



June 12, 2006

BY HAND DELIVERY

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

Re: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of the 1,400 leading not-for-profit hospitals and health systems allied in Premier, I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Premier is a strategic alliance of approximately 200 independent, not-for-profit health systems that operate or are affiliated with more than 1,400 hospitals and healthcare sites nationwide. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the IPPS.

DRG CHANGES

Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our member hospitals and on all hospitals in the country, we strongly urge a one-year delay in implementing these policy proposals. More time is needed to review these complex proposals and to offer viable alternatives to the proposed changes discussed in the *Federal Register*.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing

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care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

The magnitude of these changes cannot be minimized. CMS would re-distribute about \$1.5 billion in Medicare payments across U.S. hospitals. Many of the hospitals that would lose revenues are among the leading institutions in the country, providing the best care available today as well as leading innovation to improve future healthcare.

Premier supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. We wholeheartedly support your initiative to make payments more accurate and fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. We have several serious concerns and comments, however, with the CMS proposal for calculating DRG weights and the proposed modifications to the DRG classification system.

Methodological Concerns

- CMS does not follow the cost-based methodology recommended by the Medicare Payment Advisory Commission (MedPAC) or the methodology used to calculate cost-based weights in the outpatient prospective payment system. Instead, CMS proposed a new and complex methodology which has not been tested or subjected to external review and analysis.
- The methodology proposed by CMS raises two very serious concerns. First, CMS trimmed the data in a crucial step of the calculation, with the result that hospitals representing 25 percent of total charges for routine care were thrown out even though they were retained in other parts of the calculation. Second, in computing national average cost-to-charge ratios, CMS did not weight by hospitals' volume of cases or charges. Not accounting for volume leads to a serious distortion of the national average.
- The proposed patient classification system incorporating severity adjustment needs refining for implementation and some details of the proposal were not available for review and comment. The grouping software should be made available so that hospitals can review how the proposed changes would affect their caseload, but this was not done apparently because the software is proprietary. We strongly believe that the grouping software used by Medicare should be in the public domain.

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- Because of the methodological concerns and the unavailability of the severity DRG grouper, hospitals and the public have not had the opportunity to review the proposals adequately and assess their financial impact. The table below illustrates our concerns regarding the methodology and the impact it would have on selected types of hospitals and selected DRGs.

IMPACT OF HSRVcc ON HOSPITALS, BY TYPE		CMS	Corrected
	Urban (2,517)	-0.5%	-0.3%
	Large Urban (1,391)	-0.2%	-0.2%
	Other Urban (1,126)	-1.0%	-0.5%
	Urban, At Least 300 Beds (580)	-1.4% to -2.1%	-0.8% to -1.2%
	Rural (1,005)	+3.0%	+1.6%
	Major Teaching (237)	-1.5%	-0.9%
	Specialty Cardiac (54)	-10.4%	-5.8%
	Specialty Orthopedic (73)	-3.3%	+2.9%
	Specialty Surgical (151)	-3.6%	-1.6%
IMPACT ON SELECTED DRGs OF HSRVcc		CMS	Corrected
558	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W/O Maj Cv Dx	-35%	-21%
557	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W Major Cv Dx	-26%	-15%
125	Circulatory Disorders Except Ami, W Card Cath W/O Complex Diag	-28%	-20%
124	Circulatory Disorders Except Ami, W Card Cath & Complex Diag	-19%	-14%
535	Cardiac Defib Implant W Cardiac Cath W Ami/Hf/Shock	-26%	-16%
536	Cardiac Defib Implant W Cardiac Cath W/O Ami/Hf/Shock	-25%	-13%

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Weight Calculation Methodology

- Premier supports a change from charge-based to cost-based weights accompanied by specific actions to address known limitations in the accuracy of the Medicare cost report data. Two shortcomings are particularly important. First is the problem of charge compression. To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost. Specifically, CMS converts charges to costs by "backing out" the *average*



mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of \$1,000 would be reduced to a cost of \$500 after adjusting for the mark-up.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock". This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and over-estimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates. Premier strongly believes that changing to cost-based weights must address the distortion caused by charge compression.

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- The other major issue with cost report information is the accuracy of the estimates of routine and ancillary costs. Studies comparing cost report information with information from sophisticated hospital accounting systems raise questions about the accuracy of the cost report data. An earlier ProPAC study, for example, found that the cost report overstated routine costs by more than 12 percent and understated ancillary costs by nearly 5 percent. This significant issue should be addressed as CMS implements cost-based weights. A one-year delay will provide the time needed to make improvements in the cost report system.
- Premier questions the accuracy of the hospital relative value (HSRV) method. We believe that accurately determined cost-based weights are the gold standard and that HSRV, distorts the cost-based weights. We note that cardiac surgery and cardiology services, especially interventional cardiology services, are performed primarily in the type of hospitals that are disadvantaged by the HSRV methodology. The weights for these services are disadvantaged by HSRV even though the hospitals performing them tend to mark up their charges for these services less than they mark up their charges for other services. In fact hospitals losing under HSRV have lower charges for these cardiac services than do hospitals which win under HSRV. HSRV disadvantages cardiac services because hospitals performing the preponderance of these services tend to charge more than average for typical



cases, therefore their charges for the very expensive cardiac cases are down-weighted in calculating the HSRV weights. In addition, cardiac services tend to be higher weighted services and thus are disadvantaged by the compression of the DRG weights that is a hallmark of the HSRV methodology.

Consolidated Severity-Adjusted DRGs

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In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG (CS-DRG) model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals. We especially note that numerous recent changes to improve the DRG classification of particular types of cases are not carried over to CS-DRGs. **We also note that case complexity, a significant factor in driving hospital resources, is not considered by the CS-DRG approach proposed by CMS. Page 24014 of the *Federal Register* notes that CMS will develop a plan to address this issue. We believe this should be addressed before implementation vs. after.** Hospitals need to know how resource use will effect payments. Also, we oppose a “behavioral” offset which will reduce payments even further before implementation of the consolidated severity-adjusted DRG and note that CMS should release details of any behavioral offset in any case.

Given the number and magnitude of issues in the proposed changes in DRG classification and weight calculation, Premier strongly urges CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY’08. The additional time will allow hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.



NEW TECHNOLOGY

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. **Premier also is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, as we have previously requested.**

We also are concerned about CMS' ability to implement add-on payments for new services and technologies in the near future or to make appropriate DRG classifications for new technologies. Unique procedure codes must be created and assigned to recognize new technologies and the ICD-9-CM classification system is close to exhausting codes to identify new health technologies. The ICD-9 system is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10) were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology, as required under the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.

To date, despite these recommendations, as well as the recommendations of several federal healthcare agencies and offices and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that absent a switch to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this looming problem will only impede the efforts to achieve President Bush's goal for an electronic health record by 2014.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, there were many impassioned discussions on the need to start limiting the

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creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories represented a deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g. musculoskeletal system, circulatory system, etc.) were available. The plan was to use codes in category 00 first and then begin populating chapter 17.

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Category 00 is now full, and the C&M committee is entertaining proposals for codes in category 17. At the April C&M meeting a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (e.g., cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one-and-a-half years. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule.

Thus, Premier strongly recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously. HHS should take the necessary steps to avert this crisis and avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than respond to a crisis that will likely result in unreasonable implementation timeframes. **It is imperative that the rulemaking process start immediately.**

Additional Payment for New Technologies

Premier supports CMS' proposal to continue to make new technology add-on payments for Endovascular Graft Repair of the Thoracic Aorta and for the Restore® Rechargeable Implantable Neurostimulator. We also urge CMS to approve new technology add-on payments for NovoSeven® for Intracerebral Hemorrhage. The technology is a drug that promotes hemostasis by activating clotting factors. Because the technology is not currently FDA approved, in the proposed rule CMS does not present an analysis on whether the technology meets the criteria for the new technology add-on payment in this proposed rule. However, CMS summarizes information submitted by the applicant on the cost and substantial clinical improvement criteria. Similar to the previous approval of Xigris, we believe that the availability of an add-on payment would help to facilitate patient access to this important and costly therapy.



PROPOSED CHANGES TO DRG CLASSIFICATIONS

1. Carotid Artery Stents

Medicare covers percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Federal Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. Most cases of carotid artery stents are assigned to DRGs 533 (Extracranial Procedures with CC) and 534 (Extracranial Procedures without CC). **Premier supports the idea that all carotid stenting cases should be assigned to DRG 533 only, bypassing DRG 534 and we disagree with the CMS decision not to make this change.**

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2. Insertion of Epicardial Leads for Defibrillator Devices

The ICD-9-CM Coordination and Maintenance Committee expanded the category of codes for defibrillators and pacemakers so that the codes for leads would no longer be restricted to pacemakers. This change would guide coders to use code 37.74 for the insertion of epicardial leads for both defibrillators and pacemakers. This change was adopted for the ICD-9-CM and will become effective on October 1, 2006.

Subsequently a commenter noted to CMS that this coding advice would restrict some defibrillator cases from being assigned to the defibrillator DRGs. The commenter recommended that the following combinations be added to DRGs 515, 535, and 536 so that all types of defibrillator device and lead combinations would be included: code 37.74 and code 00.54; code 37.74 and code 37.96; and code 37.74 and code 37.98.

Premier agrees with the CMS proposal to make this change.

3. Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs

In the FY 2006 IPPS final rule, CMS published a list of "major cardiovascular conditions (MCVs)". A patient with a condition on this list was expected to have a more complicated patient stay requiring greater resource use. An MCV can be present as either a principal or secondary diagnosis. In the same rule, CMS also adopted new DRGs 547 through 558 as an interim step to better recognize severity in the DRG system for FY 2006 until a more comprehensive analysis of the APR DRG system could be completed.

A commenter has questioned why CMS did not apply the MCV list to the defibrillator DRGs (515, 535, and 536) in addition to the pacemaker DRGs. CMS, however, did not propose additional refinements of the DRGs based on MCVs for FY 2007 in part because of their efforts to propose a broader refinement of the DRG system that would



focus on consolidated severity-adjusted DRGs. **Premier recommends that CMS reconsider recognizing MCVs in defining the defibrillator DRGs.**

4. Hip and Knee Replacements

In the FY 2006 final rule, CMS deleted DRG 209 (Major Joint and Limb Reattachment Procedures of Lower Extremity) and created new DRGs 544 (Major Joint Replacement or Reattachment of Lower Extremity) and 545 (Revision of Hip or Knee Replacement) because they found revisions of joint replacements to be significantly more resource intensive than original hip and knee replacements. After publication of the final rule, a number of hospitals and coding personnel advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) also includes codes that describe procedures that are not bilateral or that do not involve multiple major joints. The commenters recommended removing codes from DRG 471 that do not specifically identify bilateral or multiple joint procedures. **Premier agrees with the CMS proposal to make this change for FY 2007.**

5. Spinal Fusion

In the FY 2006 IPPS final rule, CMS created new DRG 546 (Spinal Fusions Except Cervical with Curvature of the Spine or Malignancy). After publication of the final rule, CMS received numerous suggestions including:

- Incorporate Bone Morphogenic Protein (BMP), code 84.52 into DRG 546.
- Apply a clinical severity concept to all back and spine surgical DRGs.
- Subdivide the spine DRGs based on the use of specific spinal devices such as artificial discs.
- Create 10 new spine DRGs.

Premier disagrees with the CMS position that it is premature to make changes at this time and we urge CMS to make the suggested changes in the final rule for FY 2007.

EXTERNAL DATA

Premier continues to be concerned about CMS' refusal to make use of external data, especially since these data sometimes are more complete and reliable than program data. We urge CMS to make greater use of external data as well as to facilitate public access to MEDPAR data. Although we very much appreciate timely release of the MedPAR file this year coincident with public availability of the proposed rule, Premier is very concerned that CMS does not make these data available quarterly as it has done

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previously. We made similar comments last year and are hopeful that this year CMS will have a favorable response.

QUALITY

Date for Beginning Collection of Expanded Measures

CMS should delay implementation of the expanded set of measures until July 1, 2006 discharges. The rule, as proposed, is problematic in that it would require hospitals to retroactively collect data on the expanded quality measures for patients who were discharged prior to the rule's implementation—as far back as January of this year. A delay would allow hospitals to allocate resources for this expanded data collection. Not all hospitals participating in Hospital Quality Alliance currently submit the Surgical Infection Prevention measures. A delay until July 1, 2006 discharges would allow hospitals to begin with the Surgical Care Improvement Project revised specifications.

Proposed Measure Expansion

The Institute of Medicine (IOM) report and the proposed rule discuss three measures from The Leapfrog Group (computerized provider order entry, intensive care intensivists, and evidence-based hospital referrals). On behalf of our hospitals, we support consideration of structural measures that meet quality measure standards such as evidence-based, clear operational definitions, delineated process for validation and auditing that ensures reliability (both within and across hospitals) and measure an area of quality within the control of the provider. **We do not believe the three Leapfrog Group measures discussed in the IOM report meet the quality measure standards necessary for inclusion in CMS national quality measurement initiatives.**

Validation

The parameters of the validation process should be stated explicitly and documented. This includes clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation specs and requirements were clear and well- documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and changes their attendant processes. **Premier proposes that any modifications to the technical processes be published 120 days prior to the effective/implementation date.**

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Further, Premier believes that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period.

An alternative method of data validation would be to use the monthly data points of each clinical measure and not rely on chart abstract. A proposed method of validation is to use a process similar to the quarterly Outlier validation Joint Commission requires of the core measure vendors. A monthly data point that exceeds three (3) standard deviations is considered an outlier. When an outlier is identified the hospital is requested to verify the data is accurate. This validation process relies on inter-hospital variability

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Joint Commission Initiated Outlier Analysis After Data Transmission

A negative outlier is defined by the Joint Commission as a quarterly data point that is greater than three standard deviations from the national average in a direction that indicates substandard performance. The national average and the standard deviation for the national hospital quality measures are calculated for the quarter using only those data points in the period that have a sample size greater than or equal to 30. The performance measure means and standard deviations will be made available quarterly to measurement systems and hospitals on the Joint Commission's extranet to use for quality improvement activities.

The type of standard deviation described above is based on what is known as inter-hospital variability. The inter-hospital variability is most useful for identifying data points that are "outliers" relative to a population of hospitals.

Since standard deviations and upper limits change from quarter to quarter based on the processing of retransmitted historical data for the hospital or other hospitals using the same measure, a past quarter may become an outlier that was not considered an outlier in a previous quarter's calculations.

Each quarter, after data transmission, the Joint Commission will identify any extreme outlier values that are of significant concern. Before we follow up with individual hospitals, it is critical that the accuracy of these extreme values is verified with the measurement systems. For this reason, measurement systems will review the identified outlier data points and identify one of three possible outcomes. They will confirm either that the values accurately represent the performance of each hospital, indicate that the values may be a result of the measurement systems computation issues, or verify that the values may be a result of hospital data quality issues, all of which will need to be addressed.

This process is efficient and can be completed in one month.



PLAN FOR HOSPITAL VALUE-BASED PURCHASING PROGRAM

Section 5001(b) of Public Law 109-171 (Deficit Reduction Act of 2005) requires the Secretary of Health and Human Services to develop a plan to implement a value based purchasing program for payments under the Medicare program for subsection (d) hospitals beginning with fiscal year 2009. Such a plan shall include consideration of the following issues:

(A) The on-going development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings; (B) the reporting, collection, and validation of quality data; (C) the structure of value based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the value based payments and; (D) The disclosure of information on hospital performance.

In developing such a plan, the DRA states the Secretary shall consider experience with such demonstrations that are relevant to the value based purchasing program. Premier is please to be collaborating with CMS on the Premier Hospital Quality Incentive Demonstration and looks forward to evaluating and reviewing the issues with CMS.

HEALTH INFORMATION TECHNOLOGY

While the need for automating the measurement process into electronic medical records (EMR) is a desired goal, the Premier HQI demonstration project is being implemented without the use of EMR. **It is more important to fix ineffective processes than to implement technology that supports retention of broken process systems.** Any lack of automation across the sector is no excuse for delaying quality process improvement. Finally, **any federal funding for physician or hospital information technology should come from “new money/funds” and not be mandated through the hospital conditions of participation.**

HOSPITAL-ACQUIRED INFECTIONS

Premier welcomes the increasing attention to the prevention of hospital-acquired infections (HAI), particularly the transparency of efforts involving both healthcare providers and consumers—we welcome evidence-based approaches to the prevention of adverse events in any healthcare setting. We believe that every effort should be made to eliminate HAIs by applying state-of-the-art science even as our hospitals care for sicker patients in an increasingly complex environment. We also recognize this is only accomplished in a culture of safety that promotes fixing systems over assigning blame.

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While zero tolerance of HAIs is a goal all our members endorse, it is important to be aware that systematic review of several studies demonstrates that the preventable proportion of HAIs ranges between 10 to 70 percent; for surgical site infections in particular, this range of preventable infections is between 40 to 60 percent.¹ We note the CMS Surgical Care Improvement Project (SCIP) goal in this regard is a target of 25 percent reduction in morbidity and mortality associated with surgical care.

After studying CMS' proposal, Premier agrees with the intent of the proposed change. We do not think that HAIs which could be prevented based on interventions developed from scientifically sound, evidence-based practices should receive higher payments.

As Premier participates in a variety of infection prevention strategies, we are pleased as well to acknowledge dramatic successes in infection reduction achieved by implementing an entire group (i.e., bundle) of evidenced-based practices. This strategy results in better outcomes than when each practice is implemented individually. There are numerous well publicized initiatives that demonstrate improved outcomes when all the right processes occur together. In areas specifically measuring HAI incidence, unprecedented reductions in rates of central line-associated bloodstream infections (CLA-BSI) and ventilator-associated pneumonia (VAP) for example, have been reported by hospitals participating in local, regional, state and national initiatives such as the Pittsburgh Regional Health Initiative, Maryland Patient Safety Center, Michigan's Keystone Center and others. However, even within these successful collaborations, HAIs occur despite near complete adherence with high quality, validated processes of care in the participating facilities. These findings suggest that additional studies are needed to elucidate other modifiable risk factors for HAIs. Such limitations of science-based interventions have implications for providers even with payer incentives for prevention.

Premier would like to focus on one of the most notable initiatives related to surgical site infection (SSI) –namely CMS's success using bundling in the Surgical Infection Prevention Project SIPP-- now developed into CMS's SCIP. SCIP has built its processes for preventing SSI from a series of widely accepted evidence-based (EB) guidelines including (1) the *CDC Guidelines for the Prevention of Surgical Site Infection* in which the literature is reviewed and categorized based on the weight of evidence in the recommendations²; (2) peer-reviewed guidelines on surgical antibiotic prophylaxis³; and

¹ Harbarth S, Saxa H, Gastmeier P. The preventable proportion of nosocomial infections: an overview of published reports. *Journal of Hospital Infection* (2003) 54, 258–266

² CDC. The "Guideline for Prevention of Surgical Site Infection, 1999" is available online at www.cdc.gov/ncidod/dhqp Published simultaneously in *Infection Control and Hospital Epidemiology*; *AJIC: American Journal of Infection Control* 1999;27:97-134

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(3) guidelines for antibiotic prophylaxis in cardiac surgery⁴. SCIP has already demonstrated that in *certain* patients, in *certain* procedures, SSIs *can* be prevented, and rates certainly reduced when such guidelines are applied. For example, in the initial SIP collaborative, a one-year demonstration project sponsored by CMS concluded that “the infection rate decreased 27 percent, from 2.3 percent to 1.7 percent in the first versus last three months.”⁵

Limitations

What we do *not* know from applying even the best of EB guidelines in prospective controlled trials is *–how many can truly be prevented* as such initiatives continue over time throughout all of our hospitals. Therefore, cases which could *reasonably have been prevented are only those in whom all evidence based practices have been followed and indeed no infection develops*.

We *do* know that thousands of our hospitals are demonstrating their determination to reduce infections by applying these guidelines systematically through participation in SCIP. In the selection of two conditions involving just surgical procedures, conditions already demonstrating good results when bundles are applied properly, the challenge will remain to avoid penalizing hospitals for a specific DRG grouping which cannot separate an identified HAI from associated co-morbidities associated with patients’ underlying conditions such as diabetes.

Using the example of SCIP, if a hospital-associated SSI was identified in a patient, the direct method to identify whether it was truly preventable would involve a review process to determine if the case met *all* the EB SCIP surgical measures currently applicable to that specific patient. If this SSI case analysis shows that the hospital did not implement and document all SCIP measures, the hospital would not receive the reimbursement rate for the associated CC.⁶ However, if the hospital documented that all possible processes were

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³ Bratzler et al. Antimicrobial Prophylaxis for Surgery: An Advisory Statement from the National Surgical Infection Prevention Project. CID 2004;38 (15 June) 1706.

⁴ Antibiotic Prophylaxis in Cardiac Surgery - Duration of prophylaxis. *Report from the Society of Thoracic Surgeons Workforce on Evidence Based Surgery*. ©2005 The Society of Thoracic Surgeons. approved exception for discontinuance of antibiotic prophylaxis. Available from <http://www.sts.org/sections/aboutthesociety/practiceguidelines/antibioticguideline/>

⁵ Dellinger EP, Hausmann SM, Bratzler DW, et al Hospitals collaborate to decrease surgical site infections. Am J Surg. 2005 Jul;190(1):16-7.

⁶ Nolan T, Berwick D. All-or-None Measurement Raises the Bar on Performance JAMA, March 8, 2006—Vol 295,1178-1171



applied, the hospital should not carry the financial burden for the patient’s SSI, since the hospital has complied with the ‘state of the art’ in terms of infection prevention. This approach would provide incentives to hospitals to apply all recommended practices, and would fairly reimburse cases for which a HAI develops *despite* adherence to such practices.

Such a process would permit learning more about what those “unknown factors” are that lead to infection even when there is adherence to all known EB practices. Hospitals could continue to use tools like root cause analysis to determine why some patients still develop infection despite applying all current scientific practices known to prevent infections. This approach would be viewed positively by patients, would encourage hospital staff to work even harder to improve, and most importantly would teach us even more than we currently know about infection prevention. This approach would also support accountability to the patient –the most important factor in this equation - while still promoting a learning environment in the hospital with regard to infection prevention.

However, this approach is impractical for numerous reasons; including the data analysis burden to CMS, as well as a hospital appeals process which would have to be defined and developed in order to fairly exclude individual cases from payment.

CMS will be challenged to determine the truly preventable infections and would not, and should not, penalize hospitals for what they cannot prevent or control. We would therefore suggest developing other approaches that do not rely on patient level data, but function as a proxy for patient-level review.

Recommended Approach

Premier proposes a measurement system that emphasizes adherence with systems and processes of care that have achieved a high quality of evidence demonstrating correlations with reduction in infection rates. Documentation of systems or processes is typically straightforward and subsequent analyses can be employed to determine correlation. These systems and the frequency of outcomes, such as SSIs, should use aggregate data to establish thresholds for when the DRG CC change is actually applied.

We recommend as one possible approach that hospitals should:

- Accept that patients with the selected condition may be identified as having a specific HAI (that may or may not be preventable).
- Accept that such identified cases will result in maintaining the lower-payment DRG *unless* they can provide measurable achievements that demonstrate the application of EB practices in a variety of initiatives. These can include any

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number of practices in the local, regional, state or federal levels. Thresholds could be developed not just for participation and reporting but actual levels of performance—even as CMS moves forward in its stated direction of “pay for performance.” Once again we refer to initiatives like PRHI, Keystone, and SCIP to learn what thresholds would be reasonable based on each community’s success and local patient populations.

This may not be the optimum moment to suggest the initial conditions that most closely correlate with preventable HAIs given CMS’s proposal to move to a consolidated DRG system, the complexities of coding and the need for expertise on coding and the DRG GROUPER. Premier is prepared to provide input as these processes develop and are implemented. CMS is aware of the multiple EB guidelines from CDC, and without listing them all at the moment, we offer a few other recent resources beyond the prevention of surgical site infections noted earlier.^{7 8}

What Premier has learned and can share is that the need to continually improve our members’ safety culture, working closer as teams and applying the evidence gained in studies are all key strategies to improve safety and quality of care. The processes are critical, intensive, and complex but rewarding in the achievement of greatly reduced incidence of infection.

We urge CMS to consider in this federal mandate continuation of CMS’ current direction that *rewards good performance*, supports hospital efforts to develop and maintain a non-punitive culture of safety, and yet provides the necessary accountability implied in the current Congressional budget language. Premier would ask that CMS link the proposed language to its current successful implementation of *process measurement* –even as the outcome of such processes is being validated in various methods.

We are eager to participate with CMS in the development of the final rule and more specifically with the development of indicators and systems to implement the rule once finalized. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

⁷ McKibben L, Horan, T, Tokars JI, Fowler G, Cardo DM, Pearson ML, Brennan PJ. and the Healthcare Infection Control Practices Advisory Committee* Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. *Am J Infect Control* 2005;33:217-26.

⁸ McKibben L, Fowler G, Horan T, Brennan PJ. Ensuring rational public reporting systems for health care-associated infections: Systematic literature review and evaluation recommendations *Am J Infect Control* 2006;34:142-9.

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In closing, Premier appreciates the opportunity to comment on the FY '07 IPPS proposed rule. Please do not hesitate to contact me, Margaret Reagan, corporate vice president of Premier at 202-879-8003 if you would like to discuss these comments further.

Sincerely,

A handwritten signature in black ink that reads "Margaret Reagan". The script is fluid and cursive, with the first letters of each word being capitalized and prominent.

Margaret Reagan
Corporate Vice President

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