient is often transferred as soon a possible to a stroke center. The facility to which the patient is transferred does not realize increased reimbursement, as the tPA was not administered there. ASITN requested that CMS give permission to code the administration of tPA as if it had been given in the receiving facility. This would result in the receiving facility being paid the higher weighted MS-DRGs 061, 062, or 063 instead of MS-DRGs 064, 065, or 066.

Because CMS lacks the data to identify these patients, they are not proposing an MS-DRG modification for the stroke patients receiving tPA in one facility prior to being transferred to another facility. CMS advised the ASITN to present a request at the diagnostic portion of the ICD-9-CM Coordination and Maintenance Committee meeting on March 20, 2008, for a code that would recognize the fact that the patient had received a thrombolytic agent for treatment of the current stroke. If a diagnosis code is created by the National Centers for Health Statistics (NCHS) as a result of that meeting, it can be added to the list of codes published in the FY 2009 IPPS final rule that will go into effect on October 1, 2008. With such information appearing on subsequent claims, CMS will have the data needed to properly evaluate the request. Therefore, because CMS lacks the data to identify these patients, they are not proposing an MS-DRG modification for the stroke patients receiving tPA in one facility prior to being transferred to another facility.

b. Intractable Epilepsy with Video Electroencephalogram (vEEG)

CMS received a recommendation from an individual representing the National Association of Epilepsy Centers that a new MS-DRG be established for patients with intractable epilepsy who receive an electroencephalogram with video monitoring (vEEG) during their hospital stay. CMS performed an analysis of the FY 2007 MedPAR data and concluded that: 1) the data do not support the creation of a new subdivision for MS-DRG 101 for cases with intractable epilepsy and vEEG; and, 2) the data does not support moving the cases from MS-DRG 101 to MS-DRG 100. No changes are proposed.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Automatic Implantable Cardioverter-Defibrillators (AICD) Lead and Generator Procedures

After publication of the FY 2008 IPPS final rule, CMS received a recommendation from a manufacturer that MS-DRG 245 (AICD Lead and Generator Procedures) be subdivided to separate the implantation or replacement of the AICD leads from the implantation or replacement of the AICD pulse generators. CMS analyzed FY 2007 MedPAR data and found that the average charges for the implantation or replacement of the AICD pulse generators are significantly higher than for the implantation or replacement of the AICD leads. Therefore, CMS proposes the following:

- Create a new MS-DRG 265 titled "AICD Lead Procedures" that would include procedure codes that identify the AICD leads (codes 37.95, 37.97 and 00.52).
- Revise the title for MS-DRG 245 to "AICD Generator Procedures" and include procedure codes 37.96, 37.98, 00.54.

b. Left Atrial Appendage Device

ICD-9-CM code 37.90 (Insertion of left atrial appendage device) was created for use beginning October 1, 2004. This code was designated as a non-operating room (non-O.R.) procedure, and had an effect only on cases in MDC 5, CMS DRG 518 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or Acute Myocardial Infarction). With the adoption of MS-DRGs in FY 2008, CMS DRG 518 was divided into MS-DRGs 250 and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC, and without MCC, respectively).

CMS received a request from a manufacturer's representative to reassign code 37.90 to an MS-DRG that would adequately cover the costs associated with the complete procedure or the creation of a new MS-DRG that would reimburse hospitals adequately for the cost of the device.

CMS analyzed FY 2007 MedPAR data and concluded the data do not support either the creation of a unique MS-DRG or the assignment of procedure code 37.90 to another higher-weighted MS-DRG.

4. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Hip and Knee Replacements and Revisions

For FY 2009, CMS received a complex request from the American Association of Hip and Knee Surgeons (AAHKS), a specialty group within the American Academy of Orthopedic Surgeons (AAOS), concerning modifications of the lower joint procedure MS-DRGs. AAHKS recommendations included the following:

- Consolidate and reassign certain joint procedures that have a diagnosis of an infection or malignancy into MS-DRGs that are similar in terms of clinical characteristics and resource utilization.
- Reclassify certain specific joint procedures, which AAHKS refers to as "routine," out of their current MS-DRG assignments.

CMS notes that they made changes to the MS-DRGs in FY 2008 as a result of a request by the AAHKS to recognize two types of partial knee replacements as less complex procedures. CMS has not yet had the opportunity to review data under the new MS-DRGs. However, CMS analyzed the impact of the AAHKS recommendations using cases prior to the implementation of MS-DRGs and found that the data and clinical analysis do not support making these changes at this time. Therefore, CMS does not propose any revisions to the joint procedure MS-DRGs for FY 2009.

5. MDC 18 (Infections and Parasitic Diseases (Systemic or Unspecified Sites): Severe Sepsis

CMS received a request from a manufacturer to incorporate the term "severe sepsis" into the titles of three MS-DRGs with the most significant concentration of severe sepsis patients. The change is intended to assist in quality improvement efforts and to provide a better reflection on the types of patients included in these MS-DRGs. CMS agrees with the recommendation and proposes the following revisions of the current MS-DRG titles. New terminology is highlighted with underlining.

- MS-DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ Hours)
- MS-DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ Hours with MCC)
- MS-DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ Hours without MCC)

6. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): Traumatic Compartment Syndrome

In the FY 2008 IPPS final rule, CMS inadvertently omitted the addition of traumatic compartment syndrome codes 958.90 through 958.99 to the multiple trauma MS-DRGs. For FY 2009, CMS proposes the following:

- Add traumatic compartment syndrome codes 958.90 through 958.99 to MS-DRGs 963 (Other Multiple Significant Trauma with MCC) and MS-DRG 965 (Other Multiple Significant Trauma without CC/MCC) in MDC 24.
- Add codes 958.90 through 958.99 to the list of principal diagnosis of significant trauma.
- Add code 958.91 to the list of significant trauma of upper limb.
- Add code 958.92 to the list of significant trauma of lower limb.
- Add code 958.93 to the list of significant abdominal trauma.

7. Medicare Code Editor (MCE) Changes

The MCE is a software program that detects and reports errors in the coding of Medicare claims data. The MCE screens are designed to identify cases that require further review before classification into a DRG. For FY 2009, CMS proposes to make the following changes to the MCE edits.

a. List of Unacceptable Principal Diagnoses in MCE

NCHS has modified the Official Coding Guidelines for FY 2009 by making diagnosis code V62.84 (Suicidal ideation) acceptable as a principal diagnosis as well as an additional diagnosis. In order to conform to this change by NCHS, CMS proposes to remove code V62.84 from the MCE list of "Unacceptable Principal Diagnoses" for FY 2009.

b. Diagnoses Allowed for Males Only Edit

There are four diagnosis codes that were inadvertently left off of the MCE edit titled “Diagnoses Allowed for Males Only.” CMS proposes to add these codes to this MCE edit: 603.0 (Encysted hydrocele), 603.1 (Infected hydrocele), 603.8 (Other specified types of hydrocele), and 603.9 (Hydrocele, unspecified).

c. Limited Coverage Edit

As explained above in the summary of MS-DRG changes, CMS proposes to remove procedure code 37.52 (Implantation of internal biventricular heart replacement system) from the MCE "Non-Covered Procedure" edit and to assign it to the "Limited Coverage" edit. CMS proposes to include in this proposed edit the requirement that ICD-9-CM diagnosis code V70.7 (Examination of participant in clinical trial) also be present on the claim.

8. Surgical Hierarchies

The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource intensive, performs as a decision rule within the GROUPER under which cases are assigned to a single DRG when an inpatient stay entails multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource intensive surgical class. For FY 2009, CMS proposes a revision of the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) by placing MS-DRG 245 (AICD Generator Procedures) above proposed new MS-DRG 265 (AICD Lead Procedures).

9. CC Exclusion List Proposed for FY 2009

CMS created the CC Exclusions List in 1987 to: (1) preclude coding of CCs for closely related conditions; (2) preclude duplicative or inconsistent coding from being treated as CCs; and (3) ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

For FY 2009, CMS proposes to make limited revisions to the CC Exclusions List to take into account the changes that will be made in the ICD-9-CM diagnosis coding system effective October 1, 2008. Tables 6G and 6H, Additions to and Deletions from the CC Exclusion List, respectively, which will be effective for discharges occurring on or after October 1, 2008, are not published in the proposed rule because of the length of the two tables. Instead, CMS is making them available through the Internet on the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS. A complete updated MCC, CC, and Non-CC Exclusions List is also available through the Internet on the CMS Web site at: http:/www.cms.hhs.gov/AcuteInpatientPPS.

10. Review of Procedure Codes in Former CMS DRGs 468, 476, and 477

Each year, CMS reviews cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Non-extensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS-DRGs adopted for FY 2008, CMS DRG 468 was split three ways and became MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC). CMS DRG 476 became MS-DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC). CMS DRG 477 became MS-DRGs 987, 988, and 989 (Non-extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC). For FY 2009, CMS does not propose to change the procedures assigned to these DRGs.

CMS also conducts an annual review of procedures producing assignment to MS-DRGs 981 through 983 (formerly CMS DRG 468) or MS-DRGs 987 through 989 (formerly CMS DRG 477) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these DRGs into one of the surgical DRGs for the MDC into which the principal diagnosis falls. For FY 2009, CMS does not propose to remove any procedures from MS-DRGs 981 through 983 or MS-DRGs 987 through 989.

CMS also conducts an annual review of the list of ICD-9-CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS-DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly, CMS DRGs 468,

476, and 477, respectively), to ascertain whether any of those procedures should be reassigned from one of these three DRGs to another of the three DRGs based on average charges and the length of stay. For FY 2009, CMS does not propose to move any procedure codes among these DRGs.

Finally, CMS does not propose to add any diagnosis codes to MDCs for FY 2009.

11. Changes to the ICD-9-CM Coding System

The ICD-9-CM Coordination and Maintenance Committee presented proposals for coding changes for implementation in FY 2009 at a public meeting held on September 27-28, 2007 and finalized the coding changes after consideration of comments received at the meetings and in writing by December 3, 2007. Those coding changes are announced in Tables 6A through 6F in the Addendum to this proposed rule. The Committee held its 2008 meeting on March 19-20, 2008. Proposed new codes for which there was a consensus of public support and for which complete tabular and indexing changes can be made by May 2008 will be included in the October 1, 2008 update to ICD-9-CM. Code revisions that were discussed at the March 19-20, 2008 committee meeting but that could not be finalized in time to include them in the Addendum to this proposed rule are not included in Tables 6A through 6F. These additional codes will be included in Tables 6A through 6F of the final rule with comment period and be marked with an asterisk (*).

Copies of the minutes of the procedure codes discussions at the committee's September 27-28, 2007 meeting can be obtained from the CMS Web site at: http://cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp. The minutes of the diagnosis codes discussions at the September 27-28, 2007 meeting are found at: http://www.cdc.gov/nchs/icd9.htm. These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

G. Recalibration of MS-DRG Weights

The Secretary is required by statute to revise the DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. For the current year (FY 2008), 50 percent of the relative weight for an MS-DRG was based on the two-thirds cost-based weight/one-third charge-based weight calculated using FY 2006 MedPAR data grouped to the Version 24.0 (FY 2007) DRGs. The remaining 50 percent of the FY 2008 relative weight for an MS-DRG was based on the two-thirds cost-based weight/one-third charge-based weight calculated using FY 2006 MedPAR grouped to the Version 25.0 (FY 2008) MS-DRGs. In FY 2009, CMS proposes that the relative weights be based on 100 percent cost weights computed using the Version 26.0 (FY 2009) MS-DRGs.

In developing relative weights for the FY 2009 proposed rule, CMS used two data sources:

- FY 2007 MedPAR data for discharges occurring on October 1, 2006, through September 30, 2007, based on bills received by CMS through December 2007, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2007 MedPAR file used in calculating the relative weights includes data for approximately 11,433,806 Medicare discharges. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded. The data also exclude critical access hospitals (CAHs), including hospitals that subsequently became CAHs after the period from which the data were taken; and
- FY 2006 Medicare cost report data files from Hospital Cost Report Information System (HCRIS) (that is, cost reports beginning on or after October 1, 2005, and before October 1, 2006), which represent the most recent full set of cost report data available. CMS used the December 31, 2007 update of the HCRIS cost report files.

As in calculating the weights for FY 2008, charges were converted to costs using national average CCRs. The 15 national average CCRs used for FY 2009 proposed rule are:

Group	CCR
Routine Days	0.527
Intensive Days	0.476
Drugs	0.205
Supplies & Equipment	0.341
Therapy Services	0.419
Laboratory	0.166
Operating Room	0.293
Cardiology	0.186
Radiology	0.171
Emergency Room	0.291
Blood and Blood Products	0.449
Other Services	0.419
Labor & Delivery	0.482
Inhalation Therapy	0.198
Anesthesia	0.150

H. Proposed Medicare Severity Long-Term Care Diagnosis-Related Groups (LTC-DRGs)

Consistent with CMS's historical practice of having LTC-DRGs correspond to the DRGs applicable under the IPPS, CMS adopted the use of MS-LTC-DRGs, which

correspond to the MS-DRGs as adopted under the IPPS. Long-term care hospitals (LTCHs) do not typically treat the full range of diagnoses as do acute care hospitals. Thus, CMS uses low-volume quintiles in determining the DRG relative weights for DRGs with less than 25 LTCH cases (low-volume MS-LTC-DRGs). CMS also adjust for cases in which the stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay (short stay outliers).

CMS did not propose any methodological changes involving the determination of the hospital specific relative values; treatment of severity levels in developing the proposed relative weights; identification of and quintile assignment for proposed low volume MS-LTC-DRGs; and the determination of the proposed FY 2009 MS-LTC-DRG relative weights. The use of more current data, however, resulted in proposed changes to the above.

I. Proposed Add-On Payment for New Technologies

The new medical service or technology add-on payment policy provides additional payments for cases with high costs involving eligible new medical services or technologies. To qualify, services must be new, more costly than existing technology and represent a substantial clinical improvement. Table 10 in section XIX of the interim final rule with comment period published in the *Federal Register* on November 27, 2007, contained the final thresholds that CMS is using to evaluate applications for new technology add-on payments for FY 2009 (72 FR 66888 through 66892). An applicant must demonstrate that the cost threshold is met using information from inpatient hospital claims.

Proposed regulatory change: CMS accepts applications for add-on payments for new medical services and technologies on an annual basis by a specified deadline (for example, applications for FY 2009 were due in November 2007). As is the case for three of the four applicants for FY 2009 add-on payments, applications often must be submitted before final FDA approval. In the past, CMS has advised applicants that their medical service or technology must receive FDA approval early enough in the IPPS rulemaking cycle to allow CMS enough time to fully evaluate the application prior to the publication of the IPPS final rule. Also, CMS has indicated in prior final rules (69 FR 49018-49019 and 70 FR 47344) that its practice is to analyze the new medical service or technology add-on payment criteria in the following sequence: newness, cost threshold, and finally substantial clinical improvement.

To more clearly define the application process parameters, CMS proposes to amend the regulations at §412.87 as follows:

a) add a new paragraph (c) to codify its current policy and specify that it will consider whether a new medical service or technology meets the eligibility criteria in §412.87(b) and announce the results in the *Federal Register* as part of the annual updates and changes to the IPPS;

b) remove the second sentence of (b)(1) that specifies that CMS will determine whether a new medical service or technology meets the substantial clinical improvement criteria and announce the results of its determination in the *Federal Register* as part of the annual updates and changes to the IPPS;
c) include in the new paragraph (c) of §412.87 a deadline of July 1 of each year as the date by which IPPS new medical service or technology add-on payment applications must receive FDA approval.

According to the proposed rule, these changes codify the current practice of fully evaluating new medical service or technology add-on payment applications prior to publication of the final rule in order to maintain predictability within the IPPS for the upcoming fiscal year. The proposed July 1 deadline provides CMS with sufficient time to fully consider all of the new medical service or technology add-on payment criteria for each application. CMS states that applications that have not received FDA approval by July 1 would not be considered in the final rule, even if they were summarized in the corresponding IPPS proposed rule.

FY 2009 Status of Technologies Approved for FY 2008 Add-On Payments

In the FY 2008 final rule, CMS did not approve any applications for add-on payments in FY 2008.

FY 2009 Applications for New Technology Add-On Payments

CMS received four applications for new technology add-on payments for FY 2009, as follows:

a. CardioWest™ Temporary Total Artificial Heart System (CardioWest™ TAH-t)

SynCardia Systems, Inc. submitted an application for approval of the CardioWest™ temporary Total Artificial Heart system (TAH-t) for new technology add-on payments for FY 2009. The TAH-t is a technology that is used as a bridge to heart transplant device for heart transplant-eligible patients with end-stage biventricular failure. The TAH-t pumps up to 9.5 liters of blood per minute. This high level of perfusion helps improve hemodynamic function in patients, thus making them better heart transplant candidates.

The TAH-t was approved by the FDA on October 15, 2004, for use as a bridge to transplant device in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The TAH-t is intended to be used in hospital inpatients. Some of the FDA's post-approval requirements include that the manufacturer agree to provide a post-approval study demonstrating that the success of the device at one center can be reproduced at other centers. The study was to include at least 50 patients who will be followed up to 1 year, including (but not limited to) the following endpoints; survival to transplant, adverse events, and device malfunction.

Medicare currently does not cover artificial heart devices, including the TAH-t. However, on February 01, 2008, CMS proposed to reverse a national non-coverage determination that would extend coverage to this technology within the confines of an FDA-approved clinical study. (To view the proposed National Coverage Determination (NCD), the proposed rule refers readers to the CMS Web site at http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=211&.) Should this proposed coverage decision be finalized, it would become effective on May 01, 2008.

Because the TAH-t has not been covered under the Medicare program (and, therefore, no Medicare payment has been made for this technology), CMS assumes that none of the costs associated with the technology would be reflected in the Medicare claims data used to recalibrate the MS-DRG weights. Thus, despite the device's FDA approval date, the proposed rule concludes that it appears to be "eligible to be considered 'new' for purposes of the new technology add-on payment if and when the proposal to reverse the national non-coverage determination concerning this technology is finalized."

The proposed rule invites comments on whether TAH-t meets the cost criterion, but also states that the average standardized charges per case for patients eligible for the TAH-t would appear to exceed the relevant thresholds. Finally, the proposed rule seeks comments regarding whether the TAH-t represents a substantial clinical improvement. The manufacturer states that the TAH-t is the only mechanical circulatory support device intended as a bridge-to-transplant for patients with irreversible biventricular failure. It also asserts that the TAH-t improves clinical outcomes because it has been shown to reduce mortality in patients who are otherwise in end-stage heart failure. In addition, the manufacturer claims that the TAH-t provides greater hemodynamic stability and end-organ perfusion, thus making patients who receive it better candidates for eventual heart transplant.

None of the other three technologies for which CMS received applications for add-on payments had received FDA approval at the time the proposed rule was prepared. Consequently, the proposed rule describes the applicants' claims that the technologies satisfy the three eligibility criteria. CMS, however, did not complete its own evaluation pending FDA approval.

The other three technologies seeking add-on payments in FY 2009 are:

b. Emphasys Medical Zephyr® Endobronchial Valve (Zephyr® EBV)

Emphasys Medical submitted an application for the Emphasys Medical Zephyr® Endobronchial Valve (Zephyr® EBV). The Zephyr® EBV is intended to treat patients with emphysema by reducing volume in the diseased, hyperinflated portion of the emphysematous lung with fewer risks and complications than with more invasive surgical alternatives. Zephyr® EBV therapy involves placing small, one-way valves in the patients' airways to allow air to flow out of, but not into, the diseased portions of

the lung thus reducing the hyperinflation. A typical procedure involves placing three to four valves in the target lobe using a bronchoscope, and the procedure takes approximately 20 to 40 minutes to complete. The Zephyr® EBVs are designed to be relatively easy to place, and are intended to be removable so that, unlike more risky surgical alternatives such as Lung Volume Reduction Surgery (LVRS) or Lung Transplant, the procedure has the potential to be fully reversible. Currently, the Zephyr® EBV has yet to receive approval from the FDA, but the manufacturer indicated to CMS that it expects to receive its FDA approval in the second or third quarter of 2008.

While CMS recognizes that the Zephyr® EBV therapy is significantly less risky than LVRS and lung transplant, it expresses concern that the benefits as shown in the VENT pivotal trial may not outweigh the risks when compared with medical therapy alone. Further, CMS notes that, according to the applicant, the Zephyr® EBV is intended for use in many patients who are ineligible for LVRS and/or lung transplant (including those too sick to undergo more invasive surgery and those with lower lobe predominant disease distribution), but that certain patients (that is, those with upper lobe predominant disease distribution) could be eligible for either surgery or the Zephyr® EBV. CMS welcomes comments from the public on both the patient population who would be eligible for the technology, and whether the Zephyr® EBV represents a substantial clinical improvement in the treatment of patients with emphysema.

c. Oxiplex®

FzioMed, Inc. submitted an application for Oxiplex®, an absorbable, viscoelastic gel made of carboxymethylcellulose (CMC) and polyethylene oxide (PEO) that is intended to be surgically implanted during a posterior discectomy, laminotomy, or laminectomy. The manufacturer asserts that the gel reduces the potential for inflammatory mediators that injure, tether, or antagonize the nerve root in the epidural space by creating an acquiescent, semi-permeable environment to protect against localized debris. These proinflammatory mediators (phospholipase A and nitric oxide), induced or extruded by intervertebral discs, may be responsible for increased pain during these procedures. The manufacturer also asserts that Oxiplex® is a unique material in that it coats tissue, such as the nerve root in the epidural space, to protect the nerve root from the effects of inflammatory mediators originating from either the nucleus pulposus, from blood derived inflammatory cells, or cytokines during the healing process. Oxiplex® is expecting to receive premarket approval from the FDA by June 2008.

CMS is concerned that Oxiplex® may be substantially similar to adhesion barriers that have been on the market for several years and also notes that Oxiplex® has been marketed as an adhesion barrier in other countries outside of the United States. The manufacturer maintains that Oxiplex® is different from adhesion barriers in several ways, including chemical composition, method of action, surgical application (that is, it is applied liberally to the nerve root and surrounding neural tissues as

opposed to minimally only to nerve elements), and tissue response (non-inflammatory as opposed to inflammatory). CMS invites comments from the public on this issue.

The manufacturer claims that Oxiplex® gel creates a protective environment around the neural tissue that limits nerve root exposure to post-surgical irritants and damage and thus reduces adverse outcomes associated with Failed Back Surgery Syndrome (FBSS) following surgery." The manufacturer also claims that the Oxiplex® gel reduces leg and back pain after discetomy, laminectomy, and laminotomy. The manufacturer also asserts that the use of Oxiplex® is consistent with fewer revision surgeries. (During the FDA Investigational Device Exemption (IDE) trial, one Oxiplex® patient required revision surgery compared to six control patients.) CMS states, however, that there may be insufficient evidence to support the manufacturer's claims that Oxiplex® reduces pain associated with spinal surgery. In addition, CMS did not find evidence to support the manufacturer's claims regarding mode of action, degree of dural healing, degree of wound healing, and local tissue response such as might be shown in animal studies. CMS invites comments regarding whether Oxiplex® represents a substantial clinical improvement. It also seeks comments on whether the cost threshold is satisfied (the manufacturer's claim in this regard is described in the proposed rule).

d. TherOx Downstream® System

TherOx, Inc. submitted an application for the TherOx Downstream® System (Downstream® System), which uses SuperSaturatedOxygen Therapy (SSO2). The therapy is designed to limit myocardial necrosis by minimizing microvascular damage in acute myocardial infarction (AMI) patients following intervention with Percutaneous Transluminal Coronary Angioplasty (PTCA), and coronary stent placement by perfusing the affected myocardium with blood that has been supersaturated with oxygen. SSO2 therapy refers to the delivery of superoxygenated arterial blood directly to areas of myocardial tissue that have been reperfused using PTCA and stent placement, but which may still be at risk. The desired effect of SSO2 therapy is to reduce infarct size and thus preserve heart muscle and function. The DownStream® System is the console portion of a disposable cartridge-based system that withdraws a small amount of the patient's arterial blood, mixes it with a small amount of saline, and supersaturates it with oxygen to create highly oxygen-enriched blood. The superoxygenated blood is delivered directly to the infarct-related artery via the TherOx infusion catheter. SSO2 therapy is a catheter laboratory-based procedure. Additional time in the catheter lab area is an average of 100 minutes. The manufacturer claims that the SSO2 therapy duration lasts 90 minutes and requires an additional 10 minutes post-procedure preparation for transfer time. The TherOx Downstream® System is currently not FDA approved; however, the manufacturer states that it expects to receive FDA approval in the second quarter of 2008.

The applicant asserts that the Downstream® System is a substantial clinical improvement because it reduces infarct size in acute AMI where PTCA and stent placement have also been performed. Data was submitted from the Acute Myocardial Infarction Hyperbaric Oxygen Treatment (AMIHOT) II trial which was presented at the October 2007 Transcatheter Cardiovascular Therapeutics conference, but has not been published in peer reviewed literature, that showed an average of 6.5 percent reduction in infarct size as measured with Tc-99m Sestamibi imaging in patients who received supersaturated oxygen therapy. CMS notes, however, that those patients also showed a significantly higher incidence of bleeding complications. CMS recognizes that a reduction of infarct size may correlate with improved clinical outcomes, but it questions whether the degree of infarct size reduction found in the trial represents a substantial clinical improvement, particularly in light of the apparent increase in bleeding complications. CMS invites comments from the public on this matter and also on whether the cost criterion is satisfied (the manufacturer's claim in this regard is described in the proposed rule).

IV. Outliers

Using the same methodology as was used to calculate the outlier threshold in FY 2008, CMS proposes to establish an outlier fixed-loss cost threshold for FY 2009 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $21,025. With this threshold, CMS projects that outlier payments will equal 5.1 percent of total IPPS payments. The outlier fixed-loss cost threshold for FY 2008 is $22,635.

For purposes of estimating the proposed outlier threshold for FY 2009, CMS assumed 3.0 percent case-mix growth in FY 2009 compared with its FY 2007 claims data (that is, a 1.2 percent increase in FY 2008 and an additional 1.8 percent increase in FY 2009). The 3 percent case-mix growth was projected by the Office of the Actuary as the amount case-mix is expected to increase in response to adoption of the MS-DRGs as a result of improvements in documentation and coding that do not reflect real changes in patient severity of illness. The proposed rule notes that if CMS did not take the 3 percent projected case-mix growth into account, its estimate of total payments would be too low, and as a result, its estimate of the outlier threshold would be too high. While it assumes 3 percent case-mix growth for all hospitals in its outlier threshold calculations, the FY 2009 national standardized amounts used to calculate the outlier threshold reflect the statutorily mandated documentation and coding adjustment of -0.9 percent for FY 2009, on top of the -0.6 percent adjustment for FY 2008.

V. Proposed Changes to the Hospital Area Wage Index (AWI)

A. Requirements of Section 106 of the MIEA-TRHCA (Pub. L. 109-432)

Section 106(b)(2) of the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) directs the

Secretary of Health and Human Services ("Secretary") to include in the FY 2009 IPPS NPRM one or more proposals to revise the wage index adjustment. The Secretary was also instructed to consider MedPAC's recommendations on the Medicare wage index classification system in developing these proposals

1. **Wage Index Study Requirement**. The MIEA-TRHCA required MedPAC to submit to Congress no later than June 30, 2007 a report on the Medicare wage index. The law required the report to include any alternatives that MedPAC recommends to the method to wage index computation.

   In MedPAC's June 2007 Report to Congress[1] MedPAC made three broad recommendations:

   - Congress should repeal the existing hospital wage index statue, including reclassifications and exceptions, and give the Secretary the authority to establish a new wage index system;
   - The Secretary should establish a hospital compensation index that –
     i. Uses wage data from all employers and industry-specific occupational weights;
     ii. Is adjusted for geographic differences in the ratio of benefits to wages;
     iii. Is adjusted at the county level and smoothes large differences between counties; and
     iv. Is implemented so that large changes in wage index values are phased in over a transition period; and
   - The Secretary should use the hospital compensation index for the home health and skilled nursing facility prospective payment systems and evaluate its use in the other Medicare fee-for-service payment systems.

   In the FY 2009 IPPS NPRM, CMS said that it had retained Acumen, LLC to (1) conduct a detailed impact analysis of the MedPAC proposal and (2) assist CMS in developing a proposal (or proposals) that addresses the law's direction. CMS said it would present any analyses and proposals in the FY 2009 IPPS final rule or in a special *Federal Register* notice issued after the final rule is published.

2. **CMS Proposals in Response to Requirements of the MIEA-TRHCA.** As noted above, the MIEA-TRHCA requires the Secretary to consider MedPAC's recommendations on the Medicare wage index classification system. In the June 2007 Report to Congress, MedPAC said that more than one-third of hospitals received a higher wage index due to geographic reclassifications or other wage index exceptions. CMS noted that MedPAC had recommended eliminating the geographic reclassification and other wage index exception options. And CMS noted that the President's FY 2009 budget included a proposal to apply the geographic reclassification budget neutrality requirement at the state level than

[1] See MedPAC's web site at: http://www.medpac.gov/documents/jun07_EntireReport.pdf

the national level. Some, but not all, of these changes require statutory changes. Accordingly, CMS proposed the following changes.

a. Proposed Revision of the Reclassification Average Hourly Wage Comparison Criteria

Current regulations set the average hourly wage comparison criteria that an individual hospital must meet in order to be reclassified. An urban hospital, must demonstrate that its average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located and at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation. The wage comparisons for rural hospitals were reduced to 106 percent and 82 percent respectively to "compensate for the historic economic underperformance of rural hospitals.

CMS noted that it has not evaluated or recalibrated the average hourly wage criteria since they were established in FY 1993. After performing an updated analysis, CMS proposed to increase the criterion for the comparison of a hospital's average hourly wage to that of the area to which the hospital seeks reclassification to 88 percent for urban hospitals and 86 percent for rural hospitals for new reclassifications beginning with the FY 2010 wage index. The urban and rural criteria for the comparison of a hospital's average hourly wage to that of its geographic area would be unchanged.

Finally, CMS is proposing to adjust the criterion for both urban and rural group reclassifications to be the equal of the proposed 88 percent/108 percent urban hospital standard. CMS is proposing the 88 percent/108 percent standard "because this would ensure that the hospitals in the county group are at least as comparable to the proximate area as are individual hospitals within their own areas.

b. Within-State Budget Neutrality Adjustment for the Rural.

Current law established the rural floor by requiring that the wage index for hospitals in an urban area of a State cannot be less than the area wage index determined for the State's rural area. By regulation, CMS applies the related budget neutrality adjustment nationwide to the AWI of all rural hospitals and all other urban hospitals with an AWI above the respective State's rural AWI. Because CMS observed that a few States are benefiting at the expense of many, it proposes to revise existing regulation so as to apply this budget neutrality adjustment on a state-by-state basis, rather than nationally. The proposed policy change would be effective FY 2009. As noted by CMS, the proposed policy, if finalized, would provide that all hospitals within each state would, in effect, be responsible for funding the rural floor adjustment applicable within that specific state.

Appendix B from the NPRM lists the percentage of total payments each state either received or contributed to fund the current rural floor and imputed floor provisions with the national budget neutrality adjustment. According to this table, 48 states would benefit from the proposed change while 12 states would be adversely impacted.

c. Within-State Budget Neutrality Adjustment for Geographic Reclassification

Current statutory law provides a budget neutrality adjustment across all hospitals nationwide to ensure that the effects of geographic reclassification do not increase aggregate IPPS payments. CMS expects Congress will change the application of the budget neutrality adjustment from a nationwide basis to a state-by-state basis for all reclassifications and wage index exceptions. CMS is calling for comments regarding MedPAC's recommendations for reforming the wage index, the agency's plan for reviewing the wage index and the above regulatory proposals for modifying the current hospital wage index.

B. Core-Based Statistical Areas Used for the AWI

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. CMS defines hospital market areas based on the Core-Base Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB) and announced in December 2003.

The proposed rule would apply title changes to the CBSAs as announced by OMB on November 20, 2007. The revised titles include:

- Hammonton, New Jersey qualifies as a new principal city of the Atlantic City, New Jersey CBSA. The new title is Atlantic City-Hammonton, New Jersey CBSA;
- New Brunswick, New Jersey, located in the Edison, New Jersey Metropolitan Division, qualifies as a new principal city of the New York-Northern New Jersey-Long Island, New York, New Jersey, Pennsylvania CBSA. The new title for the Metropolitan Division is Edison-New Brunswick, New Jersey CBSA;
- Summerville, South Carolina qualifies as a new principal city of the Charleston-North Charleston, South Carolina CBSA. The new title is Charleston-North Charleston-Summerville, South Carolina;
- Winter Haven, Florida qualifies as a new principal city of the Lakeland, Florida CBSA. The new title is Lakeland-Winter Haven, Florida;
- Bradenton, Florida replaces Sarasota, Florida as the most populous principal city of the Sarasota-Bradenton-Venice, Florida CBSA. The new title is Bradenton-Sarasota-Venice, Florida. The new CBSA code is 14600;

- Frederick, Maryland replaces Gaithersburg, Maryland as the second most populous principal city in the Bethesda-Gaithersburg-Frederick, Maryland CBSA. The new title is Bethesda-Frederick-Gaithersburg, Maryland;
- North Myrtle Beach, South Carolina replaces Conway, South Carolina as the second most populous principal city of the Myrtle Beach-Conway-North Myrtle Beach, South Carolina CBSA. The new title is Myrtle Beach-North Myrtle Beach-Conway, South Carolina;
- Pasco, Washington replaces Richland, Washington as the second most populous principal city of the Kennewick-Richland-Pasco, Washington CBSA. The new title is Kennewick-Pasco-Richland, Washington.

The OMB bulletin is available at https://www.whitehouse.gov/OMB - go to "Bulletins" or "Statistical Programs and Standards." CMS will apply these changes to the IPPS beginning October 1, 2008.

C. Proposed Occupational Mix Adjustment to the Proposed FY 2009 Wage Index

Current law requires the collection of data every three years on the occupational mix of employees for each hospital. The purpose of the adjustment is to control for the effect of hospitals' employment choices on the wage index. CMS is proposing to use the entire 6-month 2006 Medicare Wage Index Occupational Mix Survey (2006 survey) to calculate the occupational mix adjustment for the FY 2009 wage index. The 2006 survey provided for the collection of hospital specific wage and hours data for the period January 1, 2006 through June 30, 2006.

The occupational mix adjustment would be applied to 100 percent of the FY 2009 wage index.

CMS said it still considering a penalty for hospitals that did not respond to the occupational mix survey. CMS said, however, that any hospital not participating in the occupational mix survey may be penalized beginning FY 2010.

D. Other proposed wage index policies for FY 2009

1. The proposed FY 2009 wage index would be updated using data from the FY 2005 Medicare Report

2. Medicare Geographic Classification Review Board (MGCRB) Reclassifications

The MGCRB has completed its FY 2009 reclassifications requests by approving 314 hospitals for wage index reclassifications for FY 2009. As reclassifications are effective for 3 years – there are a total of 813 hospitals approved for FY 2007, FY 2008 and FY 2009.

Applications for FY 2010 reclassifications are due to the MGCRB by September 2, 2008.

3. The Labor Related Share of the Proposed Wage Index to Continue at 69.731 percent

VI. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

A. Proposed Changes to the Post-Acute Transfer Policy

The purpose of the IPPS post-acute transfer payment policy is to avoid providing an incentive for a hospital to transfer patients to post-acute care providers, including rehabilitation, long-term care, psychiatric, cancer, children, home health or skilled nursing facilities. As regards home health facilities, an acute care hospital patient discharged to a home health agency would be considered transferred for postacute care if the patient received home health services within 3 days after the discharge date. Originally CMS adopted 10 DRGs that were subject to the transfer payment policy from FY 1999 through FY 2003. During FY 2008, 273 out of 745 MS-DRGs are subject to the post-acute care payment transfer policy or about 36 percent. CMS says that this proportion will be very similar in FY 2009.

CMS is proposing to revise the home health service threshold in order for the discharge to be subject to the post-acute care transfer policy. CMS proposes to expand the threshold from 3 days to 7 days based on further analysis of more current data.

B. Quality Measures for FY 2008

The proposed rule would significantly expand the quality measures that hospitals must report in order to receive a full annual update factor for FY 2010, rather than the market basket minus 2.0 update that applies to non-reporting hospitals under the IPPS. During rulemaking last year, CMS finalized a quality reporting measure set for hospitals to qualify for a full IPPS update factor for fiscal year 2009 that includes 30 measures. Of these 30 measures, 3 mortality measures are calculated by CMS from hospital claims data, and the other 27 require hospitals to submit data.

New measures proposed. In this rule, CMS is proposing that for the FY 2010 update factor, 43 new measures be added to the quality reporting measure set, and that one existing measure be retired, for a total of 72 measures to be included in the measure set. Hospitals would begin reporting on the new measures at varying points during 2009. CMS summarizes the new measures as follows:

- 1 Surgical Care Improvement Project (SCIP) measure proposed last year
- 4 nursing sensitive measures

- 3 readmission measures
- 6 venous thromboembolism measures
- 5 stroke measures
- 9 Agency for Healthcare Research and Quality (AHRQ) measures
- 15 cardiac surgery measures

A number of the proposed new measures have not been endorsed by the NQF. CMS indicates that they expect endorsement to have occurred prior to the issuance of the final inpatient rule, and at that time they will finalize the FY 2010 measure set contingent on the status of NQF endorsement. If some measures have not been endorsed in time, CMS will finalize them as part of the hospital outpatient/ambulatory surgery rule for CY 2009, if NQF endorsement occurs in the interim. This approach follows precedent: two measures proposed for FY 2009 were finalized as part of the CY 2008 outpatient rule. Moreover, the SCIP measure proposed for FY 2010 was originally proposed by CMS to be included in the quality reporting measure set for FY 2009, but the NQF endorsement did not occur until after the CY 2008 hospital outpatient payment rule was finalized, and as a result this measure was not included in the final inpatient quality reporting measure set for FY 2009.

CMS views the proposed readmission measures as hospital efficiency measures because high rates of readmission are linked to higher costs and lower quality of care. CMS seeks other ways in which to address efficiency, along with outcomes and patient experience in moving beyond process-of-care measures.

The following table lists the proposed measures for FY 2010, the proposed beginning reporting date, and whether NQF has endorsed the measure.

Quality Measures Proposed for the FY 2010 Update Under Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)	**Proposed Start Date for Hospital Reporting (discharges beginning)**	**NQF Endorsement**
Heart Attack (Acute Myocardial Infarction)		
● AMI-1 Aspirin at arrival *	In use	
● AMI-2 Aspirin prescribed at discharge *	In use	
● AMI-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction *	In use	
● AMI 6 Beta blocker at arrival *	In use	
● AMI-5 Beta blocker prescribed at discharge *	In use	
● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival**	In use	
● AMI-4 Adult smoking cessation advice/counseling**	In use	
● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)[a]	In use	
Heart Failure (HF)		
● HF-2 Left ventricular function assessment *	In use	
● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II	In use	

Quality Measures Proposed for the FY 2010 Update Under Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)	**Proposed Start Date for Hospital Reporting (discharges beginning)**	**NQF Endorsement**
Receptor Blocker (ARB) for left ventricular systolic dysfunction *		
● HF-1 Discharge instructions**	In use	
● HF-4 Adult smoking cessation advice/counseling**	In use	
Pneumonia (PN)		
● PN-2 Pneumococcal vaccination status *	In use	
● PN-3b Blood culture performed before first antibiotic received in hospital**	In use	
● PN-4 Adult smoking cessation advice/counseling**	In use	
● PN-6 Appropriate initial antibiotic selection**	In use	
● PN-7 Influenza vaccination status**	In use	
● PN-5c Timing of receipt of initial antibiotic following hospital arrival [a]	In use	
Surgical Care Improvement Project (SCIP) – [named SIP for discharges prior to July 2006]		
● SCIP-1 Prophylactic antibiotic received within 1 hour prior to surgical incision**	In use	
● SCIP-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time**	In use	
● SCIP-VTE-1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients***	In use	
● SCIP-VTE-2: VTE prophylaxis within 24 hours pre/post surgery***	In use	
● SCIP Infection 2: Prophylactic antibiotic selection for surgical patients***	In use	
● SCIP-Infection 4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose*****	In use	
● SCIP Infection 6: Surgery Patients with Appropriate Hair Removal*****	In use	
● SCIP Cardiovascular 2: Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker During the Perioperative Period******	1/1/09	
Mortality Measures (Medicare patients)		
● MORT-30-AMI Acute Myocardial Infarction 30-day mortality Medicare patients***	In use	
● MORT-30-HF Heart Failure 30-day mortality Medicare patients***	In use	
● MORT-30-PN Pneumonia 30-day mortality Medicare patients****	In use	
Patients' Experience of Care		
● HCAHPS patient survey***	In use	
Readmission Measures (Medicare patients)		
● Heart Attack (AMI) 30-Day Risk Standardized Readmission Measure (Medicare patients)******	Claims calculation	Pending
● Heart Failure (HF) 30-Day Risk Standardized Readmission Measure (Medicare patients)******	Claims calculation	Pending
● Pneumonia (PN) 30-Day Risk Standardized Readmission Measure (Medicare patients) ******	Claims calculation	Pending
Inpatient Stroke Care		
● STK-1 DVT Prophylaxis******	7/1/09	Pending
● STK-2 Discharged on Antithrombotic Therapy******	7/1/09	Pending
● STK-3 Patients with Atrial Fibrillation Receiving Anticoagulation Therapy******	7/1/09	Pending
● STK-5 Antithrombotic Medication By End of Hospital Day Two******	7/1/09	Pending
● STK-7 Dysphasia Screening******	7/1/09	Pending
Venous Thromboembolic Care		
● VTE-1: VTE Prophylaxis******	1/1/09	Pending

Quality Measures Proposed for the FY 2010 Update Under Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)	**Proposed Start Date for Hospital Reporting (discharges beginning)**	**NQF Endorsement**
● VTE-2: VTE Prophylaxis in the ICU******	1/1/09	Pending
● VTE-4: Patients with overlap in anticoagulation therapy******	1/1/09	Pending
● VTE-5/6: (as combined measure) patients with UFH dosages who have platelet count monitoring and adjustment of medication per protocol or nomagram******	1/1/09	Pending
● VTE-7: Discharge instructions to address: followup monitoring, compliance, dietary restrictions, and adverse drug reactions/interactions******	1/1/09	Pending
● VTE-8: Incidence of preventable VTE******	1/1/09	Pending
AHRQ Patient Safety Indicators		
● Death among surgical patients with treatable serious complications******	10/1/09[b]	Yes
● Iatrogenic pneumothorax, adult******	10/1/09[b]	Yes
● Postoperative wound dehiscence******	10/1/09[b]	Yes
● Accidental puncture or laceration******	10/1/09[b]	Yes
AH**RQ Inpatient Quality Indicators (IQI**)	10/1/09[b]	
● Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) ******	10/1/09[b]	Yes
● Hip fracture morality rate******	10/1/09[b]	Yes
AHRQ IQI Composite Measures	10/1/09[b]	
● Mortality for selected surgical procedures (composite) ******	10/1/09[b]	Yes
● Complication/patient safety for selected indicators (composite) ******	10/1/09[b]	Yes
● Mortality for selected medical conditions (composite) ******	10/1/09[b]	Yes
Nursing Sensitive Measures		
● Failure to Rescue******	4/1/09	Yes[c]
● Pressure Ulcer Prevalence and Incidence by Severity ******	4/1/09	Yes[c]
● Patient Falls Prevalence******	4/1/09	Yes[c]
● Patient Falls with Injury******	4/1/09	Yes[c]
Cardiac Surgery Measures		
● Participation in a Systematic Database for Cardiac Surgery ******	1/1/09[d]	Yes
● Pre-operative Beta Blockade******	1/1/09[d]	Yes
● Prolonged Intubation******	1/1/09[d]	Yes
● Deep Sternal Wound Infection Rate******	1/1/09[d]	Yes
● Stroke/CVA******	1/1/09[d]	Yes
● Postoperative Renal Insufficiency******	1/1/09[d]	Yes
● Surgical Reexploration******	1/1/09[d]	Yes
● Anti-platelet Medication at Discharge******	1/1/09[d]	Yes
● Beta Blockade Therapy at Discharge******	1/1/09[d]	Yes
● Anti-lipid Treatment at Discharge******	1/1/09[d]	Yes
● Risk-Adjusted Operative Mortality for CABG******	1/1/09[d]	Yes
● Risk-Adjusted Operative Mortality for Aortic Valve Replacement******	1/1/09[d]	Yes
● Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair******	1/1/09[d]	Yes
● Risk-Adjusted Mortality for Mitral Valve Replacement and CABG Surgery******	1/1/09[d]	Yes
● Risk-Adjusted Mortality for Aortic Valve Replacement and CABG Surgery ******	1/1/09[d]	Yes

* Measure included 10 measure starter set established in November 2003.
**Measure included in 21 measure expanded set effective for FY 2007 payments.
***Measure added in CY 2007 OPPS/ASC final rule with comment period effective for FY 2008 IPPS update factor.

****Measure added in FY 2008 IPPS final rule with comment period effective for FY 2009 update factor.
*****Measure added in CY 2008 OPPS/ASC final rule with comment period effective for FY 2009 update factor.
******Measure proposed in FY 2009 IPPS proposed rule for application to FY 2010 update factor.

[a] CMS proposes updates to these measures to follow revised NQF specifications.
[b] Data would be submitted quarterly to CMS by 4/1/10 beginning with 10/1/09 discharges.
[c] Measure endorsed by NQF, but CMS indicates that endorsement might change as the result of field testing to be completed late in 2008. Inclusion in the final rule will take account of possible changes in NQF endorsement.
[d] CMS would accept data from the Society of Thoracic Surgeons (STS) registry beginning on 7/1/09 on a quarterly basis for discharges occurring after 1/1/09. Other hospitals would report directly to CMS.

Retirement of measure on pneumonia oxygenation assessment. Retirement of a measure from the reporting requirements is proposed for the first time. CMS states that performance on the Pneumonia Oxygenation Assessment measure is near 100% for the "vast majority" of hospitals. Because there is no significant opportunity for improvement on this measure, CMS believes the burden on hospitals of abstracting and reporting the data outweighs the benefits from public reporting. CMS may seek to reintroduce the measure in the future if it determines that the quality of care has deteriorated.

More generally, CMS seeks comments on whether other measures should be retired, and on considerations regarding measure retirement. In particular, CMS seeks comments on whether it should retire a "topped out" measure even if the measure still reflects best practice, whether there are reasons to retire a measure other than high overall performance, and once a measure is retired, whether continued compliance should be monitored by resuming data collection after 1 or 2 years or another means. Commenters are referred to the discussion of inclusion and retirement of measures in the January 17, 2007 CMS Hospital Value-Based Purchasing (VBP) Issues Paper.

Change in reporting requirements for small number of cases. CMS is proposing to eliminate data reporting requirements for hospitals that treat a small number of patients covered by data submission requirements. Specifically, beginning January 1, 2009, hospitals that have five or fewer Medicare/nonMedicare heart attack discharges in a quarter would not be required to submit patient-level data for that quarter. The hospital would still have to submit aggregate heart attack population and sample size counts to CMS for that quarter as part of its RHQDAPU data submission. A similar quarterly exemption of five or fewer is proposed for heart failure, pneumonia, and SCIP. Again, quarterly counts of these cases would be required. For Hospital Consumer Assessment of Healthcare Providers and System (HCAHPS), hospitals with five or fewer patients in a month for whom the HCAHPS survey would be required would not have to submit surveys for those patients. A count of the total number of HCAHPS-eligibles for that month would be required as part of the quarterly data submission.

Updating of Existing Measures. Two existing measures have had specifications updated by the NQF, and CMS proposes to update the measures for FY 2010. NQF endorsement of the AMI measure regarding the timing of Percutaneous Coronary Intervention (PCI) was changed from intervention received within 120 minutes of hospital arrival to 90 minutes. In addition, the pneumonia measure pertaining to initial antibiotic treatment was changed from within 4 hours of hospital arrival to within 6 hours. Hospital data submission will remain unchanged, but beginning with discharges after January 1, 2009, CMS will calculate the measures using the updated timing intervals.

CMS proposes that in the future, it will act on updates to existing measures made by a consensus building entity like NQF through a subregulatory process. Notification will be made through the Qualitynet website and in the specifications manual where data collection and measure specification changes are needed.

Possible measures for 2011 and beyond. CMS identifies 59 additional measures or measure sets for possible inclusion in the measure set for FY 2011 or later and invites comments on these and any others that might be considered. Comments should address which measures should be included, any data collection and reporting challenges posed, and ways of reducing these challenges. The list includes measures pertaining to a range of areas such as complications of vascular surgery, healthcare associated infections, timeliness of emergency care, surgical care improvement, healthcare acquired conditions, hospital inpatient cancer care measures, "never events," and preventable hospital-acquired conditions. (See table below.) CMS notes its intention to develop measures for certain common and high-cost DRGs, naming chronic pulmonary obstructive disease, inpatient diabetes care, and chest pain.

Possible Measures and Measure Sets for the RHQDAPU Program for FY 2011 and Subsequent Years	
Topic	**Quality Measure**
Chronic Pulmonary Obstructive Disease Measures	
Complications of Vascular Surgery	
	● AAA stratified by open and endovascular methods ● Carotid Endarterectomy ● Lower extremity bypass
Inpatient Diabetes Care Measures	
Healthcare Associated Infection	
	● Central Line-Associated Blood Stream Infections ● Surgical Site Infections
Timeliness of Emergency Care Measures, including Timeliness	
	● Median Time from ED Arrival to ED Departure for Admitted ED Patients ● Median Time from ED Arrival to ED Departure for Discharged ED Patients ● Admit Decision Time to ED Departure Time for Admitted Patients
Surgical Care Improvement Project (SCIP) – named SIP for discharges prior to July 2006 (3Q06)	
	● SCIP Infection 8 - Short Half-life Prophylactic Administered Preoperatively Redosed Within 4 Hours After Preoperative Dose

Possible Measures and Measure Sets for the RHQDAPU Program for FY 2011 and Subsequent Years	
Topic	**Quality Measure**
	● SCIP Cardiovascular 3 - Surgery Patients on a Beta Blocker Prior to Arrival Receiving a Beta Blocker on Postoperative Days 1 and 2
Complication Measures (Medicare patients)	
Healthcare Acquired Conditions	
	● Serious reportable events in healthcare (never events)
	● Pressure ulcer prevalence and incidence by severity
	● Catheter-associated UTI
Hospital Inpatient Cancer Care Measures	
	● Patients with early stage breast cancer who have evaluation of the axilla
	● College of American Pathologists breast cancer protocol
	● Surgical resection includes at least 12 nodes
	● College of American Pathologists Colon and rectum protocol
	● Completeness of pathologic reporting
Serious Reportable Events in Healthcare ("Never Events")	
	● Surgery performed on the wrong body part
	● Surgery performed on the wrong patient
	● Wrong surgical procedure on a patient
	● Retention of a foreign object in a patient after surgery or other procedure
	● Intraoperative or immediately post-operative death in a normal health patient (defined as a Class 1 patient for purposes of the American Society of Anesthesiologists patient safety initiative)
	● Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
	● Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
	● Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
	● Patient death or serious disability associated with patient elopement (disappearance) for more than four hours
	● Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility
	● Patient death or serious disability associated with a medication error (e.g., error involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
	● Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
	● Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility
	● Stage 3 or 4 pressure ulcers acquired after admission to a health care facility
	● Patient death or serious disability due to spinal manipulative therapy
	● Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
	● Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
	● Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility
	● Patient death associated with a fall while being cared for in a health care facility
	● Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
	● Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider

Possible Measures and Measure Sets for the RHQDAPU Program for FY 2011 and Subsequent Years	
Topic	**Quality Measure**
	● Abduction of a patient of any age
	● Sexual assault on a patient within or on the grounds of a health care facility
	● Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care facility
Average Length of Stay Coupled with Global Readmission Measure	
Preventable Hospital-Acquired Conditions (HACs)	
	● Catheter-Associated Urinary Tract Infection (UTI)
	● Vascular Catheter-Associated Infection
	● Surgical Site Infections – Mediastinitis after Coronary Artery Bypass Graft (CABG)
	● Surgical Site Infections following Elective Procedures – Total Knee Replacement, Laparoscopic Gastric Bypass, Litigation and Stripping of Varicose Veins.
	● Legionnaires' Disease
	● Glycemic Control – Diabetic Ketoacidosis, Nonketotic Hypersmolar Coma, Hypoglycemic Coma
	● Iatrogenic pneumothorax
	● Delirium
	● Ventilator-Associated Pneumonia (VAP)
	● Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)
	● *Staphylococcus aureus* Septicemia
	● Clostridium-Difficile Associated Disease (CDAD)
	● Methicillin-Resistant *Staphylococcus aureus* (MRSA)

Reporting burden and data collection options. CMS invites comments on the potential reporting burden for hospitals with respect to the additional proposed measures, particularly those requiring chart abstractions, stating that it intends to work to simplify data abstraction specifications that add to the burden. CMS notes that it proposes to stagger the initial reporting dates for the new measures, and that not all of the 43 measures proposed for addition will require new hospital reporting. Specifically, performance on the 3 proposed measures regarding 30-day readmissions for Medicare patients will be calculated by CMS based on Medicare hospital claims data. In addition, CMS states that 85% of hospitals with a cardiac surgery program already report the data for the proposed cardiac surgery measures to a cardiac surgery registry operated by the Society of Thoracic Surgeons, and CMS would accept the data directly from this registry. With respect to the AHRQ measures, CMS seeks comments on alternative means of data submission. It notes that a large number of hospitals already submit the necessary all-payer data on a voluntary basis to state hospital associations or state health agencies, and seeks comments as to whether these organizations should be permitted to transmit these data on behalf of hospitals. Alternatively, CMS states that it could initially calculate the AHRQ measures using Medicare-only claims data, which would delay hospital submission of all-payer claims data.

Additional methods of data collection are identified as under consideration for the future, and CMS seeks comments on these as well. Discussed in particular is the CMS Continuity Assessment Record and Evaluation (CARE), an internet-based data collection instrument allowing "real-time" transmission. Also under consideration are collecting data from existing clinical registries and use of data derived from electronic

versions of laboratory test reports that are maintained by hospitals as part of the patient's medical record. CMS would use these latter data to risk adjust claims-based outcomes measures such as the mortality measures.

CMS indicates that it intends to "harmonize" measures across settings and other programs, noting that the readmission measures are also used in Quality Improvement Organizations (QIOs) 9th Scope of Work, and that some measures for heart attack and surgical infection used in quality reporting by physicians and by hospitals for outpatient care align with the inpatient measures.

Data submission schedule. Data submission for patient level measure data for the first 4.5 months after the end of the quarter (August 15, 2009 for the first calendar quarter of 2009 discharges) and 4 months after the end of the quarter for aggregate population and sample size counts. For the proposed cardiac surgery and AHRQ measures, alternative deadlines are proposed: June 1, 2009 for 1st calendar quarter 2009 discharges and two months after the end of the preceding quarter for cardiac measures, and April 10, 2010 for 4th quarter 2009 discharges a3 months after the end of the quarter for the AHRQ measures. CMS states that these alternatives are proposed to make more timely information available to consumers, and in the case of the cardiac measures to coordinate with the STS quarterly submission deadline.

Validation procedures. The rule includes proposed RHQDAPU chart validation requirements for the FY 2010 update factor. Most FY 2009 measures will be validated using data from 4th quarter 2007 through 3rd quarter 2008 discharges. Two SCIP measures will be validated using data from 2nd and 3rd quarter CY 2008 discharges. CMS is seeking comments on the validation process for FY 2011 and beyond, specifically regarding the impact of adding measures to the validation process, challenges posed by the new measures, whether CMS should switch from the use of a quarterly validation sample of five charts per hospital to randomly selecting a sample of hospitals and selecting more charts to improve the reliability of hospital level validation estimates, and whether the validation sample should be selected by clinical topic to ensure that all reported measures are covered by the validation sample.

Data attestation. Referencing the burden it would place on hospitals, CMS is deferring a requirement discussed in last year's inpatient rule that would have, beginning in FY 2009, required hospitals to separately attest to the accuracy and completeness of their quality data submission. Instead, for FY 2010 and beyond, CMS is seeking comment on the electronic implementation of the attestation requirement at the point of submission to the QIO Clinical Warehouse.

C. Medicare Hospital Value-Based Purchasing

The proposed rule includes a reference to the Hospital Value-Based Purchasing plan report that was submitted to the Congress in November 2007, with CMS indicating that testing of the plan is underway, which will produce information on performance

scores and financial impacts for individual hospitals which can be grouped and aggregated. Comments are sought on whether the results of the testing should be shared publicly, what the appropriate mechanism might be, and what type of results would be most useful. Posting of results on the Hospital Compare website and the CMS website are offered as possible means of publicly sharing the results.

D. Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs): Volume Decrease Adjustment

Under the IPPS, special payment protections are provided to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs). These hospitals are paid based on the payment option that the Medicare fiscal intermediary determines will yield the highest aggregate payment. The law requires that SCHs and MDHs receive a payment adjustment if a SCH or MDH experiences a decrease of more than 5 percent in its total number of inpatient discharges from one cost reporting period to the next, if the circumstances leading to the decline were beyond the hospital's control. CMS is proposing to slightly modify the methodology for calculating the average nursing hours per patient day.

E. Rural Referral Centers (RRC)

While there were no proposed changes to the appropriate methodology, the proposed rule includes proposed revisions to the qualifying criteria for designation as a RRC.

A hospital may qualify as a RRC if there are 275 or more beds available for use

A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum CMI and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume).

- As regards the CME prerequisite, the hospital's case-mix index (CMI) must be at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally;

  CMS is proposing that for a rural hospitals to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2008, they must have a CMI value for FY 2007 that is at least--

  - 1.4285; or
  - The median CMI value for urban hospitals calculated by CMS for the census region in which the hospital is located. The proposed median CMI values by region are set forth in the following table:

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.2515
2. Middle Atlantic (PA, NJ, NY)	1.2691
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3589
4. East North Central (IL, IN, MI, OH, WI)	1.3572
5. East South Central (AL, KY, MS, TN)	1.3040
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.3557
7. West South Central (AR, LA, OK, TX)	1.4405
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.4692
9. Pacific (AK, CA, HI, OR, WA)	1.3872

- As regards the discharge prerequisite, the hospital's number of discharges must be at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year.)

  Therefore, CMS is proposing that, a hospital, in order to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2008, must have as the number of discharges for its cost reporting period that began during FY 2006 at least--
    - 5,000 (3,000 for an osteopathic hospital); or
    - The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table.

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,158
2. Middle Atlantic (PA, NJ, NY)	10,443
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,344
4. East North Central (IL, IN, MI, OH, WI)	8,900
5. East South Central (AL, KY, MS, TN)	7,401
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,988
7. West South Central (AR, LA, OK, TX)	5,816
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,919
9. Pacific (AK, CA, HI, OR, WA)	8,600

F. Indirect Medicare Education (IME) Adjustment

The proposed rule would continue the IME adjustment factor at 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

G. Payments to Medicare Advantage (MA) Organizations: Collection of Risk Adjustment Data

CMS is required to make advance monthly payments to a MA organization for each beneficiary enrolled in the MA plan offered by the organization. In addition, CMS is required to adjust the monthly payments to take into account the health status of the MA plan's enrollees. In support of this risk adjustment requirement, CMS began requiring since July 1998 certain information from the MA plans. Initially CMS requested comprehensive data but subsequently allowed MA plans to submit "abbreviated data."

Noting the fact that beginning with CY 2007, 100 percent of payments to MA plans are risk adjusted, CMS is proposing to essentially return to the requirement for MA plans to submit comprehensive data. That is, CMS is proposing to repeal the option for MA plans to submit "abbreviated data."

H. Hospitals Emergency Services under the Emergency Medical Treatment and Labor Act (EMTALA)

The law imposes specific obligations on certain Medicare participating hospitals and CAHs. These obligations concern individuals who come to a hospital emergency department and request examination or treatment for a medical condition, and apply to all of these individuals, regardless of whether they are beneficiaries of any program under the law.

CMS proposes to clarify EMTALA to state that when an individual covered by EMTALA is admitted as an inpatient and remains un-stabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept the individual, assuming that the transfer of the individual is an appropriate transfer and the participating hospital with specialized capabilities has the capacity to treat the patient. CMS said that the intent of this proposal is not to encourage patient dumping to hospitals with specialized capabilities. CMS said it expects the admitting hospital to ensure it is providing needed treatment within its capabilities prior to transferring the individual.

CMS is also proposing that, as part of the obligation to have an on-call list, hospitals may choose to participate via a "community call plan." Each hospital participating in the plan must have written policies and procedures in place to respond to situations

in which the on-call physician is unable to respond due to situations beyond his or her control.

I. Application of Incentives to Reduce Avoidable Readmissions to Hospitals

CMS is considering options for developing incentives to reduce avoidable readmissions, including some that would require statutory change. Citing work by MedPAC, potentially avoidable readmissions are identified as adding to program costs, and may reflect poor quality care. Issues pertaining to the proper measurement of and accountability for readmissions are discussed, such as the time period from discharge to readmission. Efforts might be focused on all readmissions or targeted at costly ones. In addition to risk adjustment of readmission data, accountability issues include consideration of all providers involved in care than acute care hospitals, such as physicians, rehabilitation hospitals, skilled nursing facilities, and home health agencies.

CMS cites a number of best-practice interventions for reducing avoidable readmissions, identified from the literature or Medicare demonstration projects. In order promote adoption of such efforts, three approaches CMS presents for comments are:

- Direct adjustment to DRG payments. An individual hospital's payments could be adjusted for those readmissions determined to be avoidable because the hospital did not follow evidence-based best practices for avoiding readmissions. The magnitude of the adjustment could be based on patient specific risk factors and the apportionment of accountability among providers. Alternatively, the adjustment could be aggregated to the regional or national level. CMS identifies possible unintended consequences such as hospitals resisting medically necessary readmissions, or discharging patients to the most comprehensive and costliest post-acute care in order to avoid readmissions. CMS indicates this approach would require new statutory authority.

- Performance-based payment adjustment. A second approach described would rely on a performance-based system like the VBP plan described in CMS' November 2007 report to the Congress. Hospital-specific risk adjusted readmission rates could be included in the VBP system, along with other measures of care coordination related to readmissions. CMS states that implementation of the VBP methodology would require new statutory authority.

- Public reporting. A third option for which CMS seeks comment is public reporting of hospital-specific, risk-adjusted readmission rates. CMS believes this would not require new statutory authority

VII. Proposed Changes to the IPPS for Capital-Related Costs

A. Proposed Capital Federal Rate Update for FY 2009

The FY 2008 Federal capital rate was $426.14 for all hospitals. CMS is proposing an update of 0.7 percent for determining the proposed FY 2009 rate (see the below table for details).

CMS Proposed FY 2009 Update Factor to the Capital Federal Rate

Capital Input Price Index	1.2
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	-1.0
Projected Case-Mix Change	1.0
Subtotal	1.2
Effect of FY 2007 Reclassification and Recalibration	-0.5
Forecast Error Correction	0.0
Total Update for Hospitals	0.7

After additional adjustments including a reduction 0.9 percent for non-real case mix change, CMS is proposing an over update factor of a -1.14 percent (see the below table for details). The result is that CMS is proposing a FY 2009 Federal capital rate of $421.29.

Comparison of Factors and Adjustments:
FY 2008 Capital Federal Rate and
Proposed FY 2009 Capital Federal Rate

	FY 2008	Proposed FY 2009[4]	Change	Percent Change[5]
Update Factor[1]	1.0090	1.0070	1.0070	0.70
GAF/DRG Adjustment Factor[1]	0.9996	1.0007	1.0007	0.07
Outlier Adjustment Factor[2]	0.9523	0.9427	0.9899	-1.01
Exceptions Adjustment Factor[2]	0.9997	0.9998	1.0001	0.01
MS-DRG Coding and Documentation Improvements Adjustment Factor[3]	0.9940	0.9910	0.9910	-0.90
Capital Federal Rate	$426.14	$421.29	0.9886	-1.14

[1] The update factor and the GAF/DRG budget neutrality factors are built permanently into the capital rates. Thus, for example, the incremental change from FY 2008 to FY 2009 resulting from the application of the proposed 1.0007 GAF/DRG budget neutrality factor for FY 2009 is 1.0007.

[2] The outlier reduction factor and the exceptions adjustment factor are not built permanently into the capital rates; that is, these factors are not applied cumulatively in determining the capital rates. Thus, for example, the net change resulting from the application of the proposed FY 2009 outlier adjustment factor is0.9427/0.9523, or 0.9899.

[3] Proposed adjustment to FY 2009 IPPS rates to account for documentation and coding improvements expected to result from the adoption of the MS-DRGs.

[4] Proposed factors for FY 2009.

[5] Percent change of individual factors may not sum due to rounding.

B. Revisions to the Capital IPPS Based on Data on Hospital Medicare Capital Margins

Based on its evaluation of hospital Medicare capital margins, CMS reviewed its decision in the FY 2008 IPPS final rule to (1) discontinue the 3.0 percent additional payment that had been provided to hospitals located in large urban areas for FY 2008 and beyond and begin, effective, FY 2008, a three-year phase-out of the capital payment teaching adjustment. In FY 2009 the formula for determining the amount of the teaching adjustment was revised so that adjustment amounts will be half of the amounts provided in FY 2008. In FY 2010 and after, hospitals will no longer receive an adjustment for teaching activity under the capital IPPS. CMS is, however, providing additional opportunity for public comment during the FY 2009 NPRM cycle for the IPPS.

VIII. Proposed Changes For Hospitals and Hospital Units Excluded from the IPPS

Only cancer hospitals, children's hospitals and religious non-medical health care institutions (RNHCIs) remain subject to the rate-of-increase limit. Inpatient psychiatric, inpatient rehabilitation and long-term care hospitals are now subject to their respective prospective payment systems. CMS is proposing that the percentage increase in the rate-of-increase limits would be the proposed percentage increase in the FY 2009 IPPS operating market basket, which is estimated to be 3.0 percent.

Proposed change to the regulations governing hospitals-within-hospitals: In 1994 CMS (then known as the Health Care Financing Administration (HCFA)) published long term care hospital hospital-within-hospital (LTCH HwH) regulations to address inappropriate Medicare payments to entities that were effectively units of other hospitals. In response to an admitted gap in its effort to allow certain HwHs to meet the HwH criteria, CMS is proposing an exception to the restrictions for certain HwHs that are state hospitals and are co-located with another state hospital.

IX. Disclosure Required of Certain Hospitals and CAHs Regarding Physician Ownership

In the FY 2008 IPPS final rule with comment period, CMS required a hospital (including CAHs) to disclose to all patients whether it is physician-owned and, if so, the names of the physician owners. The regulation, however, omitted the requirement for disclosure if the hospital was owned by an immediate family member of a physician. Therefore, CMS is proposing to require such disclosure. In addition, CMS is proposing an exclusion to this requirement in the situation in which a physician (or immediate family member) owner makes no referrals to the respective hospital. CMS is also proposing that a hospital must furnish the list of physician (or immediate family member) owners when requested by a patient. Finally, CMS is

proposing to require all physicians to disclose in writing to all patients they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member.

X. Physician Self-Referral Provisions

A. "Stand in the Shoes" Provisions

The physician self referral law prohibits a physician from making referrals for certain designated health service (DHS) payable by Medicare with which he or she (or an immediate family member) has a financial relationship and prohibits the entity from filling claims with Medicare for those referred services. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse.

A provision of a final rule published September 2007 treated referring physicians as standing in the shoes of their physician organization for purposes of applying the rules that describe direct and indirect compensation arrangement. In response to numerous comments, however, CMS had second thoughts and on November 15, 2007 delayed the effective date until December 4, 2008. The delay was only applicable to:

- With respect to an academic medical center (AMC), compensation arrangement between faculty practice plan and another component of the same AMC; and
- With respect to an integrated health care system, compensation arrangements between an affiliated DHS entity and an affiliated physician practice in the same integrated health care system.

CMS said that given the widespread impact of the "stand in the shoes" provisions, it believed that a more refined approach was appropriate. As a consequence it is proposing several options and asking for comments. These options include:

1. A physician would be deemed not to stand in the shoes of his or her physician organization if the compensation arrangement between the physician organization and the physician satisfied the requirement for exception for a bona fide employment relationship; the exception for personal service arrangements or the exceptions, or the exception for fair market value compensation. The physician would need to meet only one of these three exceptions.
2. Another approach would only cover owners of a physician organization as standing in the shoes of that physician organization.
3. A third approach would adopt the provisions of the September 2007 final rule. These provisions provide that when determining whether a direct or indirect compensation arrangement exists between a physician and an entity to which the physician refers Medicare patients for DHS, the referring

physician stands in the shoes of: (1) another physician who employs the referring physician; (2) his or her wholly owned professional corporation; (3) a physician practice that employs or contracts with the referring physician or in which the physician has an ownership interest; or (4) a group practice of which the referring physician is a member or independent contractor. CMS said that it would promulgate separate exceptions, to the extent necessary to protect non-abusive arrangement.

In addition, CMS is proposing to provide that an entity that furnishes DHS would be deemed to stand in the shoes of an organization in which it has 100 percent ownership interest and would deem to have the same compensation arrangements with the same parties and on the same terms as does the organization that it owns.

B. Gainsharing

The term "gainsharing" typically refers to an arrangement under which a hospital give physicians a share of the reduction in the hospital's costs attributable in part to the physician's efforts. The provision of monetary or non-monetary rewards by a hospital to a physician, however, through a gainsharing arrangement would constitute a financial relationship with an entity for purpose of the physician self-referral status. Such a relationship is generally prohibited. In addition, gainsharing arrangements also implicate two specific fraud and abuse statutes – the Civil Monetary Penalty and appropriate provisions of the anti-kickback statute.

The HHS Office of Inspector General (OIG) historically has been wary of gainsharing arrangements. The OIG, however, has issued several favorable advisory opinions regards individual gainsharing arrangement, although the opinions (like all OIG opinions) do not have general applicability.

MedPAC, in its March 2005 Report to Congress on specialty hospitals recommended that gainsharing arrangement between physicians and hospitals be permitted under certain circumstances. CMS said that it has long been interested in evaluating the association between payments and the quality of care. To this end, CMS, reviewed the three gainsharing demonstration programs which it initiated -= the first in 1991.

In calling for gainsharing comments, CMS noted its interest in appropriately structure percentage-based compensation formula. In the proposed FY 2008 rule CMS proposed to clarify the percentage-base compensation arrangements but had not finalized the proposed provisions. The proposal would have provided that such an arrangement may be used only for paying for personally performed physician services and such arrangements must be based on the revenues directly resulting from the physician services. CMS went on to say that the proposal was still under "active consideration."

CMS said it was specifically interested in receiving comments on (1) what types of requirements and safeguards should be included in any exception for gainsharing

arrangements; and (2) whether certain services, clinical protocols, or other arrangements should not qualify for the exception.

C. Physician-Owned Implant and Other Medical Device Companies

CMS said that it has recently become aware of an increase in physician investment in implant and other medical device manufacturing, distribution and purchasing companies. While concerned about potential abuse and overuse, CMS is not proposing specific proposal regarding these types of companies. Rather CMS is calling for comments as to whether the physician self-referral rules should be used to address such companies or should the matter be better address through enforcement of the False Claims Act, the anti-kickback statute or similar fraud and abuse laws.

XI. Financial Relationships Between Hospitals and Physicians

Since December 1991, CMS has not engaged in a comprehensive reporting initiative to examine financial relationships between hospitals and physicians. The Deficit Reduction Act of 2005 required CMS to develop a strategic and implementing plan to address certain issues relation to physician-owned specialty hospitals. In order to assist in the preparation of this report, CMS sent a voluntary survey to 130 specialty hospitals and 220 competitor hospitals. In the subsequent August 2006 report to Congress CMS said it would implement a regular disclosure process, but that its design had not been completed at that time. Following up on this commitment, CMS developed an information collection instrument, called the Disclosure of Financial Relationships Report (DFRR). CMS is proposing to send the DFRR to 500 hospitals, which is the number CMS felt was necessary to provide sufficient information. CMS estimated that the average number of hours to complete the survey was 31 hours; CMS is asking for comments on this estimate. Hospitals will have up to 60 days to complete and return the form. CMS is proposing not to impose civil monetary penalties, at this time, for failure to timely submit the form. The 24-page form is included in the NPRM as Appendix C.

XII. Appendices

A: CMS Impact Analysis of Proposed Changes For FY 2008 (Final Rule Table I)
B: FY 2009 IPPS Estimated Payments with Proposed Within-State Rural Floor and Imputed Floor Budget Neutrality

TABLE I.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2009

	No. of Hospitals[1] (1)	Proposed FY 2009 Cost Based DRG Weights & MS-DRG Changes[2] (2)	Proposed FY 2009 Wage Data[3] (3)	Proposed FY 2009 DRG, Rel. Wts. and Wage Index Changes[4] (4)	FY 2009 MGCRB Reclass-ifications[5] (5)	Application of Proposed Rural Floor and Imputed Rural Floor, Including Proposed Within State Budget Neutrality[6] (6)	Proposed FY 2009 Out-Migration Adjustment[7] (7)	All Proposed FY 2009 Changes w/ CMI Adjustment Prior to Estimated CMI Growth[8] (8)	All Proposed FY 2009 Changes w/ CMI Adjustment and Estimated CMI Growth[9] (9)
All Hospitals	3,528	0.1	-0.1	0	0	0	0	2.3	4.1
By Geographic Location:									
Urban hospitals	2,542	0.2	-0.1	0.1	-0.2	0	0	2.4	4.2
Large urban areas	1,402	0.5	-0.1	0.3	-0.4	-0.1	0	2.6	4.4
Other urban areas	1,140	0	0	-0.1	-0.1	0.1	0	2.2	3.9
Rural hospitals	986	-1	0	-1.1	2.1	-0.1	0.1	1.5	3.3
Bed Size (Urban):									
0-99 beds	643	-0.7	-0.1	-0.8	-0.4	0.1	0	1.6	3.4
100-199 beds	829	0.1	0	0	-0.1	0.1	0	2.2	4
200-299 beds	483	0.2	0	0.2	-0.2	-0.1	0	2.4	4.2
300-499 beds	411	0.3	0	0.3	-0.2	0	0	2.6	4.3
500 or more beds	176	0.5	-0.3	0.1	-0.3	0	0	2.5	4.3
Bed Size (Rural):									
0-49 beds	338	-2.3	0.1	-2.3	0.6	0	0.2	0.7	2.5
50-99 beds	373	-1.2	0	-1.3	1.1	-0.1	0.2	1.2	3
100-149 beds	166	-0.9	0.1	-0.8	2.5	0	0.1	1.5	3.3
150-199 beds	67	-0.6	-0.1	-0.8	3	-0.1	0	2	3.8
200 or more beds	42	-0.3	-0.1	-0.4	3.2	-0.1	0	2.1	3.9
Urban by Region:									
New England	121	0	0	-0.1	0.5	0.1	0	1.2	3
Middle Atlantic	348	0	-0.5	-0.5	0.1	0	0	1.2	3
South Atlantic	385	0.4	-0.3	0.1	-0.4	0	0	2.7	4.4
East North Central	394	0.5	-0.5	-0.1	-0.4	0	0	2.4	4.1
East South Central	163	-0.1	-0.2	-0.2	-0.2	0	0	2.4	4.2
West North Central	157	-0.1	0.2	0.1	-0.7	0	0	2.8	4.5
West South Central	371	0.4	0	0.3	-0.6	0	0	2.9	4.7
Mountain	157	0.3	0.1	0.5	-0.2	0	0	3.2	5
Pacific	393	0.4	0.9	1.2	-0.2	0	0	3.4	5.2
Puerto Rico	53	-0.2	-0.7	-0.9	-0.7	0	0	1.4	3.2
Rural by Region:									

	No. of Hospitals[1] (1)	Proposed FY 2009 Cost Based DRG Weights & MS-DRG Changes[2] (2)	Proposed FY 2009 Wage Data[3] (3)	Proposed FY 2009 DRG, Rel. Wts. and Wage Index Changes[4] (4)	FY 2009 MGCRB Reclass-ifications[5] (5)	Application of Proposed Rural Floor and Imputed Rural Floor, Including Proposed Within State Budget Neutrality[6] (6)	Proposed FY 2009 Out-Migration Adjustment[7] (7)	All Proposed FY 2009 Changes w/ CMI Adjustment Prior to Estimated CMI Growth[8] (8)	All Proposed FY 2009 Changes w/ CMI Adjustment and Estimated CMI Growth[9] (9)
New England	23	-0.8	-0.4	-1.3	2.4	-0.9	0	0.6	2.3
Middle Atlantic	70	-0.9	-0.1	-1.1	2	0	0.1	1.3	3.1
South Atlantic	172	-0.6	-0.1	-0.7	2.2	0	0.1	1.9	3.7
East North Central	121	-0.9	-0.3	-1.3	1.6	0	0.1	1.4	3.2
East South Central	176	-1.3	-0.1	-1.4	2.7	0	0.1	1.6	3.4
West North Central	113	-0.9	0.1	-0.8	1.7	0	0.1	1.6	3.4
West South Central	200	-1.7	0.5	-1.3	2.5	0	0.1	1.3	3.1
Mountain	75	-0.9	0	-1	0.5	0	0.1	1.2	3.1
Pacific	36	-0.7	0.6	-0.2	1.8	-0.3	0	1.8	3.6
By Payment Classification:									
Urban hospitals	2,584	0.2	-0.1	0.1	-0.2	0	0	2.4	4.2
Large urban areas	1,424	0.4	-0.1	0.3	-0.4	-0.1	0	2.6	4.4
Other urban areas	1,160	0	0	-0.1	0	0.1	0	2.2	3.9
Rural areas	944	-1	0	-1.1	2	-0.1	0.1	1.5	3.3
Teaching Status:									
Nonteaching	2,485	-0.2	0	-0.2	0.3	0	0	2.2	4
Fewer than 100 residents	805	0.2	0	0.1	-0.2	0	0	2.4	4.2
100 or more residents	238	0.5	-0.3	0.2	-0.3	0	0	2.5	4.2
Urban DSH:									
Non-DSH	838	-0.3	-0.2	-0.4	-0.1	0	0	1.8	3.6
100 or more beds	1,534	0.4	-0.1	0.3	-0.3	0	0	2.6	4.3
Less than 100 beds	354	-0.7	0	-0.8	0	0	0	1.6	3.4
Rural DSH:									
SCH	389	-1.5	0	-1.5	0.4	0	0.1	1.5	3.3
RRC	206	-0.6	0	-0.6	3.4	-0.1	0	1.9	3.7
100 or more beds	39	-0.8	0	-0.9	1.3	0	0.4	1.3	3.1
Less than 100 beds	168	-1.7	0	-1.8	1.3	0	0.3	0.6	2.4
Urban teaching and DSH:									
Both teaching and DSH	811	0.4	-0.1	0.3	-0.4	0	0	2.5	4.3
Teaching and no DSH	172	-0.1	-0.2	-0.3	0	0	0	1.8	3.6
No teaching and DSH	1,077	0.2	0	0.2	0	0.1	0	2.5	4.3

	No. of Hospitals[1] (1)	Proposed FY 2009 Cost Based DRG Weights & MS-DRG Changes[2] (2)	Proposed FY 2009 Wage Data[3] (3)	Proposed FY 2009 DRG, Rel. Wts. and Wage Index Changes[4] (4)	FY 2009 MGCRB Reclass-ifications[5] (5)	Application of Proposed Rural Floor and Imputed Rural Floor, Including Proposed Within State Budget Neutrality[6] (6)	Proposed FY 2009 Out-Migration Adjustment[7] (7)	All Proposed FY 2009 Changes w/ CMI Adjustment Prior to Estimated CMI Growth[8] (8)	All Proposed FY 2009 Changes w/ CMI Adjustment and Estimated CMI Growth[9] (9)
No teaching and no DSH	524	-0.2	-0.2	-0.4	-0.3	0	0	1.9	3.7
Special Hospital Types:									
RRC	197	-0.4	-0.1	-0.4	3.2	0	0	2.3	4.1
SCH	355	-1.3	0.1	-1.3	0.4	0	0.1	1.2	3
MDH	156	-1.8	0.1	-1.8	0.5	0	0.2	2	3.8
SCH and RRC	102	-0.5	0.1	-0.5	1.7	0	0	2.2	4.1
MDH and RRC	12	-1.3	0.1	-1.3	0.9	-0.3	0	1	2.8
Type of Ownership:									
Voluntary	2,027	0.1	-0.1	0	0	0	0	2.3	4
Proprietary	827	0	0	-0.1	0	-0.1	0	2.4	4.1
Government	587	0.1	-0.1	0	0.1	0.1	0	2.6	4.4
Medicare Utilization as a Percent of Inpatient Days:									
0-25	255	0.8	-0.1	0.7	-0.4	-0.2	0	3.2	4.9
25-50	1,350	0.3	0	0.3	-0.3	0	0	2.7	4.4
50-65	1,431	-0.1	-0.2	-0.3	0.4	0.1	0	1.9	3.7
Over 65	392	-0.8	-0.2	-1	0.5	0	0.1	1.2	3
FY 2009 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	805	0	0	0	2	-0.1	0	2.1	3.8
Non-Reclassified Hospitals	2,723	0.2	-0.1	0	-0.7	0	0	2.4	4.2
Urban Hospitals Reclassified	445	0.2	0	0.2	1.5	-0.2	0	2.1	3.9
Urban Nonreclassified, FY 2009:	2,075	0.3	-0.1	0.1	-0.7	0.1	0	2.5	4.3

	No. of Hospitals[1] (1)	Proposed FY 2009 Cost Based DRG Weights & MS-DRG Changes[2] (2)	Proposed FY 2009 Wage Data[3] (3)	Proposed FY 2009 DRG, Rel. Wts. and Wage Index Changes[4] (4)	FY 2009 MGCRB Reclass-ifications[5] (5)	Application of Proposed Rural Floor and Imputed Rural Floor, Including Proposed Within State Budget Neutrality[6] (6)	Proposed FY 2009 Out-Migration Adjustment[7] (7)	All Proposed FY 2009 Changes w/ CMI Adjustment Prior to Estimated CMI Growth[8] (8)	All Proposed FY 2009 Changes w/ CMI Adjustment and Estimated CMI Growth[9] (9)
All Rural Hospitals Reclassified Full Year FY 2009:	360	-0.7	0	-0.7	3.3	-0	0	1.8	3.7
Rural Nonreclassified Hospitals Full Year FY 2009:	565	-1.5	-0	-1.6	-0.4	-0.1	0.3	1	2.8
All Section 401 Reclassified Hospitals:	29	-1.3	-0.2	-1.6	0.6	0	0	1.6	3.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	61	-1	-0.2	-1.3	3.2	-0.2	0.1	1	2.8
Specialty Hospitals									
Cardiac specialty Hospitals	20	-2.2	-0.1	-2.4	-0.7	0.1	0	0	1.8

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2007, and hospital cost report data are from reporting periods beginning in FY 2006 and FY 2005.
[2] This column displays the payment impact of the changes to the V26 GROUPER and the recalibration of the DRG weights based on FY 2007 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act.
[3] This column displays the payment impact of updating the wage index data to the FY 2005 cost report data.
[4] This column displays the combined payment impact of the changes in column 2 and column 3 and the budget neutrality factors for DRG and wage index changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act.
[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2009 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2008. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.992333.
[6] This column displays the effects of the rural floor and the imputed rural floor, including the proposal to apply the budget neutrality adjustment within State.
[7] This column displays the impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.
8 This column shows changes in payments from FY 2008 to FY 2009, including the proposed FY 2009 -0.9 percent documentation and coding adjustment, but not the projected 1.8 percent increase in case-mix expected to occur in FY 2009 due to improvements in documentation and coding. It incorporates all of the changes displayed in Columns 4, 5, 6, 7 (the changes displayed in Columns 2 and 3 are included in Column 4). It also reflects the impact of the FY 2009 update, and changes in hospitals' reclassification status in FY 2009 compared to FY 2008.
[9]This column shows changes in payments from FY 2008 to FY 2009 including the proposed FY 2009 -0.9 percent documentation and coding adjustment and the projected 1.8 percent increase in case-mix expected to occur in FY 2009 due to improvements in documentation and coding. It incorporates all of the changes displayed in Columns 4, 5 ,6 ,7 ,8 (the changes displayed in Columns 2 and 3 are included in Column 4). It also reflects the impact of the FY 2008 update, and changes in hospitals' reclassification status in FY 2009 compared to FY 2008. The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

FY 2009 IPPS Estimated Payments with Proposed Within-State Rural Floor and Imputed Floor Budget Neutrality

State	Current Policy Application of National Rural Floor and Imputed Floor Budget Neutrality	Proposed Policy Application of Rural Floor and Imputed Floor Budget Neutrality within Each State
Alabama	-0.1	0.3
Alaska	0.0	-0.2
Arizona	-0.2	0.3
Arkansas	-0.1	0.3
California	0.7	-0.8
Colorado	0.0	-0.1
Connecticut	2.1	-2.2
Delaware	-0.2	0.3
Washington, D.C.	-0.2	0.3
Florida	0.0	0.0
Georgia	-0.1	0.3
Hawaii	-0.1	0.3
Idaho	-0.1	0.3
Illinois	-0.2	0.1
Indiana	-0.1	0.0
Iowa	0.1	-0.1
Kansas	-0.1	0.3
Kentucky	-0.1	0.3
Louisiana	-0.1	0.0
Maine	-0.1	0.3
Massachusetts	-0.2	0.3
Michigan	-0.2	0.3
Minnesota	-0.2	0.3
Mississippi	-0.1	0.3
Missouri	-0.1	0.0
Montana	-0.1	0.2
Nebraska	-0.1	0.3
Nevada	-0.2	0.3
New Hampshire	1.1	-1.2
New Jersey	0.7	-0.8
New Mexico	-0.1	0.0
New York	-0.2	0.3
North Carolina	-0.1	0.1
North Dakota	0.1	-0.1
Ohio	-0.1	0.1
Oklahoma	-0.1	0.1

State	Current Policy Application of National Rural Floor and Imputed Floor Budget Neutrality	Proposed Policy Application of Rural Floor and Imputed Floor Budget Neutrality within Each State
Oregon	-0.1	0.0
Pennsylvania	-0.1	0.1
Rhode Island	-0.2	0.3
South Carolina	-0.1	0.0
South Dakota	-0.1	0.3
Tennessee	0.0	0.0
Texas	-0.1	0.1
Utah	-0.1	0.3
Vermont	3.5	-3.4
Virginia	-0.1	0.0
Washington	-0.1	-0.1
West Virginia	0.0	-0.1
Wisconsin	-0.1	-0.1
Wyoming	0.0	0.1