



May 14, 2009

AAMC Summary and Analysis

FISCAL YEAR 2010 MEDICARE INPATIENT PPS PROPOSED RULE: PROVISIONS OF INTEREST TO THE ACADEMIC MEDICAL COMMUNITY

On May 1, 2009, the Centers for Medicare & Medicaid Services (CMS) published its annual proposed rule containing changes to the Medicare hospital inpatient prospective payment system (IPPS) and the PPS payment update for Federal fiscal year (FFY) 2010. A display copy of the proposed rule is available at http://www.federalregister.gov/OFRUpload/OFRData/2009-10458_PI.pdf. (Note that page numbers listed below correspond to pages in the display copy.) The rule is scheduled to be published in the *Federal Register* on May 22, 2009, and final changes would take effect for discharges on or after October 1, 2009.

Comments on the proposed rule are due **June 30, 2009**.

CMS plans to move forward with the elimination of capital IME payments in FY 2010, which would result in an aggregate cut of approximately \$360 million. In addition, CMS proposes to update the IPPS market basket by 2.1 percent, but also to make a corresponding “documentation and coding” reduction of 1.9 percentage points. The agency believes this offset is necessary to remove the effect of increases in aggregate payments caused by changes in hospital coding and documentation practices under the MS-DRG system that do not reflect increases in illness severity. The 2.1 percent update for inflation is lower than in prior years, which CMS states reflects the slowing rate of inflation. With all changes, CMS estimates that **teaching hospitals with 100 or more residents will see average operating per case payment decreases of 0.3 percent**, compared to operating decreases of 0.5 percent and 0.7 percent for other teaching and nonteaching hospitals, respectively. With all other changes, CMS estimates that **teaching hospitals with 100 or more residents will see average capital per case payment decreases of 14.4 percent**, compared to capital decreases of 3.8 percent and 0.6 percent for other teaching and nonteaching hospitals, respectively. The significant capital payment reductions for major teaching hospitals are largely due to the elimination of capital IME payments, scheduled to take effect in FFY 2010, as well as the documentation and coding reduction.

Highlights of the Proposed Rule Include:

- Elimination of capital IME payments
- 2.1 percent market basket update, with a -1.9 percent coding offset
- Decrease in the labor-related share from 69.7 percent to 67.1 percent
- 21 percent increase in the outlier payment threshold
- “Clarification” of the definition of a “new medical residency training program”
- Changes to the bed and day calculations used for IME and DSH payments
- 4 new Hospital Compare quality measures
- Revisions to EMTALA waiver regulations

I. MAINTAINING POLICY TO MOVE FORWARD WITH ELIMINATING CAPITAL IPPS TEACHING ADJUSTMENT IN FY 2010 (pages 462-63)

Background

In CMS's FFY 2008 IPPS final rule with comment period, CMS announced the agency's plans to eliminate the capital IME adjustment beginning with a 50 percent reduction in FFY 2009 and a complete elimination in FFY 2010 and beyond. The American Recovery and Reinvestment Act of 2009 (ARRA) directed CMS to rescind the 50 percent reduction to capital IME payments for FY 2009 but did not address the FFY 2010 elimination.

Proposed Rule

This proposed rule updates the regulations to reflect that ARRA requires the full capital IME adjustment to be paid in FY 2009. The proposed rule states, however, that the agency intends to move forward with its plans to eliminate the capital IPPS teaching adjustment in its entirety for FY 2010.

Analysis

Eliminating capital IME payments will result in an aggregate cut to teaching hospitals of about \$360 million. The proposed rule indicates that capital payments to teaching hospitals with 100 or more residents will decline by 14.4 percent, an impact largely attributable to elimination of capital IME payments, as well as the documentation and coding reduction.

Elimination of the capital IME adjustment will result in negative capital PPS margins for teaching hospitals. CMS has the authority to rescind the elimination of this adjustment. The AAMC has consistently urged CMS to rescind its decision to eliminate the capital IME adjustment and will continue to do so in the Association's comment letter. **WE URGE AAMC MEMBERS TO SUBMIT COMMENT LETTERS URGING CMS TO RESCIND THIS DETRIMENTAL REGULATION.**

II. IPPS PAYMENT RATE UPDATE

Proposed Rule

For FFY 2010, the proposed rule would implement a full market-basket increase (currently estimated at 2.1 percent) to the standardized payment amount for hospitals that comply with the requirements for reporting quality data. Hospitals that do not submit quality data will receive an increase equal to the market basket increase minus 2.0 percentage points, or 0.1 percent.

Analysis

The actual update will reflect the most recent estimate of the market basket increase at the time the final rule is published in early August. As mentioned above, the average estimated actual

change in per case payments will be less than the market basket increase due to a documentation and coding offset and other budget neutrality requirements.

III. DOCUMENTATION AND CODING OFFSET (pages 66-95)

Background

Hospitals receive predetermined (prospective) specific rates for each Medicare discharge. To determine the payment, each discharge is assigned to a specific diagnosis-related group (DRG). Each DRG has a relative weight that increases as the case complexity increases. The per case payment equals the product of the relative weight and the standardized amount, adjusted by the hospital's wage index and increased by any relevant payment adjustments (such as DSH or IME).

In FY 2008, to better recognize severity of illness in Medicare hospital payment rates, CMS began a transition from 538 "CMS DRGs" to 746 "Medicare Severity DRGs" (MS-DRGs). For FY 2008, Medicare per case payments were based on a blend comprising 50% of the CMS DRG relative weight and 50% of the MS-DRG relative weight. In FY 2009, the payments are based on 100% of the MS-DRG weights.

Under MS-DRGs, cases generally are assigned to one of three severity levels: cases with no complications or comorbidities (CCs); cases with a CC; or cases with a major CC (MCC). In general, an MS-DRG assignment for a case is based on diagnosis and procedure codes that the hospital includes on the Medicare claim submitted to CMS. Because MS-DRGs better reflect patient severity, there is an increased number of diagnosis and procedure codes that contribute to determining to which MS-DRG a case is assigned.

The MS-DRG relative weights for FY 2008 were calibrated with the intention that the change from CMS DRGs to MS-DRGs would be budget neutral, with Medicare payments only increasing if there is an actual increase in the severity of patients treated. CMS was concerned, however, that payments might increase because of the incentives for hospitals to document and code their Medicare claims more accurately, which would result in more cases being assigned to higher weighted DRGs.

Consequently, when CMS finalized the MS-DRG policy in the FY 2008 inpatient final rule, the Agency included a 4.8 percent offset to the standardized amount to negate any payment increases that were not associated with real case-mix increase. The offset was to be phased in over three years (-1.2% in FY 2008; -1.8% in FY 2009; and -1.8% in FY 2010). In the fall of 2007, Congress (PL 110-90) reduced the coding adjustment to -1.5% (-0.6% in FY 2008 and -0.9% in FY 2009).

Importantly, however, PL 110-90 gave CMS the authority to make "appropriate adjustments" to the extent that a retroactive analysis of actual claims data for FYs 2008 and 2009 indicate that coding changes did not comport with the legislated reductions. In other words, if in FY 2008 and FY 2009, coding changes resulted in payments that were more than the legislated offset, CMS is required to reduce the standardized amount for subsequent fiscal years to eliminate the

effect of the coding changes. In addition, CMS is authorized to make a further reduction to the standardized amount to “recoup” payments made in FYs 2008 and FY 2009 due to coding changes. The recoupment adjustments may be made during FYs 2010, 2011 and 2012.

Proposed Rule

The proposed rule would reduce the updated standardized amount for FY 2010 by 1.9 percentage points to account for documentation and coding adjustments. This amount reflects CMS’s estimate of the FY 2008 payment increase due to documentation and coding (2.5%) less the 0.6% reduction that was implemented in FY 2008 due to PL 110-90. This amount would be a prospective adjustment. CMS chose not to propose an additional “recoupment” adjustment but stated instead that the agency would address this issue in the FY 2011 and FY 2012 rulemakings.

Analysis

To estimate the increase in payments due only to coding changes (and not “real” case-mix changes), CMS “ran” the 2008 hospital claims through both the FY 2008 GROUPER (which assigns cases to DRGs) and the FY 2007 GROUPER and examined the difference in the case-mix index (CMI) under each grouper. (The CMI is the average of the DRG weights for all of the cases). Because the exact same claims were run through each grouper, according to CMS, any change in CMI is due to coding changes occurring in FY 2008, and not changes due to different patients in 2008. This computation produced a document and coding increase of 2.5 percent.

CMS also performed analyses indicating that almost all of the CMI change was due to “within” base DRG changes, which indicates that the base diagnosis did not change but that the coding had changed such that the case was assigned to a higher severity level within the base DRG. According to CMS, the MS-DRGs that had the most coding improvements were heart failure, chronic obstructive pulmonary disease, and simple pneumonia and pleurisy.

In addition to addressing the FY 2008 coding adjustments, CMS stated its analyses indicate that in FY 2009, estimated coding improvements will be 2.3%, which would exceed by 1.4% the -0.9% adjustment that was applied to the FY 2009 standardized amount, pursuant to PL 110-90. CMS chose not to address the FY 2009 coding issue in this proposed rule, because the agency does not yet have all of the FY 2009 claims. CMS will wait until next year to make any adjustments related to 2009 after performing analyses on a full year of actual claims.

To assess CMS’s views on the overall impact of coding changes, it is important to review the table on page 85. It is sobering, suggesting that between prospective and recoupment adjustments for FYs 2008 and 2009, the agency believes it must adjust the standardized amount by a total -8.5 percent between FYs 2010 and 2012. Given that CMS proposes to make a 1.9 percent reduction in FY 2010, the remaining adjustment would be -6.6 percent.

The AAMC, along with the AHA, has been working throughout this past year with outside consultants to monitor and prepare for the proposed rule. We are continuing to analyze the data that has just been released by CMS.

IV. PROPOSED CHANGES TO THE HOSPITAL WAGE INDEX AND LABOR-RELATED SHARE

Background

A portion of the standardized payment amount for each hospital is adjusted by the “wage index,” which reflects relative differences in costs across geographic areas attributable to local labor markets. The portion of the standardized amount that is adjusted by the wage index is referred to as the “labor-related share.”

For FFY 2010, the wage index values for each labor market area will be based on data submitted by hospitals for cost reporting periods that began in FFY 2006. Note that the wage data collected on FY 2006 cost reports include overhead costs for contract labor that were not collected on earlier cost reports. The wage index values will also reflect an occupational mix adjustment based on the FY 2007/2008 occupational mix survey. The intent of this adjustment is to ensure that the wage index reflects only geographic differences in the prices hospitals pay for labor and not differences in the mix of their employees (e.g., registered nurses versus licensed practical nurses). Like last year, CMS proposes to adjust 100 percent of the wage index for occupational mix.

A. Proposed Decrease to the Labor-Related Share (pages 303-10)

Proposed Rule

CMS is proposing to decrease the labor-related share from 69.7 percent to 67.1 percent for hospitals with wage indices greater than 1.0. (The labor-related share for hospitals with wage indices less than 1.0 will remain at 62 percent, as required by the Medicare Modernization Act.) CMS explained that the decline is in part a result of more recent survey data that, for the first time, account for professional services obtained outside a hospital’s local labor market. Previously, all professional fee expenses were considered to vary with the local labor market and were included in the labor-related share. CMS also attributed the decline to consolidation of administrative functions in home offices that are not in the same local labor market as individual hospitals.

Analysis

If finalized, the proposed decrease would have a negative impact on many teaching hospitals, because they are in geographic areas with wage indices greater than 1.0.

B. Solicitation of Comments Regarding Penalties for Failure to Submit Occupational Mix Data (pages 232-44)

Background

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) requires CMS to collect data every three years on the occupational mix of short-term acute care

hospital employees for purposes of constructing an occupational mix adjustment to the wage index. For the most recent FY 2007-2008 survey, the response rate was 89 percent, down from 90.7 percent for the 2006 survey and 93.8 percent for the 2003 survey. For purposes of calculating the FY 2010 wage index, hospitals that did not respond to the survey or submitted unusable data were assigned the average occupational mix adjustment for the labor market area.

Proposed Rule

In the proposed rule, CMS expressed concern about the increasing number of hospitals that fail to submit occupational mix data and the impact the declining response rate may have on area wage indices. The agency is, therefore, soliciting comments on whether to impose a penalty (for example, assigning the occupational mix factor that would result in the greatest negative adjustment to the hospital's wage index) to hospitals that do not respond or submit unusable occupational mix data.

C. Continued Phase-In of Within-State Budget Neutrality for Rural and Imputed Floors (pages 229-30)

Background

The rural floor requires that an urban wage index may not be lower than the wage index for any rural hospital in that state, while the imputed floor sets a minimum wage index for states without rural areas or rural IPPS hospitals. In the FY 2009 IPPS final rule, CMS adopted a policy to apply budget neutrality adjustments to the rural and imputed floors on a statewide, rather than national basis.

Proposed Rule

This proposed rule simply discusses the ongoing three-year phase-in of this policy. In FY 2009, hospitals received a blended wage index that was 20 percent of a wage index with the State level adjustment and 80 percent of a wage index with the national adjustment. In FY 2010, the blended wage index will reflect 50 percent of the State level adjustment and 50 percent of the national adjustment. In FY 2011, the adjustment will reflect 100 percent of the State level adjustment.

V. OUTLIER PAYMENT THRESHOLD (pages 637-53)

Background

If the costs of a particular Medicare case exceed the relevant MS-DRG operating and capital payment (including any DSH, indirect medical education (IME), or new technology add-on payments) plus a fixed-loss cost threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

Proposed Rule

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's MS-DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus \$24,240. The threshold would be applicable for both operating and capital outlier payments. In FFY 2009, the threshold was the MS-DRG payment plus any IME and DSH payments, plus new technology payments, plus \$20,045.

Analysis

The FY 2010 proposed cost threshold is 21 percent higher than the level in FY 2009. Outlier payments are funded through a 5.1 percent reduction in the PPS standardized payment amount. Consequently, CMS sets the outlier cost threshold at a level the agency believes will result in outlier payments that equal 5.1 percent of total DRG payments. CMS estimates that outlier payments represented 5.4 percent of total DRG payments in FY 2009, 0.3 percentage points greater than the 5.1 percent target. Thus, according to CMS, the outlier threshold must be increased to avoid making outlier payments in excess of 5.1 percent. Furthermore, CMS states that more cases would qualify for outlier payments in FY 2010, because overall payments are projected to be lower in FY 2010 compared to FY 2009. Thus, in order to maintain total outlier payments at 5.1 percent, CMS believes the outlier threshold must be increased.

The AAMC is very concerned about the dramatic increase in the outlier threshold and the corresponding impact on teaching hospitals that historically have received these payments. We will be doing analyses to verify CMS's calculations and to assess whether such a significant increase is warranted.

VI. PROPOSALS AFFECTING BOTH DGME AND IME PAYMENTS

A. "Clarification" of the Definition of New Medical Residency Training Program (pages 423-28)

Background

Teaching hospitals are subject to a cap on the number of residents that may be counted for direct graduate medical education (DGME) and indirect graduate medical education (IME) payments. In general, this cap is based on the number of full time equivalent (FTE) residents the hospital has claimed in its most recent cost reporting period ending on or before December 31, 1996. New teaching hospitals are given three years to establish residency programs, after which a resident cap is determined based on the resident counts in those programs.

Proposed Rule

The proposed rule would "clarify" the definition of "new medical residency training program" (at 42 C.F.R. § 413.79(l)) when a new teaching hospital is attempting to establish its resident cap. The regulations define "new medical residency training program" as one "that receives initial accreditation by the appropriate accrediting body or begins training residents on or after

January 1, 1995.” Following this definition, many hospitals have relied solely on accreditation of a new program by the appropriate accrediting body for purposes of determining whether the program’s residents could be included in the resident cap. CMS now states that the agency will look beyond accreditation to factors including (but not limited to) whether there is a new program director, new teaching staff, and new residents in the program.

Analysis

Although CMS insists that this has always been the agency’s policy and that its proposal is merely a “clarification,” the AAMC is concerned that CMS is in fact specifying new criteria for qualifying as a new program and applying these new criteria retroactively. We welcome your comments and insights on the effects of this proposed “clarified” definition.

B. Submission Deadline Flexibility for New Hospitals Joining GME Affiliated Groups (pages 428-31)

Background

Under current regulations, existing teaching hospitals that meet specified criteria may enter into Medicare GME affiliation agreements, under which they may combine their respective resident caps and redistribute them according to their agreement. The sum of the new caps under the affiliation agreement may not, however, exceed the aggregate combined cap.

Proposed Rule

CMS proposes to increase flexibility in submission deadlines for new hospitals joining Medicare GME affiliated groups. Current regulations require each hospital in a GME affiliated group to submit its Medicare GME affiliation agreement to its intermediary or MAC and the CMS Central Office no later than July 1 of the residency program year during which the agreement would be in effect. This deadline precludes new hospitals opening after July 1 from immediately entering into GME affiliation agreements. CMS’s proposal permits a new hospital that opens after July 1 of a given year to submit a GME affiliation agreement at any time prior to the end of its first cost reporting period to participate in an existing participating group. Under the proposal, the agreement may begin no earlier than the date the affiliation agreement is submitted to CMS, and hospitals already participating in the affiliated group must submit an amended agreement no later than June 30 of the year the revised agreement will be in effect.

Analysis

The proposed rule would allow new hospitals to enter into affiliated groups in their first year of operation. The proposal applies only to new *hospitals* with new Medicare provider agreements (not to new residency training programs at already-existing hospitals) and only permits the joining of existing GME affiliated groups (not the formation of new affiliated groups). While CMS does not raise this issue, the proposed rule also does not appear to change the current restriction that a new urban teaching hospital may only enter into a GME affiliated group if the

new hospital's revised cap pursuant to the affiliation agreement is higher than its base year cap (see 42 C.F.R. § 413.79(e)(1)(iv)).

VII. OTHER PROPOSAL AFFECTING INDIRECT MEDICAL EDUCATION PAYMENTS: REMOVAL OF OBSERVATION BED DAYS FROM THE INTERN AND RESIDENT-TO-BED (IRB) RATIO (pages 415-422)

Background

A hospital's ratio of full-time equivalent (FTE) interns and residents-to-beds (the "intern and resident-to-bed ratio" or "IRB ratio") is a key component in determining a teaching hospital's IME payment level. The number of beds in the IRB ratio is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period. Currently, hospitals are instructed to include observation bed days in this count for patients who ultimately are admitted as inpatients.

Proposed Rule

CMS proposes to exclude all observation beds from the available bed count used to determine the IRB ratio for IME payment purposes. Under the proposed rule, no observation bed days would be included, regardless of whether patients ultimately are admitted for inpatient care.

Analysis

Because a decrease in the number of beds results in an increase in the IRB ratio, CMS predicts that its proposal to exclude observation bed days from the IME bed count will result in increased IME payments to teaching hospitals. However, while not addressed in the proposed rule, given the current requirement that the IRB ratio used for payment not be greater than the ratio in the previous year, it seems that any increase in payments would not occur until 2011. We will urge CMS to make an exception so that the impact of this change can occur in FFY 2010.

CMS also proposes a corresponding exclusion of observation bed days from the DSH payment calculation, however, (see Section VIII.C. below), which the agency states could off-set any IME payment increases resulting from this change in policy.

VIII. CHANGES AFFECTING THE DISPROPORTIONATE SHARE (DSH) ADJUSTMENT

Background

Under the Social Security Act, hospitals that serve a disproportionate number of low-income patients may qualify for a Medicare disproportionate share hospital (DSH) adjustment. Under the most common method for qualifying for the DSH adjustment, a hospital's DSH payments are based in part on the level of the hospital's disproportionate patient percentage (DPP). The DPP is the sum of what is referred to as the "Medicare fraction" (the number of inpatient days furnished to patients entitled both to Medicare Part A and SSI benefits divided by the total

number of inpatient days furnished to patients entitled to Medicare Part A benefits) and the “Medicaid fraction” (the number of inpatient days furnished to patients eligible for Medicaid but not entitled to benefits under Medicare Part A, divided by the total number of inpatient days).

A. Proposal to Include Labor and Delivery (L&D) Days in the DSH Calculation (pages 407-411)

Proposed Rule

CMS proposes to include labor and delivery (L&D) bed days in the Medicare DSH calculation, even when a patient does not occupy a routine bed prior to occupying an ancillary L&D bed. Under the current regulations, a patient in the labor and delivery room at the census-taking hour does not count in the numerator or denominator of the Medicaid fraction, unless the patient first occupied a routine inpatient bed. Under the proposed policy, all L&D days would be included, as long as the patient was admitted to the hospital as an inpatient at some point during the stay. The new policy would not apply to labor and delivery patients who are not admitted to the hospital as inpatients (e.g. false labor).

Analysis

This proposed policy change is quite narrow, as the only additional L&D days that would be counted in the Medicaid fraction would be in circumstances when an inpatient day *follows* the use of an ancillary L&D bed. The effect of this proposal would vary by hospital, depending on the proportion of the hospital’s additional L&D days that are attributable to Medicaid-eligible patients. Hospitals whose proportion of additional L&D days attributable to Medicaid-eligible patients is higher than the proportion represented by their Medicaid fraction would benefit from this proposal. (For example, a hospital whose Medicaid fraction under the old policy was 10/100 (10%), may now have 100 additional L&D days to count under the new policy. If none of these additional days was attributable to Medicaid-eligible patients, the hospital’s Medicaid fraction would decline to 10/200 (5%); but if 90 of the 100 days were attributable to Medicaid-eligible patients, the hospital’s Medicaid fraction would increase to 100/200 (50%).) In general, the AAMC believes this proposed change would benefit COH members, as teaching hospitals often treat large numbers of Medicaid-eligible labor and delivery patients. The AAMC welcomes your feedback on the effects of this proposed change.

B. Proposal to Allow Alternative Methods of Aggregating Days in the Numerator of the Medicaid Fraction (pages 411-15)

Proposed Rule

CMS proposes to offer hospitals additional options regarding the methodology used to report days in the numerator of the DPP Medicaid fraction. The agency states that its current policy requires hospitals to report Medicaid inpatient days in the cost reporting period in which a patient is discharged, but the agency acknowledges that hospitals currently may be using other methods. CMS notes that the variation may stem from differences in State Medicaid agency requirements for how to report Medicaid-eligible days. Under the proposed rule, hospitals would

be able to report Medicaid inpatient days in the cost reporting period in which the patient was discharged *or* admitted *or* based on dates of service. In deciding to change its methodology, a hospital would be required to notify CMS of an intent to change methods, retain the same method for the entire cost reporting year, and avoid “double counting” when making any change.

Analysis

During the May 6, 2009, Hospital Open Door Forum teleconference, CMS stated that a hospital must notify the agency if it intends to use a methodology other than date of discharge for reporting Medicaid-eligible days. The proposed rule and proposed regulation, however, indicate that the hospital must notify CMS if seeking to make a “change” to its methodology, while acknowledging that hospitals currently may be using other methods of counting Medicaid-eligible days other than date of discharge. The AAMC will urge CMS to clarify in the final rule precisely under what circumstances hospitals must submit a notification.

C. Proposal to Remove Observation Bed Days from the DSH Calculation (pages 415-422)

Proposed Rule

As with the IRB calculation discussed in Section VII above, CMS proposes to exclude all observation beds and patient days from the DSH calculation. Currently, hospitals are instructed to include observation bed days in this count for patients who ultimately are admitted as inpatients. Under the proposed rule, no observation bed days would be included, regardless of whether patients ultimately are admitted for inpatient care.

Analysis

CMS states that some hospitals would gain from this proposal and others would lose, depending on how the exclusion of observation patient days affects the hospital’s overall DPP. At the same time, however, CMS seems to indicate (without explaining why) that this proposal would have an aggregate negative effect on DSH hospitals, as the agency predicts that changes to DSH payment adjustments would offset additional spending attributable to excluding observation beds from the IRB fraction. The AAMC welcomes your comments and observations on the effect of this proposed policy.

CMS’s proposal to exclude observation beds and patient days would have a negative effect on hospitals whose bed counts drop below 100 under the new policy, which would subject such hospitals to limits on their DSH payments. Because of typically-large bed counts, COTH member hospitals should not be affected by the proposed rule in this manner.

IX. REBASING THE HOSPITAL MARKET BASKETS (pages 282-323)

Background

The “basket” in the phrase “market basket” refers to the mix of goods and services hospitals purchase to furnish inpatient care. Each type of good and service (e.g. employee wages) is given a “weight” such that the total of all of the weights in the market basket equals 100 percent. The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to furnish inpatient care. CMS is required to rebase the hospital market baskets every four years.

Proposed Rule

CMS proposes to rebase and revise the hospital operating and capital market baskets used as the basis for setting the standardized payment update. Among other changes, CMS proposes to update the market baskets to reflect FFY 2006, rather than 2002, cost data.

Analysis

Having updated and accurate hospital market baskets is important because of their role in determining the update to the DRG standardized payment rate.

X. HOSPITAL ACQUIRED CONDITIONS (pages 109-16)

Background

To focus on the problem of hospital-acquired infections, the Deficit Reduction Act (DRA) required the Secretary to identify at least two conditions that: are high cost, high volume, or both; result in a higher weight DRG assignment when the condition is present as a secondary diagnosis; and could reasonably have been prevented through the application of evidence-based guidelines.

Effective October 1, 2008, any claim submitted that included one of the selected conditions, and for which the condition was not documented as being present on admission (POA), and is the only complication or comorbidity (CC) or major complication or comorbidity (MCC) listed, is no longer reimbursed at the rate of the higher paying DRG. In other words, claims are now paid as if the complication did not occur.

The current list of Hospital Acquired Condition (HAC) categories is as follows:

- Foreign object retained during surgery
- Air embolism
- Blood incompatibility
- Pressure ulcers
- Falls and Trauma
- Catheter Associated Urinary Tract Infection

- Vascular Catheter Associated Infection
- Surgical site infection – Mediastinitis after Coronary Artery Bypass Graft (CABG)
- Surgical Site Infections Following Certain Orthopedic Procedures
- Surgical Site Infections Following Bariatric Surgery for Obesity
- Glycemic Control
 - Diabetic Ketoacidosis
 - Nonketotic Hypersmolar Coma
 - Secondary Diabetes with Ketoacidosis
 - Secondary Diabetes with Hypersmolarity
- Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) following certain orthopedic surgeries, specifically hip and knee replacements surgeries.

Proposed Rule

For FY 2010, CMS is not proposing any additions or deletions to the current list of HACs nor any changes to the POA reporting or payment requirements. Rather, the agency proposes only one refinement, to include two new diagnosis codes under the “falls and trauma” category:

- 813.46 Torus fracture of ulna
- 813.47 Torus fracture of radius and ulna

CMS will be conducting an evaluation of the impact of the HAC program through a joint agreement with the Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ). The evaluation will be based on early program data and will focus on the selection and maintenance of the HAC categories and the reporting of POA data.

XI. REPORTING HOSPITAL QUALITY DATA FOR ANNUAL HOSPITAL PAYMENT UPDATE (RHQDAPU) (pages 323-87)

Background

Under the hospital quality reporting program, hospitals must submit data on selected quality performance measures to receive their full market basket update. As stated above, the penalty for not reporting the full set of quality measures is a reduction in the payment update by 2 percentage points. For the FY 2010 payment determination, there are 44 required measures: 26-chart-abstracted measures; 16 claims-based measures; one structural measure; and HCAHPS, the Patient Experience of Care Survey.

Proposed Rule

CMS continues to expand the quality reporting program by proposing an additional four measures (2 chart-abstracted and 2 structural measures), to be required for the FY 2011 payment determination. The proposed measures are as follows:

- SCIP-Infection-9 Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2

- SCIP-Infection-10 Perioperative Temperature Management
- Participation in a Systematic Clinical Database Registry for Stroke Care
- Participation in a Systematic Clinical Database Registry for Nursing Care

Data submission for the two proposed SCIP measures would begin with first calendar quarter discharges for 2010. For the proposed structural measures, hospitals would indicate through a web-based tool on Quality Net Exchange whether or not they participate in this type of registry. This would be the same process as what will be implemented for the Participation in a Cardiac Surgery Registry measure currently required for FY 2010. CMS will be providing additional information in the near term regarding the definition for a Systematic Clinical Database Registry as well as examples of currently certified registries.

The proposed rule finalizes the retirement of the “AMI-6 Beta blocker at arrival” measure, which was removed from the RHQDAPU program in December 2008 because of a change in science. CMS is soliciting comments on the criteria by which measures should be retired from the quality reporting program, as well as comments on how to maintain performance on measures that were retired because of “topped out” performance.

Possible Measures for FY 2012

CMS provides a list of measures under consideration for the FY 2012 payment determination. The measures are focused in the areas of:

- Emergency Department Throughput
- Percutaneous Coronary Intervention (PCI) Outcomes – mortality and readmission
- Stroke
- Venous Thromboembolism (VTE)
- Cardiac Surgery (current Society for Thoracic Surgery Database measures)
- Nursing Sensitive
- AHRQ Patient Safety Indicators
- AHRQ Internal Quality Improvement Indicators
- Methicillin-Resistant Staphylococcus Aureus (MRSA)
- Clostridium Difficile Associated Diseases (CDAD)

CMS is soliciting comments on the appropriateness of any of the possible measures, or others not on the list, for inclusion in the FY 2012 RHQDAPU program.

Validation Process

The validation process for the FY 2011 payment determination will not change. However, CMS is proposing a new validation process for the RHQDAPU program for FY 2012 similar to what was included in the proposed Value Based Purchasing Report sent to Congress in November, 2007. Under the new process, CMS would randomly select 800 hospitals on an annual basis to participate in the validation program. The selected hospitals would be asked to submit 12 cases per quarter in the selected topic areas for validation. CMS proposes to validate three quarters of data (first calendar quarter 2010 through third calendar quarter 2010 discharges). A validation

score would be calculated for each quarter, and then the three quarters would be pooled to calculate a single validation score. Each hospital would need a score of 75% or higher to pass validation. This is a decrease from the current 80% threshold.

Data Accuracy and Completeness Acknowledgement

For FY 2011 and future year payment determinations, CMS is proposing an electronic acknowledgement from hospitals that the data they submit is complete and accurate to the best of their knowledge. Hospitals would be required to complete the acknowledgement through the same web-based tool used to report on the structural measures between January 1, 2010 and August 15, 2010.

Reporting Quality Data through Electronic Health Records

In conjunction with the requirements for Health Information Technology (HIT) through the American Recovery and Reinvestment Act (ARRA), the proposed rule outlines the steps CMS is taking toward the reporting of quality data through electronic health records (EHR).

CMS is currently working with the Healthcare Information Technology Standards Panel (HITSP) to develop standards for the reporting of three measure sets through EHR data submission, including emergency department throughput, stroke, and venous thromboembolism. The standards for these measure sets are expected by October 2009. A testing and review process will be put in place for vendors and hospitals as early as July 2010. A *Federal Register* notice will be published seeking comments on the process for testing and the selection of hospitals and vendors to participate in the testing. Any hospital interested in self-nominating for participation in the testing process may submit a letter of interest by December 31, 2009 to:

RHQDAPU Program IT Testing Nomination
Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Quality Measurement and Health Assessment Group
7500 Security Boulevard
Mail Stop S3-02-01
Baltimore, MD 21244-8532

Analysis

The Health Information Technology for Economic and Clinical Health (HITECH) Act included in the ARRA provides financial incentives for hospitals and physicians to implement and maintain electronic health record systems. The law states that in order to receive the incentive, the hospital or physician must be a “meaningful user.” While a specific definition of “meaningful user” is still being determined, the law states that a meaningful user must be able to report on quality measures to CMS utilizing an EHR. Since many COH-member hospitals have already implemented, to some degree, an electronic health record system, we welcome your insights on the key issues you have seen or envision as problematic for reporting quality measures specifically in teaching hospitals.

XII. PAYMENTS FOR NEW TECHNOLOGIES (pages 166-222)

Background

Pursuant to BIPA, CMS established a methodology in a September 7, 2001 final rule (66 Fed. Reg. 46902) that would provide additional payments to hospitals for new technologies that they use and are not yet reflected in the DRG payment system. To qualify for the additional payments, the new service or technology must meet three criteria under the DRG system:

- Be considered “new” until such time as data are available to fully reflect the cost of the technology in the MS-DRG weights through recalibration – usually 2 to 3 years beginning with FDA approval;
- Be inadequately paid under the DRG system. The adequacy of payment is established based on a threshold for each MS-DRG (a list of qualifying thresholds by MS-DRG can be found in Table 10 of the Addendum); and
- Demonstrate a substantial clinical improvement over existing services or technologies.

In the FY 2006 IPPS final rule, CMS established certain conditions that would allow new technology add-on payments for the new use of an existing technology. Specifically, the new use of the existing technology cannot be substantially similar to the use of the existing technology. The final rule included two factors to consider in determining whether the two technologies are “substantially similar”: (1) whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome; and (2) whether the product is assigned to the same or a different MS-DRG.

The additional payment is based on the hospital’s cost for the new medical service or technology. Medicare pays the lesser of (a) 50 percent of the difference between the cost of the case with the new technology and the DRG payment, or (b) 50 percent of the cost of the new technology. Payments for new services and technology were initially subject to a budget-neutrality factor. However, the law was subsequently amended, and add-on payments from FFY 2005 forward are no longer budget-neutral.

In the FY 2009 final rule, CMS approved CardioWest Temporary Total Artificial Heart System (CardioWest TAH-t) for new technology add-on payment. The maximum add-on payment is \$53,000.

Proposed Rule

CMS proposes to continue new technology add-on payments for cases involving CardioWest TAH-t in FY 2010, with a maximum add-on payment of \$53,000.

As a result of an application the agency received regarding the CLOLAR® (clofarabine) Injection (see (2) below), CMS is proposing to take into consideration for “substantial similarity” determinations whether an existing service or technology has a new indication. Under this proposal, CMS would add the following factor to the two factors (discussed above) the agency

already uses to make its determination of “substantial similarity”: whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. Because, in the CLOLAR example, the device would be used to treat a different patient population than the pediatric population for which it was originally approved, CMS believes that the new indication is not substantially similar to the previous indication and that the device would therefore be eligible for new technology add-on payments.

The agency is seeking comments on the following five applications for new technology add-on payments:

1. The AutoLITT™ System

This device has not yet received FDA approval, but the manufacturer expects approval in early 2009. CMS is concerned that this device does not meet the newness criterion and is substantially similar to the device listed as its predicate device (Visual-ase), which was approved by the FDA in 2006. The agency also expressed concern about whether the device meets the cost criterion for new technology add-on payments, because the manufacturer did not determine a case-weighted average standardized charge per case by MS-DRG. Finally, given the lack of comparative efficacy data, CMS believes that there may not be sufficient objective clinical evidence to determine whether the AutoLITT™ System meets the substantial clinical improvement criteria.

2. CLOLAR® (clofarabine) Injection

This device received approval by the FDA and has been used since December 2004 for the treatment of pediatric (ages 1-21) patients. However, the device manufacturer submitted an application to the FDA for the first time in November 2008, for a new indication for the treatment of patients who are 70-years old or older. FDA approval is expected in May 2009.

When CLOLAR receives FDA approval for the new indication, its costs may not be reflected in the relevant MS-DRG, because the technology has not been used to treat Medicare patients for purposes consistent with the new indication. However, since this technology is not new to the market, CMS must determine whether the new indication of CLOLAR is substantially similar to the previous indication.

CMS is requesting comments on: (1) the agency’s proposed modification to its analysis of whether a technology is substantially similar to another to include consideration of whether the existing service or technology has a new indication; (2) whether the current FDA-approved indication of CLOLAR is substantially similar to that of the pending one; (3) whether the costs of the device are already included in the data used to determine relative weights for the MS-DRGs to which cases involving CLOLAR map; (4) whether the device meets the cost criterion; and (5) whether it represents a substantial clinical improvement.

3. LipiScan™ Coronary Imaging System

With regard to the newness criterion, CMS is seeking comments on whether this device is substantially similar to its predicate device (InfraReDx Near Infrared (NIR) Imaging System), which was approved by the FDA in 2006. According to the agency, both use the same or similar mechanisms of action to achieve a desired therapeutic outcome, both treat patients generally assigned to the same MS-DRG, and both indications of the device are intended to treat the same patient population.

CMS is also seeking comments on whether the device meets the cost criterion, given the small sample of cases (data was based on two hospitals that used the device).

The agency is also concerned with the lack of evidence and outcome data regarding the use of this technology and is seeking comments on whether it represents a substantial clinical improvement in the Medicare population.

4. Spiration® IBV® Valve System

Although the FDA approved this technology on October 24, 2008, the agency has precluded its use pending approval by the Institutional Review Board (IRB) regarding its study sites. CMS believes the device meets the newness criterion but is requesting comments regarding the date on which the newness period should begin.

The agency is also seeking comments on whether the device meets the cost criterion and represents a substantial clinical improvement for Medicare beneficiaries. The applicant used a small sample of cases to determine the charges associated with the device and a sample of only seven patients to present outcome data.

5. TherOx Downstream® System

This technology is expected to receive FDA approval in the second quarter of 2009.

CMS is seeking comments on whether this technology meets the cost and substantial clinical improvement criteria. With regard to the substantial clinical improvement criterion, the agency is concerned that the data presented by the applicant has not shown any specific improved clinical outcomes and has not been published in peer reviewed literature. Furthermore, CMS is concerned that there was a higher number of adverse bleeding events in patients in the treatment group.

XIII. PROPOSED CHANGES TO EMTALA WAIVER REGULATIONS (pages 432-40)

Background

The Emergency Medical Treatment and Labor Act (EMTALA), also commonly referred to as the patient “anti-dumping” statute, imposes certain obligations on Medicare-participating hospitals

regarding the examination and treatment of individuals who come to a hospital emergency department for examination or treatment of a medical condition. EMTALA also permits the temporary waiver of several of the Act's requirements in emergency areas during emergency periods. In the FFY 2008 and FFY 2009 final rules, CMS revised the regulations implementing EMTALA to incorporate changes to the waiver of sanctions provisions made by the Pandemic and All-Hazards Preparedness Act.

Proposed Rule

CMS proposes to amend the EMTALA regulations in the following three ways, to make them more consistent with the statute: (1) to permit waiver of EMTALA sanctions for inappropriate transfer and relocation only if the hospital does not discriminate based on the source of an individual's payment or ability to pay; (2) to permit the Secretary to apply a waiver of EMTALA sanctions only to a portion of an emergency area or to a portion of an emergency period; and (3) to require that the "inappropriate transfer" arise out of the circumstances that gave rise to the emergency.

Analysis

The regulatory changes generally appear to accomplish CMS's goal of aligning the statutory requirements with those of the EMTALA regulations. The AAMC believes the proposed language lacks clarity. CMS should consider language such as "the need for the transfer arises out of the circumstances of the emergency," rather than the proposed "the transfer arises out of the circumstances of the emergency." The AAMC welcomes COTH-member input on additional implications of these proposed changes.

XIV. PROPOSED CHANGES TO GOVERNANCE AND CONTROL CRITERIA FOR SATELLITE FACILITIES OF HOSPITALS (pages 466-70)

Background

A satellite facility is a part of a hospital that provides inpatient services in a building also used by another hospital, or in a building located on the same campus as buildings used by another hospital. Satellite facilities meeting certain regulatory requirements are exempt from the inpatient prospective payment system.

Proposed Rule

To eliminate an inadvertent inconsistency in governance and control criteria in two sections of the regulations, CMS proposes to add a separate governing body requirement to the satellite facility regulations. This will ensure that a satellite facility is not merely a unit of the acute care hospital with which it is co-located, but rather is organizationally and functionally separate from the hospital. Under the proposed regulations, the satellite facility may not be under the control of any third entity that controls both the hospital of which the satellite facility is a part and the hospital with which the satellite facility is co-located. The proposed rule includes a

grandfathering provision that would impose the new requirement only on satellite facilities established in cost reporting periods beginning on or after October 1, 2009.

XV. OTHER TOPICS IN THE PROPOSED RULE THAT MAY BE OF INTEREST TO AAMC MEMBERS

- Proposed Changes to the Long-Term Care Hospital PPS for RY 2010 (pages 486-577)
- Proposed Changes Affecting Critical Access Hospitals (pages 470-86)
- Geographic Reclassification Criteria (pages 260-71)

If you have any questions regarding the proposed rule or this summary, or additional issues of which we should be aware, please contact Jennifer Faerberg, jfaerberg@aamc.org (quality issues), Diana Mayes, dmayes@aamc.org (new technology and outlier payments), or Lori Mihalich-Levin, lmlevin@aamc.org (GME and all other issues). Any of these staff members may also be reached by calling 202-828-0490.