



June 25, 2009

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RE: CMS-1406-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2010 Rates; Proposed Rule (Vol. 74, No. 98), May 22, 2009.

Dear Mrs. Frizzera:

On behalf of the Premier healthcare alliance serving more than 2,100 leading not-for-profit hospitals and health systems and 58,000-plus other healthcare sites, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2009 hospital inpatient prospective payment system (PPS) proposed rule. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. 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 inpatient PPS.

MS-DRG Documentation and Coding Adjustment

The TMA, Abstinence Education and QI Programs Extension Act of 2007 (P. L. 110-90) requires the Secretary to make certain coding adjustments in FY 2010 to 2012 based on the difference between the actual documentation and coding-related increase occurring in FY 2008 and FY 2009 compared to the prospective adjustments of 0.6 percent and 0.9 percent which were applied under the legislation. To determine the adjustment for FY 2010, CMS has actual data only from FY 2008. The proposed rule states that any documentation and coding-related changes occurring in FY 2009 will be addressed in the FY 2011 regulation.

In the proposed rule for FY 2010, CMS proposes to reduce the national standardized PPS amounts for FY 2010 by 1.9 percent to correct rates going forward so that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years. As described below, CMS calculated the total documentation and coding-related increase to be 2.5 percent, of which 0.6 percent was removed prospectively, leaving a balance of 1.9 percent to be removed from the rates for FY 2010.

To determine the proposed FY 2010 adjustment, CMS first compared the case-mix index (CMI) determined by grouping the FY 2008 claims data through the FY 2008 GROUPER (Version 25.0) with the CMI obtained by grouping the FY 2008 claims using the FY 2007 GROUPER (Version 24.0). This comparison resulted in a value of 1.028. CMS attributes the increase of 2.8 percent primarily to two factors:

- the effect of changes in documentation and coding under the MS-DRG system; and
- the measurement effect from the calibration of the GROUPER.

CMS then estimated the measurement effect due to the calibration of the GROUPER by dividing the CMI obtained by grouping cases in the FY 2007 claims data through the FY 2008 GROUPER by the CMI obtained by grouping cases in these same claims through the FY 2007 GROUPER. This resulted in a value of 1.003. To isolate the documentation and coding effect, CMS divided the combined effect of the changes in documentation and coding and measurement (1.028) by the measurement effect (1.003) to yield 1.025. Based on these results, CMS estimates the documentation and coding increase in FY 2008 to be 2.5 percent.

As noted, the standardized amounts for FY 2008 were reduced prospectively by 0.6 percent to account for expected documentation and coding-related increases. Because the actual FY 2008 increase of 2.5 percent exceeds the prospective adjustment by 1.9 percent, CMS proposes to correct the FY 2010 standardized amounts by reducing them by 1.9 percent. For sole community and Medicare-dependent hospitals paid using a hospital-specific rate, CMS previously has not applied a negative adjustment, and therefore proposes to apply the full adjustment of negative 2.5 percent in FY 2010 and beyond. For Puerto Rico hospitals, CMS states that documentation and coding-related increases were 1.1 percent in FY 2008. CMS has not previously applied a negative adjustment to these hospitals, and therefore proposes to apply the full adjustment of negative 1.1 percent to the Puerto Rico-specific rate, which accounts for 25 percent of payments to Puerto Rico hospitals. The remaining 75 percent of payments to Puerto Rico hospitals is based on the national standardized amount, to which CMS proposes to apply the 1.9 percent cut described above. CMS proposes to leave these adjustments in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS-DRGs do not lead to an increase in aggregate payments not reflective of an increase in real case mix.

Because data for FY 2009 are not available, CMS does not propose to adjust the FY 2010 rates to reflect actual case-mix experience in FY 2009. The proposed rule also does not propose to correct overpayments that occurred during FY 2008, citing its authority to delay making these corrections until FY 2011 and FY 2012. Premier applauds CMS for not proposing additional cuts at this time prior to obtaining and analyzing the FY 2009 discharge data. This is especially prudent given the current economic climate and lower-than-usual market basket update.

Premier understands the logic of CMS' determinations of the proposed adjustments for FY 2010 but is concerned that CMS has failed to account for real case-mix increase. As described in the FY 2009 proposed and final rules and reported in the proposed rule for FY 2010, the agency attempted to use Clinical Data Abstraction Center (CDAC) medical records data to distinguish documentation and coding changes from real case-mix changes, but found problems in the data. In the end, CMS did not use these data to estimate real case-mix increase trends. Much earlier studies performed by RAND had determined that real case-mix increase in the 1980's was between 1.0 and 1.5 percent, and the CDAC data would have provided information on real case-mix change in recent years.

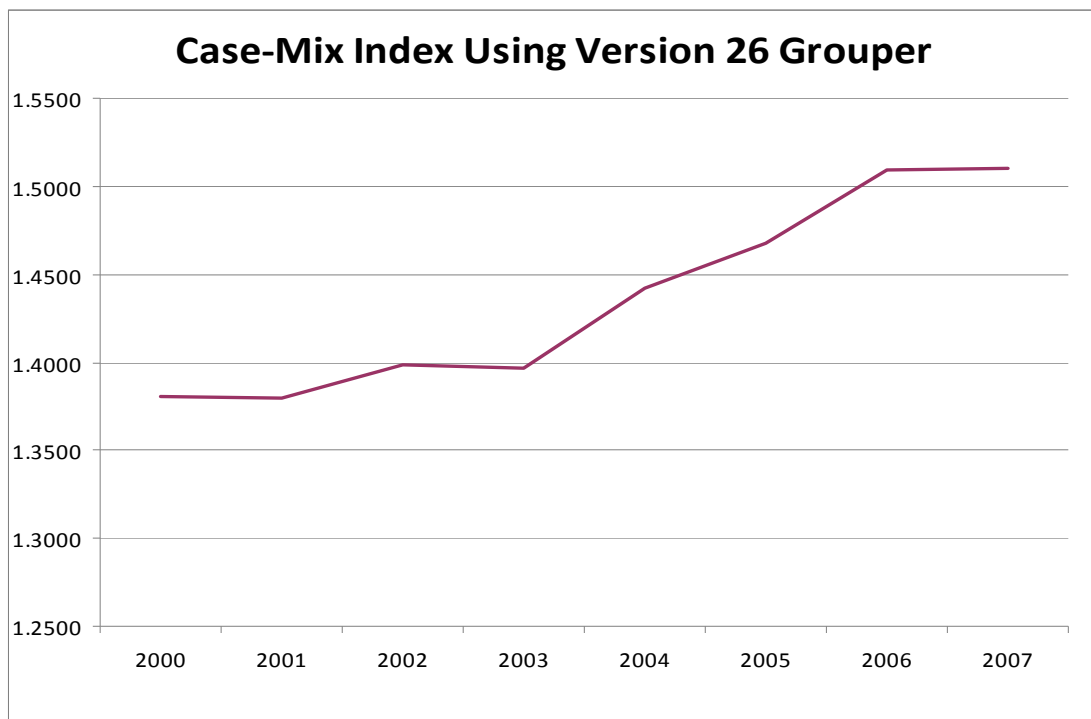
Unable to use CDAC data, CMS took another approach. It used the analysis described above showing that documentation and coding and GROUPER changes resulted in an increase of 2.8 percent. Combining this finding with a determination that overall CMI had increased 1.9 percent from FY 2007 to FY 2008, CMS inferred that real case mix was negative 0.9 percent, because the overall increase of 1.9 percent minus coding-related increase of 2.8 percent equals negative 0.9 percent. CMS further stated that a decline in real case mix is corroborated by the fact that there was an above-average relative decline in short-stay surgical cases that can be performed on an outpatient basis, such as certain high-volume pacemaker procedures.

Premier is concerned that the CMS conclusion about real case mix is inconsistent with other data showing an upward trend in the 1.0 to 1.5 range, the same as was found in the 1980's. As described in its comments on the proposed rule, the American Hospital Association (AHA) undertook further analysis of this issue, which is an integral part of CMS' proposed negative adjustment. AHA ran claims data from eight years, FY 2000 through FY 2007, through the FY 2009 GROUPER, which reflects the fully implemented MS-DRGs in order to develop a historical trend line for CMI. Because there were limited incentives for documentation and coding changes prior to the implementation of MS-DRGs in FY 2008 and because the analysis employed a constant grouper, the observed CMI change should reflect real case mix only.

The AHA analysis found that from FY 2000 through FY 2007, CMI increased by about 9.3 percent, or about 1.3 percent annually. During this period there was only one notable change that might have provided hospitals with an incentive to improve documentation and coding. In FY 2006, CMS replaced nine existing cardiac DRGs with 12 new cardiac DRGs that were based on the presence or absence of major cardiovascular conditions for cardiac patients undergoing

certain procedures. This change might have provided an incentive to improve documentation and coding. In order to account for the possibility that this change encouraged coding and documentation improvements, the AHA also looked at CMI increases from FY 2000 through FY 2005 – before either the new cardiac DRGs or the new MS-DRGs were implemented – and found that CMI increased by about 6.3 percent, or about 1.2 percent annually. These changes occurred steadily over the time period – there were not jumps in any one or two years that entirely accounted for the changes. Figure 1, below, provides a graphic depiction of the CMI changes from FY 2000 through FY 2007.

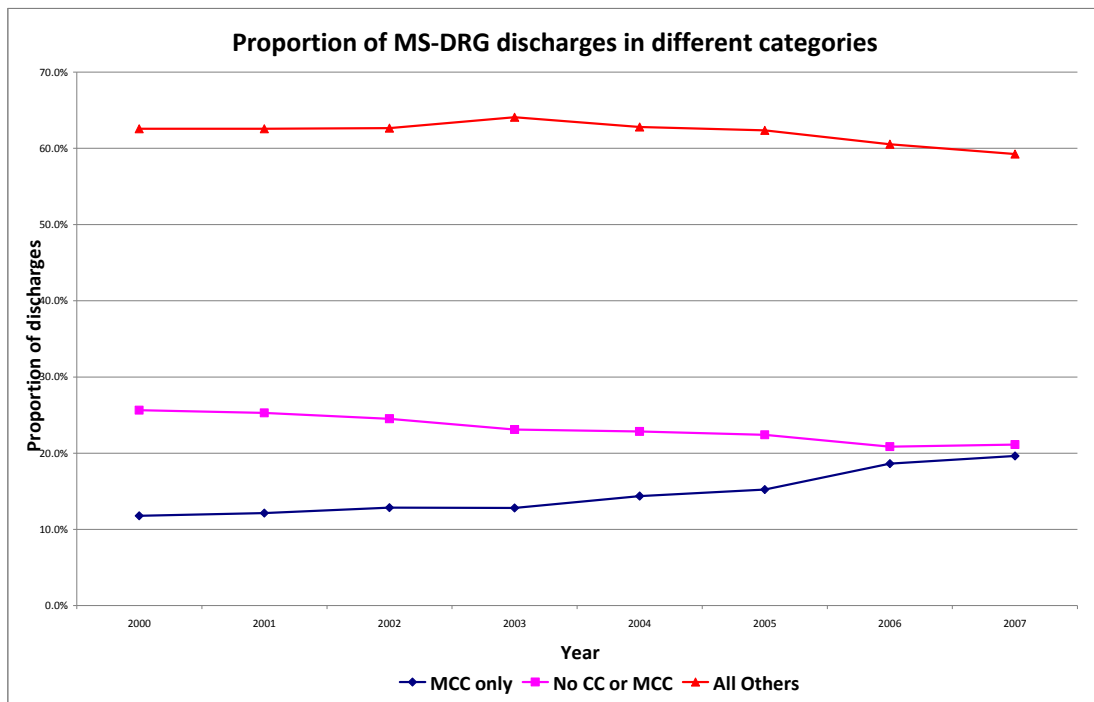
Figure 1: Case-Mix Index from FY 2000 through FY 2007 as Measured Using the Version 26 MS-DRG Grouper



The analysis performed for the AHA also examined changes in the mix of patients with and without major complications or comorbidities (MCCs) to analyze severity changes over this time period. The analysis found that the percentage of discharges for patients with MCCs increased from about 12 percent to about 20 percent from FY 2000 through FY 2007, while the percentage for patients without a CC or MCC decreased from about 26 percent to about 22 percent. These trends occurred steadily over the time period. Again, the results were similar for FY 2000 through FY 2005 – the percentage of discharges for patients with an MCC increased from about 12 percent to 15 percent and the percentage of discharges for patients without a CC or MCC

decreased from about 26 percent to about 22 percent. Figure 2, below, provides a graphic depiction of these changes in the percentage of discharges for patients with different severity levels from FY 2000 through FY 2007.

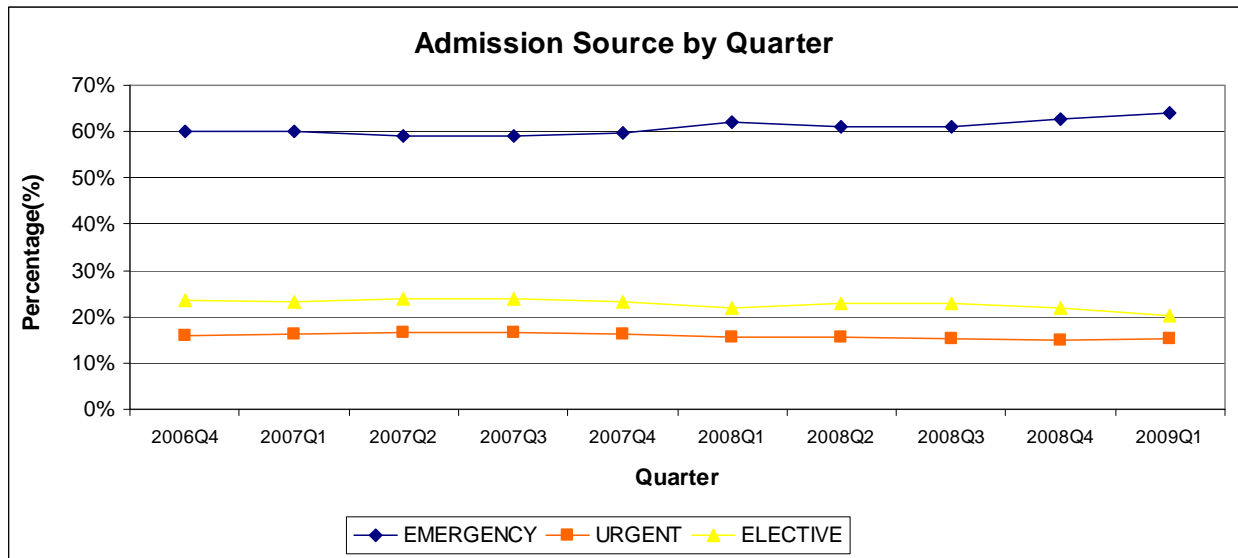
Figure 2: Percentage of Discharges by MS-DRG Severity Level from FY 2000 through FY 2007



To corroborate these findings on changes in case mix, Premier conducted analyses on our proprietary Perspective™ database that includes clinical, financial and operational data from nearly 700 hospitals to assess indicators of acuity within the Medicare population that are not based on diagnosis and procedure coding. Specifically, we looked at acute inpatients for acute care hospitals that had data across all quarters (332 hospitals across 39 states) in terms of admission source, length of stay and discharge destination.

A regression analysis found a significant increase in emergency admissions (type) of 0.42 percent per quarter or approximately 4.24 percent across the 10 calendar quarters ($p < 0.01$). As seen in the chart below, while emergency cases have increased, urgent cases have remained stable and elective cases have decreased. This suggests a shift from elective to emergent cases being admitted to hospitals. The emergency category excludes patients who, for instance, are transferred from nursing homes and suggests that more patients being admitted to hospitals are

arriving with a severely acute condition. Similarly, our analyses showed a small but significant increase in Trauma Center admissions (type) of 0.01 percent per quarter for a total of 0.10 percent increase across ten quarters ($p < 0.001$).



During the same period, the average length of stay (ALOS) remained remarkably stable. Previously, due to the payment incentives built into the inpatient PPS, ALOS decreased steadily for many years. According to an Avalere Health analysis of AHA annual survey data, the ALOS at community hospitals dropped from 7.2 days in 1987 to 5.6 in 2006. A regression analysis of our data shows a very small decrease of 0.017 days across each quarter, or 5.617 days to 5.451 days for a total of 0.17 days across the 10 quarters that is not significant (p -value 0.097). While a flattening of the ALOS does not prove an acuity increase, it does counter the notion that there has been a sudden decrease in acuity.

We also investigated whether patients were receiving more intense levels of post-acute care over this period. As shown below, there was no significant change in inpatient rehabilitation facility (IRF) or long-term care hospital (LTCH) use. However, there was a significant increase in skilled nursing facility (SNF) and in home health services, and a significant decrease in patients discharged to home or self care. The shift from patients receiving no post-acute care to receiving home health and SNF care also suggests that hospitals furnished care to more acute patients during this period.

Provider Type	% increase per quarter	% increase total	p-value
LTCH	0.01%	0.11%	0.308
IRF	-0.02%	-0.19%	0.054
SNF	0.12%	1.16%	0.002
HH	0.11%	1.14%	0.001
Home/Self care	-0.24%	-2.37%	0.008

Premier notes that it is impossible to ascertain exactly which portion of the case-mix increase experienced during the implementation of MS-DRGs was due to changes in the acuity of patients versus changes in documentation and coding. While CMS attempted reasonable analyses to differentiate between the two, CMS did not directly study changes in patient acuity and real case mix and instead established a conclusion concerning real case mix using an inference based on its estimate of documentation and coding and total case-mix change. Premier believes that this is an interesting conclusion, but it is not a robust one and not one that should be used to justify a 1.9 percent reduction in payments to hospitals. We recognize that the Premier analyses do not directly measure changes in the acuity of the Medicare patients treated by hospitals during this period, but we believe that they are additional indicators of acuity changes across time that are independent of MS-DRG coding. **Premier urges CMS to consider these indicators because we believe they show that it is unlikely that actual case mix decreased in 2008. Accordingly, we believe that a smaller portion of the increase in case mix should be attributable to documentation and coding than CMS proposed.**

Lastly, based on preliminary FY 2009 data from a subset of about 450 acute-care hospitals in our Perspective™ database, we see a flattening of change in overall case mix in the most recent quarters of data. This supports CMS' proposal to address only the FY 2008 changes in coding in this rule, and account for changes in the 2009 coding in FY 2011 and 2012. **As stated previously, CMS should only make adjustments for FY 2009 once final data are available for this period.**

CAPITAL PAYMENTS

CMS reiterates its plan to remove the adjustment to hospital capital payments for the costs associated with teaching residents in FY 2010 as initially finalized in the FY 2008 rule. If this policy is implemented, hospitals will lose \$350 million in FY 2010 and \$1.8 billion over 10 years. While CMS had planned to cut the adjustment in half in FY 2009, the American Recovery and Reinvestment Act of 2009 reversed this cut. **Given Congress' indication that this policy**

change is inappropriate and the particularly difficult financial pressures facing hospitals at this time, we believe CMS should repeal the removal of the teaching adjustment to capital payments.

The cut in capital-related payments to teaching hospitals that educate the next generation of physicians is short-sighted. Capital payments help hospitals invest in new equipment and facilities that can improve quality and reduce costs. CMS should be encouraging hospitals to make long-term investments in their facilities and information systems, not changing the rules in the middle of the game and renegeing on Medicare's share.

Premier is particularly concerned that these significant reductions in capital payments could have a highly negative impact on the adoption and dissemination of newer technologies, health information systems, electronic health records and scanning devices that are a critical part of healthcare delivery systems and improvements to enhance patient safety and quality of care. The proposed reductions could slow or reduce innovation. To justify the cut in the FY 2009 rule, CMS cites what it considers to be large inpatient capital margins over the period FY 1996-2005. The existence of positive margins is not justification to eliminate payment updates for several reasons:

- The capital prospective payment system is not, and was not designed to be, a separate payment system. Its structure and payment adjustments are based on regression analyses of *total* inpatient costs, not capital alone. HCFA (the predecessor agency to CMS) followed the 1991 recommendation of the Prospective Payment Assessment Commission (ProPAC) that hospitals should receive a single, combined payment for the capital and operating portion of their costs. Thus, while there are specific computation parameters for capital and operating, just as there are for labor and nonlabor, hospitals receive a single, combined payment. Moreover, the capital adjustments for factors such as wages, indirect teaching and disproportionate share were estimated using regression analyses of *total* costs, not capital costs alone.
- Capital investments occur in cycles and the development of the capital portion of the PPS envisioned that payments would exceed costs in some time periods. Hospitals were expected to set aside funds in anticipation of future capital needs, similar to how funded

depreciation reserves were used under the prior cost reimbursement system. These funds would permit future capital investment to be funded in part with equity financing rather than borrowing.¹

- Comments on the original proposed capital rule in 1991 suggested that Medicare permit hospitals to elect keeping the excess of capital prospective payments above inpatient capital costs on deposit with HCFA in interest bearing Medicare capital accounts. HCFA responded that deposits could be established with banking institutions, but that such actions by HCFA could be construed as involvement in hospital management practices. Again, however, HCFA recognized a capital cycle and noted that hospitals would establish funds for future capital investment.
- The goal of the capital PPS to sever the link between hospitals' capital costs and their Medicare payment is further indicated in this statement from the August 30, 1991 final rule, *“Under a cost-based payment system, hospitals have limited incentive to delay or forego a capital project because Medicare payments increase as capital costs increase and excess capacity is subsidized. Further, the current system favors debt financing over equity financing and capital investment over operating expenditures. By making Medicare's payment independent of a hospital's decisions with respect to the timing and financing of capital projects and by aligning the incentives of the capital payment system with those of the operating prospective payment system, we expect that hospitals will make efficient capital decisions.”*

An analysis of the capital prospective payment system that is not focused on total payments and total costs is flawed. MedPAC estimates overall average Medicare margins of *negative* 6.9 percent in 2009, meaning that the average hospital loses on every Medicare patient they treat regardless of whether their capital-only margins are positive. In addition, capital margins are likely to drop, as even without this cut, hospitals will not see an increase in capital payments in FY 2010 compared to FY 2009. Moreover, CMS does not plan to return the reduced payments to the base, but rather remove them from the system. This will result in further eroded total Medicare margins at a time when margins are already at an historical low.

¹ In the 1991 rulemaking to create the capital PPS, many commenters urged that Medicare's payment amount for capital should recognize the effect of age and financing variables on capital costs, but HCFA (the predecessor agency to CMS) stated in the August 30, 1991 final rule that it did *“not believe that it is appropriate to recognize the effect of age and financing variables on capital costs in the long run. We believe that the Federal capital payment should be independent of the timing and financing of capital acquisitions. Two hospitals that are identical, except that one recently purchased a new piece of equipment, while the other hospital is accumulating funds to purchase the same equipment, should not be paid differently for treating the same case. Further, two identical hospitals, one of which purchased a piece of equipment with funded depreciation, and the other of which financed the same equipment, should not receive different payments. By severing the link between Medicare payment and capital spending, we will provide neutral incentives with respect to the timing and financing of new capital acquisitions.”*

Hospitals face an incredibly tight capital market and are scaling back current projects. Additional cuts at this time will severely affect the ability of hospitals to build for the future and ensure that life-saving technologies are incorporated into projects. **Thus, Premier urges CMS to rescind its planned capital payment reduction, or at minimum, extend the transition and return the reduced payments to the base.**

QUALITY MEASURE REPORTING

In the rule, CMS proposes removing one measure, combining two measures, and adding four measures to the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program and payment in FY 2011. This brings the total number of measures required to receive a full payment update to 46. At the same time, CMS lists 69 candidate measures for payment in FY 2012. Premier is pleased that CMS listened to the concerns voiced by the field in last year's rule and has tempered the number of proposed measures for FY 2011, but we remain concerned about the volume of measures under consideration for FY 2012.

Measures for FY 2011

CMS proposes the following measures changes:

- Removes *AMI-6 Acute myocardial infarction patients without beta-blocker contraindications who received a beta-blocker within 24 hours after hospital arrival;*
- Combines *PSI-04 Death Among Surgical Patients with treatable serious complications and Nursing Sensitive Failure to Rescue* into a single measure and referenced as *PSI-04;*
- Adds *SCIP-Infection-9: Postoperative Urinary Catheter Removal on Postoperative day 1 or 2;*
- Adds *SCIP-Infection-10: Perioperative Temperature Management;*
- Adds *Participation in a Systematic Clinical Database Registry for Stroke Care;* and
- Adds *Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care.*

We believe that the SCIP measures are mature enough for public reporting and tying to payment as they are NQF endorsed and sufficiently field tested. We also believe they are based on sound evidence and hospitals can rely on clear guidelines to achieve the appropriate processes. However, we caution CMS to consider whether it is appropriate to adopt SCIP-9 in 2011 if it plans to implement the nursing sensitive measure, *Catheter-Associated Urinary Tract Infection*

(CA UTI), in 2012. These two measures work toward the same goal of reduced UTIs, and ultimately, we believe that the broader outcome measure should supplant the related process measure that is more likely to become outdated as science evolves. It would be burdensome, confusing and unnecessary for related process and outcome measures with the same objectives to continually feed into the program. CMS should build into its retirement framework a process for determining when related process measures should be removed in favor of broader, more robust outcomes measures. **Thus, Premier supports SCIP-10 in FY 2011 and supports SCIP-9 until a broad-based measure is implemented.**

We also do not believe that the two structural measures that assess participation in registries are necessary as Premier does not support the adoption of the associated registry measures in FY 2012. As discussed more thoroughly below, Premier believes that CMS should be working toward direct submission of data from hospitals' electronic health records (EHRs) to CMS rather than seeking to add intermediaries. We also believe that all measures included in RHQDAPU should be fully transparent so that hospitals can calculate their results on their own without having to pay a membership fee, purchase special software, etc. **Thus, Premier does not support the two registry measures for payment in FY 2011.**

Measures For 2012

CMS identifies 69 measures for possible inclusion in RHQDAPU beginning in FY 2012. The list includes measures pertaining to a range of areas such as stroke, venous thromboembolism (VTE), complications of care, healthcare-associated infections, timeliness of emergency care, mortality, surgical care improvement, cardiac and nursing sensitive care. While CMS provides more specific information than in last year's rule as urged by Premier, we further recommend that in the future CMS make the detailed measure specifications readily available in one location during the comment period so that the field can appropriately analyze and comment on the measures.

While we appreciate that CMS is sensitive to the burden of data collection and has proposed only four new measures for FY 2011, we remain concerned about the volume of measures being considered for FY 2012. We reiterate that CMS should continue to pursue a strategic implementation of measures and prioritize the measures according to their value in improving quality and reducing costs, their utility to beneficiaries, the level of burden imposed on providers and their readiness for implementation. As the number of measures in the program proliferates, we also ask CMS to consider whether a measure is an intermediate step on a process map of something already measured and/or likely highly correlated with another measure. The goal should be to avoid redundancy and integrate the measure that is, all things equal, closest to the outcome of interest to the patient. In addition, we propose CMS consider an assessment of the feasibility of constructing the measure from data contained in the typical hospital EHR, the degree to which the measure adds information not captured in other measures and the degree to

which the measure captures information on a “micro process” which might be subject to modifications subject to evolving medical evidence. **Then CMS should pick a manageable number of measures each year that meet these objectives and grow the program steadily.**

Measures Premier supports for the future with conditions

Premier supports the adoption of a subset of the measures below for FY 2012 assuming some recommended changes are made prior to then.

CMS proposes eight stroke measures:

- STK-1 DVT Prophylaxis for non-ambulatory stroke patients ischemic or hemorrhagic
- STK-2 Discharged on Antithrombotic Therapy – ischemic stroke
- STK-3 Patients with Atrial Fibrillation Receiving Anticoagulation Therapy after ischemic stroke
- STK-4 Ischemic stroke patients arriving ≤ 120 mins after onset of symptoms who receive t-PA within 180 mins of time last known well
- STK-5 Antithrombotic Medication By End of Hospital Day Two
- STK-6 LDL ≥ 100 or unmeasured or on anti-cholesterol medication on admission who are discharged on statin medication
- STK-8 Stroke Education
- STK-10 Assessed for rehabilitation

These evidence-based measures are currently used by The Joint Commission (TJC) for Primary Stroke Center disease certification and are consistent with the Stroke Get with the Guidelines program. Premier is also testing the following subset of these measures in the Hospital Quality Incentive Demonstration (HQID) project, focusing on the ischemic stroke population:

- STK-1 DVT Prophylaxis
- STK-2 Discharged on Antithrombotic Therapy
- STK-3 Patients with Atrial Fibrillation Receiving Anticoagulation Therapy
- STK-4 Thrombolytic Therapy Administered
- STK-5 Antithrombotic Medication By End of Hospital Day Two

- STK-6 Discharged on Cholesterol Reducing Medication
- STK-7 Dysphasia Screening
- STK-9 Smoking Cessation/Advice/Counseling

We have not encountered any difficulties with these measures as of yet, and hope to have more complete data in time for next year's rule to help inform CMS' final decision. However, we note that some data elements and allowable values for the TJC and Get with the Guidelines measures are not aligned with the National Hospital Inpatient Quality Measures (NHIQM) manual version 3.0a Stroke data elements. While we expect TJC Primary Stroke Center program to adopt the NHIQM measures in January 2010, we recommend that CMS work with these parties to ensure that all three entities are requesting the same information from the hospitals to avoid confusion and ensure more accurate measures are reported. We also urge CMS to assess whether changes need to be made in the specifications prior to implementation to ensure that these measures are consistent with those that CMS is testing for abstraction from EHRs to further reduce confusion. **If the results of the testing prove supportive, the specifications are harmonized and fully transparent, then Premier supports the inclusion of these measures in RHQDAPU in FY 2012.**

CMS proposes five venous thromboembolism measures:

- VTE-1/2: VTE Prophylaxis in received within 24 hours after initial admission to ICU or Surgery end time
- VTE-3: Patients with overlap in anticoagulation therapy
- VTE-4: Patients with UFH dosages who have platelet count monitoring and adjustment of medication per protocol or nomagram
- VTE-5: Discharge instructions to address: follow-up monitoring, compliance, dietary restrictions, and adverse drug reactions/interactions
- VTE-6: Incidence of potentially preventable VTE

Premier is supportive of CMS pursuing measures VTE-1, 2 and 3 in FY 2012, but does not support measures VTE-4, 5 and 6. The VTE measures are NQF endorsed, have clear guidelines on appropriate care, have been field tested, and detailed specifications are available. However what is listed as proposed measures in FY 2012 does not align with the VTE measures in the NHIQM manual effective with October 1, 2009 discharges. CMS should revise these measures in the final rule to align with the NHIQM title and specifications. **Assuming this is accomplished, Premier supports implementation of VTE 1, 2 and 3 in FY 2012.**

Premier is concerned by the granular level of information being reported in VTE-4 and VTE-5. Such levels of detail do not meet the objectives of the program, to encourage process change in hospitals to improve quality and to assist beneficiaries in choosing providers. In addition, such details are subject to frequent change depending on the available clinical and scientific evidence and may become outmoded. Therefore, Premier encourages CMS to focus on monitoring overall outcomes of care and metrics that broadly assess the reliable delivery of care, such as measuring a care bundle.

The measure VTE-6, “incidence of preventable VTE,” is inappropriately named and is not consistent with epidemiological principles. The epidemiologically correct definition of the incidence of preventable VTE is the number of “preventable” VTE / total number of patients at risk for preventable VTE. While it may be difficult, if not impossible, to determine what constitutes the true rate of preventable VTE, whatever may be adopted as the proper numerator for this metric (all VTE or a defined subset) the proper denominator is inarguably “all patients at risk for preventable VTE – not all patients failing to receive prophylactic therapy. It is more precise and epidemiologically sound to label VTE-6 as “Incidence of VTE in the group receiving no prophylaxis.” While we agree that it is more useful to providers and to the general public to report on the “incidence of preventable VTE,” that is not what the metric presented actually measures. The current mislabeling provides a specious definition of the metric, and it therefore threatens to provide disinformation to the public, who may, with good reason, misinterpret what is being communicated by the measure. **Thus, Premier does not support implementation of VTE 4, 5 and 6 in FY 2012.**

CMS proposes a total of eight hospital-acquired infections across the measure topics:

Measure Topic	Measure
HAI	Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)
HAI	<i>Clostridium difficile</i> infection (CDI)
Nursing Sensitive/HAI	Ventilator-associated pneumonia (VAP)
Nursing Sensitive/HAI	Catheter-associated urinary tract infection (CA-UTI)
Nursing Sensitive/HAI	Catheter-associated blood stream infections (CA-BSI)
Outcomes	Infection due to medical care
Outcomes	Post-operative sepsis
Cardiac Surgery	Deep Sternal wound infection rate

Premier is a “tier 1” partner with the Department of Health and Human Services (HHS) on its Hospital-acquired Infection (HAI) Action Plan and supported the six conditions chosen as the focus of the prevention targets in the HHS plan. As stated in the plan, catheter-associated urinary tract infections (CA-UTI), surgical site infections (SSI), catheter-associated bloodstream infections (CA-BSI) and ventilator-associated pneumonia (VAP) account for about 75 percent of the HAIs acquired in an acute care hospital setting. These four infections have the strongest

evidence and best practices for prevention. The seriousness of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* infection (CDI) warrant their inclusion on the list as well. While Premier supports these six conditions for the plan's purpose of establishing national goals, we do not believe that all of the conditions that overlap with CMS' proposal are ready to be added to the RHQDAPU program. Although we discuss some of the infections below, additional related comments are within the measure sets in which the infections were proposed.

Once NQF completes its measure maintenance review, Premier believes that CA-BSI and possibly CA-UTI will be ready for public reporting and tying to payment in FY 2012. The measures, particularly CA-BSI, have been thoroughly specified, are salient to consumers and hold important information for hospitals to use in their quality improvement programs. Premier is testing similar measures within our QUEST: High Performing Hospitals collaborative, which includes CMS representation on its advisory board, and will share results with CMS this coming year. We also note that the measures are part of the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN), and we urge CMS to adopt NHSN data elements and specifications if different from that of the American Nursing Association's measures. It is important that hospitals are able to continue using the NHSN software or other systems that report directly to NHSN without the need for manual abstraction of data to satisfy this requirement rather than having to join a registry. **We support *Central Line Catheter-Associated Blood Stream and Catheter-Associated Urinary Tract Infections* for payment in FY 2012 assuming the measures are fully transparent and hospitals do not have to join a registry to report the information.**

Measures Premier believes need substantial development before implementation

Unless significant advancements are made in the restructuring of these measures and their specifications, Premier does not support the inclusion of these measures in the RHQDAPU program in FY 2012.

CMS proposes 18 measures from the Agency for Healthcare Research and Quality (AHRQ):

- **Patient Safety Indicators (PSI)**
 - PSI-3 Decubitus Ulcer
 - PSI-7 Infection Due to Medical Care
 - PSI-8 Post-Operative Hip Fracture
 - PSI-9 Post Operative Hemorrhage or Hematoma
 - PSI-20 Post Operative Physiologic or Metabolic Derangement

- PSI-11 Post Operative Respiratory Failure
- PSI-12 Post Operative PE or DVT
- PSI-13 Post Operative Sepsis
- **Inpatient Quality Indicators (IQI)**
 - IQI-8 In-hospital Mortality for Esophageal Resection
 - IQI-9 In-hospital Mortality for Pancreatic Resection
 - IQI-12 In-hospital Mortality for CABG
 - IQI-13 In-hospital Mortality for Craniotomy
 - IQI-14 In-hospital Mortality for Hip Replacement
 - IQI-15 In-hospital Mortality for AMI
 - IQI-16 In-hospital Mortality for CHF
 - IQI-17 In-hospital Mortality for Stroke
 - IQI-18 In-hospital Mortality for GI Hemorrhage
 - IQI-20 Hip fracture mortality for Pneumonia

As noted last year, it remains unclear how data on patients from all payers would be collected and transmitted to the CMS data warehouse. TJC data vendors currently collect and submit most of the clinical data for the pay-for-reporting program; however, the vendors do not have the capability to process administrative data in a similar fashion. We also believe that the CMS Abstraction & Reporting Tool (CART) would need to be modified to collect these additional data, when it has already been unable to keep pace with reporting demands.

We also believe these measures are not sufficiently through the consensus building process. While the measures may have value to hospitals for internal quality improvement purposes, they currently lack the sensitivity and specificity required for use as comparative, publicly reported measures, especially the research-oriented PSI measures. Because they are derived from administrative data, they are less sensitive than measures derived from clinical chart abstraction at identifying relevant patients and excluding other patients. Some of the AHRQ indicators have very high false positive rates, meaning that they indicated potential problems, but further investigation showed the care was adequate and the indicator was wrong. Thus, these measures need extensive field testing and respecification.

CMS proposes eight hospital-acquired infections:

As noted earlier, Premier supports some of the HAIs proposed by CMS for inclusion in RHQDAPU, but does not support the inclusion of MRSA, CDI and VAP. Although we agree

that these infections should be the focus of the prevention targets in the HHS plan, we do not believe the measures are sufficiently developed for tying to payment. There is no question that MRSA, VAP and CDI cause major harm to patients and, in the case of MRSA and CDI, are a growing problem due to epidemic strains in the community. Premier has included VAP, CDI and hospital-acquired *Staphylococcus aureus* septicemia prevention as patient safety measures in our QUEST: High Performing Hospitals collaborative. We are also planning to include MRSA bloodstream infection in our next phase of work. We look forward to working with CMS in determining reasonable prevention rates and targets for hospitals regarding these infections through this research.

For CDI, we are concerned about the appropriateness of this infection for a number of reasons. Firstly, questions exist regarding the CDC preventability guidelines and there are concerns in the field regarding the difficulties in quantifying this condition in addition to its level of "preventability." There is still much to learn about the most accurate method to collect and report this information, since there are many issues related to establishing the timing of onset – that is, community-acquired or hospital-associated – as well as determining actual disease versus colonization. We agree that outbreaks due to transmission within hospitals are preventable by appropriate infection control precautions, but what is not well understood by providers and consumers is that cases will continue to occur in some individuals as an unintended and nonpreventable consequence following treatment with appropriate antibiotics or antineoplastics that are necessary to treat underlying conditions. In other words, sometimes CDI is a known side effect of following evidence-based care for patients that is weighed against the risk of not providing such treatments for the underlying condition.

While VAP is part of the HHS action plan, the final set of proposed plan metrics is not expected to include it because it is challenging to develop a robust definition using objective criteria for diagnosing VAP. Hospitals measure both VAP and MRSA for internal improvement processes. However, this does not mean that the measures are ready or appropriate for public reporting and tying to reimbursement in 2012. CMS should monitor the progress of the HHS-HAI plan to determine if meaningful definitions of VAP in ICUs emerge and if appropriate metrics for both MRSA and VAP develop that are useful for consumers and hospitals before it implements measures within RHQDAPU.

We note that the "Deep Sternal Wound Infection" rate, which has been listed as part of the cardiac registry measures for the past two years, is also an NHSN measure. We would be supportive of CMS considering this measure in the future if it is publicly available through NHSN and suggest that CMS might consider testing its ability to try receiving such data from CDC as discussed in the electronic health record section below.

We urge HHS to better define measures in this area, validate them and then field test them as part of its action plan before inclusion in the RHQDAPU program.

The Premier measure proposed for FY 2012, Comorbidities Adjusted Complications Index, is a broad-based measure that assesses a hospital's overall ability to avoid complications of many types. **We urge CMS to make the long-term goal to cultivate more global hospital-wide assessments of harm rather than targeting individual organisms or HACs as is its current practice.**

CMS proposes 11 nursing sensitive measures:

- Voluntary Turnover
- Practice Environment Scale-Nursing Work Index
- Hours per Patient Day
- Skill Mix
- Restraint Prevalence
- Pressure Ulcer Prevalence
- Catheter Associated Urinary Tract Infection
- Ventilator Associated Pneumonia
- Central Line Associated Blood Stream Infection in the ICU
- Patient Falls Prevalence
- Patient Falls with Injury

Some of the proposed nursing sensitive measures are currently under NQF measure maintenance review, thus CMS should not adopt these measures until the NQF process has concluded. In addition, we have reservations about the lack of evidence behind some of these measures, the data burden associated with them, and the fact that CMS already collects data on many of these conditions through its hospital-acquired condition policy. It is also unclear whether the measure data specifications, collection methods and measure calculation algorithms are fully transparent. If the measures are not fully transparent CMS should not integrate the measures in RHQDAPU. Per our earlier discussion, we note that a few of the measures are also part of NHSN and appear transparent through that mechanism, thus these measures could be adopted even if the other measures are not publicly available. **Assuming these measures are endorsed by the NQF and all methodologies are made fully transparent, Premier would consider supporting the adoption of a subset of these measures in FY 2012.**

If these measures are adopted, CMS should consider whether other highly related measures should be removed in favor of these more outcome based measures. For instance, CMS should consider removing SCIP Infection-9, a narrow process-oriented measure related to reducing UTIs, if it adopts CA-UTI. We suggest that CMS support only the broader *outcome* measure as it

would be burdensome, confusing and unnecessary for hospitals to report multiple measures with different requirements, when both have the same ultimate objective. Maintaining similar measures on different or overlapping patient populations will be confusing and burdensome to providers. The goal should be to create broader measures that apply across patient populations, are focused on outcomes and are meaningful to patients and clinicians rather than escalating the number of micro-focused process measures that are based on ever changing science. While this will take time, and more measures based on intermediate-processes will have to be adopted in the meantime, we urge CMS to consider this in its implementation plan for upcoming years.

Measures Premier does not support

Unless significant advancements are made in restructuring these measures and the transparency of their specifications, Premier does not support the inclusion of these measures in the RHQDAPU program.

CMS is proposing the addition of 16 cardiac surgery measures for payment in 2012 based on data from the Society of Thoracic Surgeons (STS) Cardiac Surgery Clinical Data Registry:

- Post Operative Renal Failure,
- Surgical Reexploration,
- Anti-platelet Medication at Discharge,
- Beta Blockade Therapy at Discharge,
- Pre-operative Beta Blockade,
- Anti-lipid Treatment at Discharge,
- Risk-Adjusted Operative Mortality for CABG,
- Risk-Adjusted Operative Mortality for Aortic Valve Replacement,
- Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair,
- Risk-Adjusted Mortality for Mitral Valve Replacement and CABG Surgery,
- Risk-Adjusted Mortality for Aortic Valve Replacement and CABG Surgery,
- Pre Operative Beta Blockade,
- Duration of Prophylaxis for Cardiac Surgery Patients,
- Prolonged Intubation,
- Deep Sternal Wound Infection Rate, and
- Stroke/CVA.

While we appreciate that CMS is looking for alternatives to reduce the reporting burden on providers, we do not believe this is the way to accomplish that goal. Our concerns are two-fold.

First, one of the cornerstones of RHQDAPU program is transparency. Public reporting of quality measures is only meaningful if the measures used are reliably comparable across all reporting institutions, which requires that institutions follow identical data collection protocols that are well specified. Consistent, identical data collection processes can only occur if the measure reporting and calculation mechanism is transparent and understood by all participants and by the public at large.

We are concerned that the monopolistic nature of methods used to derive some of the metrics in private registries could diminish the transparency of the program. While CMS does suggest that hospitals could submit data on their own to CMS, rather than through the registry, it does not mention any requirements that the entire registry data collection and measurement process be made public. **We believe that all aspects of the registry data specifications, collection and measurement calculation algorithms would need to be made publicly available before such data are integrated into the program.** This action would permit all parties to reliably replicate the measure(s) used for public reporting under the RHQDAPU program. If the information is not transparent, the data collected will not be comparable for public reporting as it will not be in the same format, using the same nomenclature. Specifically, transparency requires the following:

- The definitions for every element used in the program, including inclusion, exclusion and outlier criteria, must be defined and publicly available with enough specificity such that any participant can accurately and consistently collect this data using any methodology convenient to the institution.
- The methods used to calculate any secondary or derivative data elements from the primary data elements collected must be defined and made publicly available with enough specificity to allow institutions to calculate these measures in a consistent and comparable fashion.
- Any methods used to calculate expected values or to otherwise risk adjust the data must be defined and be made publicly available such that any institution could calculate these elements using primary or secondary data elements already specified, and do so in a timely manner without reliance on any one particular vendor or its products or services.
- Any definitions concerning outliers, groupings of data, or any other metadata must also be defined and be made publicly available if such data are required to derive or compute the publicly reported metric, the expected value for the metric, or any other derivative of the metric that may otherwise appear in public reporting.
- It must be practicable for institutions to collect and transmit data elements to CMS in a timely fashion without reliance on any one particular vendor or any proprietary products or services.

The measures from the STS registry proposed for addition in FY 2012 do not meet these transparency criteria. The 2008 NQF task force report on intellectual property even gives the STS registry as an example of measures they have endorsed, but the information provided “is inadequate for complete system evaluation by NQF and provides inadequate information for replication of the system by vendors and others.” STS has made the registry data elements available; however, the actual measure algorithms detailing how the data elements are used, derived values and other information are not in the public domain. Therefore, institutions are not able to calculate the measures in a consistent or comparable fashion. The STS specific risk factor elements are available; however, the detailed risk model specifications are not. The risk models are not transparent or in the public domain, and individual institutions would not have the ability to apply these models unless they joined the STS registry. Furthermore, the definitions of outliers and other information necessary for public reporting are not transparent. Therefore, adopting these measures for public reporting has the effect of creating a mandated monopoly.

Second, adding data submissions through registries will place yet another data abstraction burden on hospitals, even if they are already participating in the required registries. Many of the proprietary registries require significant manual abstraction of data, which is expensive and can be prone to error. Rather than continue to perpetuate a reporting environment that relies on manual abstraction of data, we would encourage CMS to evaluate measures that can utilize data that can be obtained through automated means. We strongly believe that for public reporting to be as robust and meaningful as possible, we need to repurpose data already collected in the course of care and contained in widely deployed hospital information systems. Continuing to ask hospitals to manually abstract more data adds a financial burden that is unsustainable and diverts attention from the intent of data collection – looking for opportunities to improve care outcomes, patient safety and care delivery efficiency. Specifically the majority of the data elements for the STS registry must be obtained by manual chart abstraction. STS participation requires a dedicated data manager and possibly other personnel to abstract data. Institutions participating in registries are abstracting the same medical record multiple times; quality staff is abstracting for current RHQDAPU measures, and the STS Data Manager for the registry review.

In addition, many hospitals are attempting to consolidate their quality, safety and efficiency reporting capabilities into a more centralized approach. This not only is a more efficient means to support public reporting, but also encourages looking at the interrelationships between disease states on the “whole patient,” rather than a focus on a specific diagnosis. By their nature registries tend to be focused on narrow disease populations, are often managed by decentralized specialty departments, and rely on highly specific data abstraction skills which are not easily transferable to other patient populations. Since multiple registries could be required to support reporting, relying on registry data fragments data collection, results in duplication of effort and resources, and splinters the internal analysis of improvement opportunities. The proliferation of

registries to support quality reporting is likely to add costs and inefficiency to the system, precisely at the time when many of our hospitals are attempting to improve the efficiency of their processes.

CMS has gone down this road before with the Implantable Cardiac Device (ICD) registry requirement. Hospitals began submitting data directly to QualityNet using an online tool, but in 2006 CMS discontinued this tool and transitioned the ICD reporting to The American College of Cardiology – National Cardiovascular Data Registry's (ACC-NCDR's) ICD Registry. Although this registry offers a free online tool, there are still the following registry participation requirements that mandate resources from the hospitals:

- Participation fees,
- Data Manager for chart abstraction and submission,
- Office space and computer hardware, and
- Another set of submission timelines for hospitals to keep track of and meet.

We are concerned that the use of registries will not reduce the burden on hospitals for data collection and could actually increase it. Further, requiring participation in registries to comply with public reporting may unintentionally encourage the proliferation of registries, which will decrease rather than increase efficiency.

Thus, Premier does not support the use of STS or other registry data that requires use of mandated monopoly methods in the inpatient RHQDAPU program at this time. CMS should seek other mechanisms to collect and report such cardiac measures.

More information necessary

We do not have enough information at this time to appropriately comment on the measures below. CMS should provide additional information, such as results of field testing, on these measures in next year's rule if it still believes at that time that the measures are ready for integration into the program.

CMS proposes one readmission measure:

- Percutaneous Coronary Intervention (PCI) 30-Day Risk Standardized Readmission Measure (Medicare patients).

Premier is in the preliminary stages of testing three similar measures for CMS within its HQID project. However, this testing will not be complete for at least another year. Thus, it is unclear if these measures are ready for inclusion in the program. However, CMS should continue to track these measures for subsequent inclusion.

CMS proposes two ED-Throughput measures:

- Median time from admit decision to time of departure, and
- Median time from arrival to time of departure.

The ED-Throughput measure specifications are in the NHIQM 3.0a manual; however, there are no sampling specifications. As this measure set applies to all acute care inpatients, data collection would be a substantial effort without the sampling specifications. CMS needs to provide the sampling specifications so the hospitals can have experience with collecting these measures.

CMS proposes one SCIP measure:

- Short half-life prophylactic administered preoperatively redosed within four hours after preoperative dose.

Without measure specifications available, Premier is unclear whether the SCIP redosing measure uses data elements that are already collected for the SCIP Measure set. If this is the case, Premier would support its adoption in FY 2012. If not, Premier believes this is additional burden without much additional information for consumers and hospitals.

CMS proposes three other measures:

- Lower Extremity Bypass Complications,
- PCI Mortality, and
- ICD Complications.

While it may be worthwhile to consider these measures, without the specifications it is difficult to assess the data collection and improvement possibilities associated with these measures. We urge CMS to provide additional detail in the FY 2011 rule.

Proposed Chart Validation Requirements

For FY 2011, we support the proposed change to the Clinical Data Abstraction Center (CDAC) contractor chart request process that would require chart requests to be sent via certified mail and the second notification at 30 days if records have not been received by CDAC. In the past, hospitals have unfairly failed validation because the chart requests were never received. We appreciate CMS' effort to provide hospitals with a transparent and documented process.

For FY 2012, we support the proposed change from the current chart validation process that requires five records per quarter from every hospital to 12 charts per quarter from a random sample of 800 hospitals with a minimum of 100 total charts. This more targeted approach will assure that all topic areas are validated. While it increases the number of charts required, it reduce the number of *times* hospitals have to provide charts. We encourage that the results of these validations be shared with *all* the hospitals, not just those sampled, including educational and data element clarification.

CMS also proposes to assess the accuracy of the hospital's *measure rate*, as opposed to the accuracy of the *individual data elements*. It is appropriate to focus on the hospital's measure rate, because it captures the information that is truly important to patient care. For data validation in the current program, there have been several instances in which a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, have caused hospitals to fail validation. **Validating the hospital's measure rate should eliminate hospitals failing validation due to an error in a field unrelated to patient care.**

In addition, to pass validation, CMS proposes that hospitals meet a minimum of 75 percent reliability from the chart validation instead of the 80 percent match rate currently used. **We support setting a slightly lower validation threshold for the beginning years of the new validation process as hospitals and CMS gain experience with the new system.**

For FY 2013 CMS requested specific comments about criteria for targeting validation:

- A high number of years a hospital was not randomly selected for annual validation;
- Consistently high measure denominator exclusion rates resulting in unexpectedly low denominator counts;
- Consistently high measure rates, relative to national averages;
- Small annual submission number of cases in previous years resulting in hospital exclusion from RHQDAPU program validation sample; or
- Failing multiple previous years' RHQDAPU program validations.

We urge CMS to refine the validation selection process so that hospitals selected for validation in one year are not eligible for selection again until two years later. Alternatively, CMS could ensure that no hospital is selected more than two times within a five-year period. This will help make certain that any particular hospital is not disproportionately burdened by the selection process. Additionally, CMS should consider allowing hospitals that pass validation with a very high score to receive a "pass" from the validation process for several years. Such a policy will encourage hospitals to ensure their data are as accurate as possible and reward those hospitals with high accuracy rates. Conversely, targeting consistently high measure rates, relative to national averages, will misdirect validation to the high-performing hospitals.

Electronic Health Records

CMS proposes testing electronic health records (EHR)-based submission of the emergency department efficiency, stroke and venous thromboembolism measures using the interoperable standards scheduled to be finalized in late calendar year 2009. CMS anticipates having the technical ability to accept the EHR-based data by July 1, 2010. We fully support CMS' efforts to move toward electronically abstracted and transmitted quality measures for the RHQDAPU program, which will greatly reduce the burden associated with this program. However, we have some suggestions for both a long-term strategy and how CMS can start down this path.

As you are aware, EHR adoption is increasing and is likely to accelerate due to the reimbursement incentives included in ARRA. An EHR contains in electronic form all of the information associated with the care of a patient. Currently, however, much of the data needed to submit designated quality measures for RHQDAPU is difficult to access via an automatic extraction. Due to the proprietary nature of the EHR systems in use and lack of standard definitions for both data elements and clinical concepts, it is still necessary for a nurse (or other qualified clinician) abstractor to read and interpret the data in the EHR and transcribe that interpreted data into a quality measure reporting tool. These tools, available either from CMS for no cost or from various commercial vendors for a modest fee, contain the current algorithms, sampling logic and data integrity checks required to process the data before submitting it to CMS.

CMS' proposed testing of EHR-based submission of three sets of measures is a step in the right direction. But the proposal builds on the existing RHQDAPU system rather than using this as an opportunity to truly leverage the possibilities the EHR presents for improving the quality and efficiency of healthcare. In other words, the current proposal suggests the automation of the current "manual" process of data abstraction and submission. Rather than re-specifying existing measures to work within an EHR, CMS should contemplate viewing "measures" as expressions of evidence-based care that can be embedded, in a standard way, into the clinical decision support, order sets and clinical protocol components of the EHR to remind clinicians of the best practice. The EHR could then "monitor" compliance with the evidence-based care standards and report compliance rates directly to CMS. This approach will also readily support ongoing research into the true efficacy of specific evidence-based standards, as outcomes and cost can be compared between patients treated according to the standards and those who were not.

For this approach to be successful, more than the syntactic (i.e., transaction format) and semantic (i.e., vocabulary) standards that are the current focus of the standards efforts will be needed. This approach needs standards to go one step further – to define key clinical concepts (e.g., prophylaxis antibiotics) in a way that is transferable from system to system – perhaps publishing them as a library of concepts available to all. These clinical concepts would be like

building blocks that will enable different evidence-based approaches to care (e.g., pre-operative use of antibiotics) to be defined or “constructed” in a way that is reliable, consistent and comparable.

Work on this approach is currently being pursued by the Health Level Seven (HL7) standards development organization within the context of the Quality Reporting Document Architecture and is supported by The Collaborative for Performance Measure Integration, which is working on the Health Quality Measures Format (<http://code.google.com/p/hqmf/>).

We encourage CMS to define and commit to a long-term vision and strategy for automating the reporting of quality measures that takes full advantage of the opportunities EHRs offer rather than automating the existing process. CMS should consider the work being done by HL7 and others, referenced above, as input into this long-term plan. Premier also encourages a more intense collaboration with standard setting and certification bodies to provide an interoperable environment for hospitals to automate data submission in a reliable and cost-effective way. The ever-increasing reporting requirements from multiple organizations only compound the burden on hospitals.

Premier also suggests that CMS consider, as a means to streamline reporting, testing its ability to accept electronic transmission from other federal agencies such as the Centers for Disease Control and Prevention (CDC). Premier’s SafetySurveillor™ tool is able to automatically abstract data from hospitals’ data and electronically transmit that data to CDC’s National Health Safety Network. To continue reducing hospital burden, CMS should work with its sister agency to capture that data without providers having to transmit the data a second time.

While we believe this process needs to evolve over time, we recognize that CMS needs to create a system to accept electronic transmissions from EHRs expeditiously. **Thus, we support the testing of electronic submission of a subset of both the Stroke and venous thromboembolism (VTE) measures from EHRs in FY 2010 (see measure comments above). However, we do not recommend testing the ED throughput measure as this information is most often housed in hospitals’ outpatient systems that may or may not be linked to their inpatient systems.** We also suggest that CMS seek input on alternative pilot measures that can more readily be accommodated by existing technical standards that could then evolve into the process described above.

AREA WAGE INDEX

Labor-related share

The labor-related share, or the portion of the standardized amount that is affected by the hospital wage index, is an estimate of the average proportion of hospital operating costs that are subject

to local labor market prevailing wages and are attributable to wages and wage-related costs. CMS reviews and recalibrates the labor-related share in cycle with the market basket rebasing every four years.

In preparation for the FY 2010 rule, CMS conducted an optional survey of hospitals to determine the proportion of services in each cost category that is typically bought by hospitals from vendors in their local wage area, and services that are bought from vendors outside their wage area or outside their state. Using the survey results and applying them to the cost category weights from the FY 2006-based inpatient PPS market basket, CMS proposes to *decrease* the labor-related share to 67.1 percent from the current 69.7.

The bulk of this reduction is caused by CMS' proposed treatment of professional fees, a category that includes fees for accounting and auditing services, engineering services, legal services, management and consulting services, and home office costs. Specifically, CMS proposes to treat the professional services bought in the local labor market (3.6 percent of costs) as labor-related and those bought from professionals outside their labor market (5.8 percent of costs) as nonlabor-related. If CMS continues using the existing market basket methodology, the labor share would increase from 69.7 percent in FY 2009 to 72.8 percent in FY 2010.

Premier is opposed to the proposed changes to professional fees in establishing the labor-related share. Without CMS providing additional details on their methodology and survey participants, Premier is concerned that CMS' sample of 108 hospitals is not adequately representative of all hospitals and insufficient for statistical significance. Further, because the survey was optional, there could have been systematic response bias in the data. We believe that most purchased professional services are purchased from firms in large cities, which tend to have high prevailing wages and, in many cases, may actually be higher than the prevailing wages for the area in which the hospital is located. We also believe that professional services, no matter where the services are purchased, are substitutes for hospital-employed staff and should be included as labor costs. **Thus, Premier does not support CMS' proposal to reduce the labor-related share based on a change in the treatment of professional services.**

Occupational mix

The law requires the collection of hospital data every three years on the occupational mix of employees in order to construct an occupational mix adjustment to the wage index. Premier recommends that CMS utilize calendar year 2010 for the next Occupational Mix Survey Collection, as opposed to the 12 months ending June 30, 2011. The reasons for this recommendation are as follows:

- This would allow for hospitals to have more time to collect and review the data prior to submission, increasing the collection percentage as well as the accuracy of the data. We

would recommend that the deadline to submit be expanded from two to five months after the survey period ends. This is consistent with the cost report deadlines.

- The fiscal intermediaries (FI) and Medicare Administrative Contractors (MACs) review and collection time could also be increased by an additional three months, with the hospitals having five months to submit the data. This should also increase the accuracy of the results and give the FI/MACs more opportunity to follow up with providers that did not submit data. A step could even be added to contact hospital associations, similar to the existing process for the wage index development timetable.
- The collection period should be for payrolls paid during 2010 so that it will match the data submitted for payroll tax returns.
- A calendar year collection would simplify collection for some hospitals, since data must be accumulated on a calendar year basis for payroll tax reporting.

CMS should also add an additional category for all other nursing to the upcoming survey. The all other nursing category would be helpful in refining the survey in the future. It should include all employees in the specified cost centers who are not in the specific categories. This will allow CMS and others to quantify the percent of nursing cost center employees that are not covered under the survey categories by hospital and nationally. This can direct future efforts to identify whether additional categories should be added to future surveys.

NEW MEDICAL RESIDENCY PROGRAM

Medicare regulations define a “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.” The rule clarifies that a medical residency training program cannot be considered “new” in determining its residency caps if it is the reaccreditation of a previously existing program at the same hospital *or* another hospital. 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.

It is longstanding practice that hospitals rely on the opinion of the accrediting bodies to make this determination. We are concerned that CMS is shifting this determination responsibility to the hospitals without clear guidelines and a mechanism to get formal CMS approval *before* the hospital begins operating the program and is subject to overpayments. **We urge CMS to leave the existing policy of relying on the accreditation bodies’ determination in place. If CMS chooses to finalize this new policy, then we recommend it establish a more definitive prior**

approval process, so that hospitals may have certainty with regards to the status of their new programs. We also urge CMS to clarify that this policy will not be instituted retroactively.

We support CMS' proposal to allow new programs to submit affiliation agreements after the July 1 deadline so long as the agreements are submitted before the end of the applicable cost reporting period.

EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

CMS proposes altering the regulations related to the waiver of Emergency Medical Treatment and Labor Act (EMTALA) requirements during a public health emergency and clarifies:

- Waiver of sanctions only if inappropriate transfer arises out of emergency,
- Waiver of sanctions only if hospitals do not discriminate on the basis of an individual's ability to pay, and
- Secretary has right to apply policy to only a certain portion of an emergency area or a portion of the emergency period.

Premier agrees that waiver of EMTALA sanctions should not apply if the provider discriminates based upon insurance status in determining which patients to transfer. We further agree with CMS' assertion that it has the authority to target EMTALA waivers to only those hospitals that need this flexibility due to the circumstances of the emergency and its impact on individual hospitals or groups of hospitals. This will allow the Secretary to make the decision to waive EMTALA sanctions in a more expeditious manner when a public health emergency is declared.

However, Premier is concerned that the new regulatory language asserting that the waiver of sanctions would only apply if "***the transfer arises out of the circumstances of the emergency***" could be interpreted to only apply to a patient whose emergency medical condition is the *direct* result of the public health emergency. This change is inconsistent with congressional intent and will be interpreted too narrowly to be useful for hospital emergency response in a public health emergency.

The Social Security Act states, "a transfer of an individual who has not been stabilized in violation of subsection (c) of such section ***if the transfer is necessitated by the circumstances of the declared emergency*** ..." Thus, we believe the flexibility bestowed on the Secretary does not hinge on whether the patient's emergency medical condition is tied to the declared emergency, just that the hospital's need to transfer patients to another facility in a way that may be

inconsistent with an “appropriate” transfer under EMTALA is a result of the circumstances of the emergency. For instance, the hospital may be operationally disabled and unable to perform its mission due to overwhelming numbers of patients, structural damage, utility failure or staffing shortage. In such circumstances, the hospital should not have to consider the source of a patient’s illness or injury in order to carry out a transfer that is in the best interest the patient and hospital emergency response.

To address this, we recommend that the regulatory language more closely mirror the language in the Social Security Act and recommend that CMS revise the proposed regulatory language to read, “(A) If relating to an inappropriate transfer, *the transfer is necessitated by the circumstances of the declared emergency.*”

NEW TECHNOLOGY / ICD-10

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.

CMS applies three criteria to determine whether a new technology qualifies for a add-on payment. The technology must be new within the last two years, have substantial cost and represent a significant clinical improvement. In reviewing whether applicant technologies, CMS applies the criteria sequentially and only gets to the substantial clinical improvement criterion if the technology meets the newness and cost requirements. In the past, CMS has denied applications for new uses of existing technology when the original use was approved more than two years in the past.

In the proposed rule for FY 2010, CMS acknowledges that approval of an existing technology as “new” may be warranted under certain circumstances when approved by the FDA for a new indication. The proposed rule includes an extensive discussion of this issue. In determining substantial similarity, CMS notes that they currently consider (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, and (2) whether a product is assigned to the same or a different DRG. In this proposed rule, CMS suggests a third criterion. Specifically, CMS states that it may also be appropriate to consider whether the new use involves the treatment of the same or similar type of disease and the same or similar patient population compared to existing uses of the technology. If all three criteria were considered and the new use were deemed substantially similar to one or more of the existing uses of the

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technology, CMS would conclude that the technology is not new and, therefore not eligible for the new technology add-on payment. If, however, the third criterion is not satisfied because the new use involves the treatment of a different type of disease and patient population compared to existing uses of the technology, then the technology may satisfy the newness criterion. Under current CMS policy, such a technology would have failed the newness test.

Premier supports adding the third criterion to the newness test and commends CMS for proposing it.

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.**

Premier has also urged CMS to facilitate public access to MedPAR data through the quarterly release of data. **We urge CMS to routinely release quarterly data in a timely fashion**, as it allowed in the past, so that interested parties have sufficient time to analyze the data and prepare more informed comments.

In closing, Premier appreciates the opportunity to submit these comments on the FY 2010 inpatient PPS proposed rule. Please do not hesitate to contact Danielle Lloyd, senior director for reimbursement policy, at 202.879.8002 if you would like to discuss further.

Sincerely,

A handwritten signature in black ink, appearing to read "Blair Childs". The signature is fluid and cursive, with a large initial "B" and "C".

Blair Childs
Senior Vice President, Public Affairs