June 25, 2012

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W. Room 445-G  
Washington, D.C. 20201

RE: CMS-1588-P: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals’ Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Proposed Rule (Vol. 77, No. 92) May 11, 2012

Dear Ms. Tavenner:

The Wisconsin Hospital Association is a statewide nonprofit association with a membership of more than 140 Wisconsin hospital and health systems that includes not only critical access hospitals providing crucial services to their rural communities, but also major academic medical centers providing world-class care, research, and training. On behalf of our members, we appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule on the hospital inpatient prospective payment system (PPS).

We provide detailed comments below regarding the several provisions of the proposed rule: hospital wage index; the hospital readmissions reduction program; the hospital value based purchasing program; the hospital inpatient quality reporting system; the coding adjustment; sole community and Medicare dependent hospitals; graduate medical education payments; hospital services furnished under arrangements with another hospital; and long-term care hospital payments.

1. **PPS Wage Index Rural Floor**

WHA opposes the continued application of a nationwide rural floor budget neutrality adjustment as outlined in the proposed rule. This policy unfairly skews Medicare payments, reducing payments to thousands of hospitals across the nation by $3.5 billion over a decade while benefitting a few dozen hospitals in one state. WHA requests that CMS ensure that wage index provisions in the fiscal year (FY) 2013 IPPS are implemented equitably and in keeping with long-standing Medicare policy.
As you are aware, the change in policy was brought about by the conversion of a single facility in Massachusetts – Nantucket Cottage Hospital – from a critical access hospital (CAH) to an IPPS hospital and nationwide application of budget neutrality through section 3141 of the Patient Protection and Affordable Care Act (ACA).

CMS explains the impact of the policy in the proposed rule, noting that urban hospitals in New England could receive a payment increase of 3.1 percent due to the application of the rural floor in Massachusetts. Moreover, CMS estimates that **Massachusetts hospitals will receive approximately a 5.5 percent increase in IPPS payments due to the application of rural floor.** Separately, CMS provides an impact table showing that Massachusetts hospitals will reap a $182.7 million windfall in IPPS payments alone for FY 2013 under this wage index policy. We would also note that wage index changes under the hospital outpatient prospective payment system (OPPS) consistent with the IPPS policy have been additive and therefore increase the annual windfall to the Commonwealth of Massachusetts. The impact table also instructively shows the reductions other states would absorb if this policy is permitted to stand – and we would like to thank CMS for indicating the state-by-state effect. In this regard, we would request that an updated state-by-state impact table be included in the final rule and that the table be expanded to include the cumulative impact of two years of this redistribution and that the table project the 10-year impacts brought about by this “manipulation” of the wage index.

The Medicare Payment Advisory Commission (MedPAC) has raised questions about the fairness of this wage index policy. MedPAC noted in its FY 2012 IPPS comment letter to CMS, dated June 17, 2011, that the “…exception triggered in the state of Massachusetts will have a large impact on hospital payments…” The letter observes that the hospital that triggered the change treats about 150 inpatients a year. MedPAC further noted that as a result of the budget neutral change, “…all hospitals – including rural hospitals – will absorb the financial loss…” And, indeed, the FY 2013 IPPS proposed rule states that rural hospitals in particular would see a payment reduction of -0.3 percent as a result of the application of rural floor budget neutrality.

CMS itself has expressed reservations about the nationwide budget neutrality factor, which contradicts the Agency’s stated wishes in applying wage indexes. In the Agency’s CY 2012 OPPS final rule (CMS-1525-FC), the Agency expressed concern that allowing a change in hospital status as occurred in Massachusetts through ACA distorts wage indexes across a state, saying:

“…In recent years, we have become concerned that hospitals converting their status significantly inflate wage indices across a State…. Our concern is that the manipulation of the rural floor is of sufficient magnitude that it requires all hospital wage indices to be reduced ....” (emphasis added)

The pricing of Medicare inpatient services across all of Massachusetts based on the wage index of one isolated hospital ultimately is not an accurate reflection of the state’s hospital pricing. It is, as CMS suggests, a manipulation whose sole purpose is to benefit those other hospitals rather than reflecting the true value of wages paid in Massachusetts. Furthermore, it is not in keeping with Medicare’s goal of accurately reflecting input prices in its reimbursement policies. Particularly troubling is the budget
neutral character of the adjustment through ACA section 3141, which means that all hospitals in the nation must forgo payments to fund this changed policy.

If left uncorrected, **hospitals in 49 states will experience reduced funding of more than $3.5 billion over the next ten years** as a direct result of this distortion of Medicare’s hospital wage index. Hospitals nationwide are already struggling with reduced government payments and the potential for cuts through the federal deficit reduction discussions and health care reform. Scarce Medicare funding should reward value and efficiency in health care – principles that CMS has worked tirelessly to ingrain in numerous Medicare initiatives that are presently ongoing or in the works – and not be diverted based on artful manipulation of obscure payment formulas. We respectfully ask that CMS consider the long-standing financial ramifications of the current provision that unilaterally benefits the Commonwealth of Massachusetts at the expense of hospitals across the country, and the unintended impact of this redistributive provision on the Medicare beneficiaries whom these hospitals collectively serve. While CMS did not specifically invite comments on this provision in this proposed rule, we respectfully request that CMS once again review this policy and if there is a logical outgrowth in this NPRM, based on the comments we are providing, we strongly recommend the agency reverse this misguided and harmful provision.

2. **Hospital Readmissions Reduction Program**

The ACA mandates that CMS implement a program beginning in FY 2013 under which hospitals with higher-than-expected readmission rates would see reductions in their Medicare payments. It also mandates that reductions be based on the number of "excess" readmissions at the hospital, with a cap that would limit penalties in the first year of the program to 1 percent of the hospital's base operating Medicare payments.

WHA urges CMS to make changes to these readmission measures to: 1) properly adjust for patient characteristics (dual-eligible status and race/ethnicity); 2) differentiate between planned and unplanned readmissions; 3) differentiate between related and unrelated readmissions; and 4) exclude extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse). CMS has failed to make any changes to account for these factors. **WHA strongly disagrees with CMS’s decision and believes that the agency has ignored Congress’s intent that the measures be modified to address these factors.**

WHA urges CMS to remove admissions and readmissions for beneficiaries who died in the hospital; were transferred to another hospital; were discharged against medical advice; and for percutaneous transluminal coronary angioplasty and coronary artery bypass graft procedures (AMI measure only) from the count of admissions for each condition. By using its proposed rule impact file to calculate the penalty associated with a hospital and selecting discharges based on ICD-9_CM codes, CMS is over counting admissions and therefore inflating the calculation of aggregate payments for excess readmissions.
Adjusting for Patient Characteristics: We urge CMS to direct its measure development contractor to adjust the AMI, HF and PN readmission measures for dually eligible beneficiaries and for race/ethnicity beginning with the FY 2014 readmission penalty program. There has been extensive research illustrating that readmission rates are statistically higher among dually eligible versus non-dually eligible and non-white versus white beneficiaries. These factors are beyond the control of a hospital and must be adjusted for when calculating a hospital’s readmission rate.

Planned Readmissions: We urge CMS to remove all planned readmissions from the AMI, HF and PN readmission measures, as required by the ACA. CMS has stated that it cannot make changes to the readmission measures because they are NQF-endorsed, a criterion of the ACA statutory language. However, CMS has pursued removal of planned measures in its 30-day all-cause, all-condition readmission measure. This measure excludes patients undergoing medical treatment for cancer as their primary procedure and also includes 36 categories of procedures that are considered planned. CMS and the measure developer are using a methodology to define planned readmissions for the all-cause, all-condition readmission measure; it also can and should use this methodology for all of the readmission measures. Using inconsistent methodologies across the readmission measures is inappropriate.

Unrelated Readmissions: We urge CMS to remove unrelated readmissions from the AMI, HF and PN readmission measures, as required by the ACA. If CMS continues to refrain from developing a list of procedures/conditions that it would define as unrelated, we urge it to instead work with the NUBC to allow hospitals to make a judgment on whether a readmission is unrelated.

Adding Exclusions for Certain Conditions to the Readmission Measures: We urge CMS to remove patients with extenuating circumstances from both the numerator and denominator of the AMI, HF and PN measures. The following patients should be removed from the readmission measures: transplant; end-stage renal disease; burn; trauma; psychosis; and substance abuse. The current risk adjustment methodology does not adjust for these factors; however, patients with these characteristics are often readmitted because good, sound medical practice indicates that a readmission is the best course of action. Therefore, it is unfair to penalize hospitals treating these vulnerable patients by including these appropriate readmissions in their readmission rate.

Reliability of Readmission Measures: We urge CMS to address the reliability problems with the current readmission measures. A recent study by the American Hospital Association indicates the current readmission measures are not reliable (see table below). We support a consistent rate of reliability (0.75) for these measures as used by CMS for chart-abstracted measures. It is clear from the AHA study that very few hospitals are meeting even basic levels of reliability.
### Percentage of Hospitals Achieving Acceptable Rates of Reliability

<table>
<thead>
<tr>
<th>Reliability Rate</th>
<th>AMI</th>
<th>PN</th>
<th>HF</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7</td>
<td>13%</td>
<td>16%</td>
<td>25%</td>
</tr>
<tr>
<td>0.8</td>
<td>4%</td>
<td>3%</td>
<td>9%</td>
</tr>
</tbody>
</table>

This is especially important to consider in light of the penalties that are at stake. **Penalizing hospitals while failing to guarantee that these measures have even a moderate rate of reliability is inappropriate.**

One potential solution to ensuring adequate reliability in a measure is to include only hospitals that meet a minimum case threshold. Currently, a hospital must have a minimum of 25 cases on the readmission measures in order to qualify for the Hospital Readmissions Reduction Program. However, the AHA analysis indicates that in order to achieve a rate of reliability between 0.7 and 0.8, hospitals would need to have at least 370 cases for the AMI measure, 422 cases for the PN measure and 451 cases for the HF measure. **At a minimum, we urge CMS to significantly raise the minimum case threshold to qualify for the Hospital Readmissions Reduction Program.**

### 3. Hospital Value-Based Purchasing (VBP) Program

WHA is a strong advocate of the intent of CMS Value Based Purchasing program. Wisconsin hospitals are actively engaged in public reporting, tracking measures, and improving outcomes. We are providing comments on the addition of new measures for 2015; the removal of measures; measurement domains; minimum cases; and comparing a hospital’s performance when moving from ICD-9-CM to ICD-10-CM/PCS coding.

#### Addition of New Measures for FY 2015

CMS proposes to add four new measures to the FY 2015 VBP program.

- **Administration of Statin Upon Discharge for Heart Attack Patients.** WHA supports adding this measure to the FY 2015 VBP program

- **CLABSI Measure.** Though CLABSI is an important quality measure, WHA does not support its inclusion in the FY 2015 VBP program due to a lack of validity testing. Specifically, CMS has yet to complete any CLABSI validation testing. Although validity testing has occurred at the state level for several years, unfortunately, each state uses a slightly different validation methodology.

- **Patient Safety Indicator (PSI) Composite.** WHA does not support adding the PSI composite to VBP in FY 2015, due to poor results from reliability testing. On February 13, CMS released a reliability study, required by the ACA, for claims-based measures. The study shows that the majority of claims-based measures currently used in the VBP program are unreliable,
including the proposed PSI composite. The CMS study states that “reliability of an outcome measure is the extent to which variation in the measure is due to variation in quality of care rather than random variation due to the sample of cases observed. The statistical concept of reliability (R) used to determine the minimum case size for a particular measure is whether a hospital’s ranking on that measure, compared to its performance in other periods or compared to other hospitals, is likely to be the same if we take repeated samples of the hospital’s own cases. Reliability depends on the rate’s variance between hospitals, the variance of the rate within a hospital’s own cases, and the number of discharges from a given hospital.” The table below includes the information from the study on the PSI composite.

<table>
<thead>
<tr>
<th>Months of Data</th>
<th>Median Reliability</th>
<th>Percent of Inpatient PPS hospitals with a rate of reliability = 0.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>0.67</td>
<td>73%</td>
</tr>
<tr>
<td>12</td>
<td>0.81</td>
<td>83%</td>
</tr>
<tr>
<td>18</td>
<td>0.86</td>
<td>88%</td>
</tr>
<tr>
<td>24</td>
<td>0.89</td>
<td>90%</td>
</tr>
</tbody>
</table>

CMS chose to test for a rate of reliability equal to 0.4 because Yale, a measure developer on contract to CMS for other quality measures (mortality and readmission measures) uses 0.4. However, the study also states that “R = 0.4 is considered to be the lower limit of ‘moderate’ reliability.” Achieving “the lower limit of moderate reliability” is not sufficient for a payment program. A reliability rate of 0.4 may be good enough for public reporting, but it is not good enough for a program that is tied to as much as 2.0 percent (in FY 2017 and beyond) of a hospital’s inpatient PPS payments. At a minimum, CMS must be reviewing measure reliability at 0.9 or higher. Hospitals must be assured that the incentives associated with the VBP program have high rates of reliability. We urge CMS to publish a study that repeats this analysis with the rate of reliability equal to 0.9.

CMS proposes a performance period just shy of nine months for the PSI composite, but the study shows that even a 12-month performance period only yields a median reliability of 0.81. Thus, under the proposed nine-month period, the majority of hospitals would not achieve what we believe is acceptable reliability for this measure. We therefore cannot support including this measure in VBP.

- **Medicare Spending per Beneficiary (MSPB) Measure.** The WHA recognizes that efficiency measures can be valuable and fully supports their place in the VBP program. However, hospitals need more time to gain experience with the MSPB measure and learn about their potential for performance improvement. Therefore, we urge CMS to delay its decision to finalize the MSPB measure until the FY 2014 rulemaking cycle. Doing so would still allow CMS to include the measure in the VBP program for FY 2015.
In addition, we urge CMS to be more transparent with respect to the data underlying this measure. CMS provides very little data on Hospital Compare regarding this measure – it only indicates whether the average spending for patients treated by the hospital is above or below the national average. Because the measure includes a 30-day post-discharge period, it is likely that many other costs beyond inpatient care contribute to the overall metric. Yet, CMS makes this information available only to each hospital in a confidential report, meaning the hospital cannot learn by comparing its performance to other hospitals. For example, each hospital has access to a report that provides a percentage breakdown of the dollars spent in each service category – i.e., 20 percent of spending for patients treated in Hospital X comes from a skilled nursing facility. For many hospitals, this information is new; yet, CMS does not include it on Hospital Compare. Hospitals need to see this level of transparency so they can properly benchmark their performance against other similar hospitals. We urge CMS to make these data publicly available.

We also are concerned about the lack of reliability testing on this measure. In the February reliability study referenced above, CMS failed to include testing of this measure. It is likely to yield similar reliability results as the other claims-based measures. For example, the 30-day MSPB measure is constructed in a similar manner as the 30-day mortality measures (discussed below). Given the unreliable nature of the mortality measures, in the absence of further data, we must assume a similar level of unreliability for the MSPB measure. We urge CMS to pursue a reliability analysis of the MSPB measure and publicly release the analysis prior to finalizing the measure in hospital VBP.

Finally, the MSPB measure must go through the NQF endorsement process. In the proposed rule, CMS states that it will put the MSPB measure through the NQF process but does not indicate when. We urge CMS to be more transparent regarding its intentions for NQF endorsement of this measure. In addition, the MAP did not recommend this measure for use in hospital VBP, in part due its lack of NQF-endorsement.

Removal of Measures. CMS makes a proposal to remove one measure (described below) from hospital VBP, beginning in FY 2015. In addition, we urge CMS to remove the 30-day mortality measures from the VBP program.

- **Ordering Venous Thromboembolism Prophylaxis for Surgery Patients.** We support removal of the Surgical Care Improvement Project (SCIP) measure regarding the ordering of venous thromboembolism (VTE) prophylaxis for surgery patients from the hospital VBP program. Specifically, CMS proposes to remove SCIP-VTE-1 (ordering of prophylaxis) beginning with the FY 2015 VBP program. CMS states its reason for removal is that SCIP-VTE-2 (receipt of prophylaxis) is more closely linked to outcomes than SCIP-VTE-1 because it monitors for receipt of prophylaxis, rather than simply ordering prophylaxis. We agree with CMS’s reason to remove SCIP-VTE-1 from the program and urge CMS to remove it before FY 2015. If CMS is unable to finalize removal of the SCIP-VTE-1 measure in FY 2013 and 2014 because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to remove the measure.
• **Mortality Measures.** On April 29, 2011, CMS issued a final rule on the hospital VBP program. In that rule, CMS finalized three 30-day mortality measures (heart attack, heart failure and pneumonia) for the FY 2014 hospital VBP program. **However, on February 13, 2012, well after the mortality measures were finalized, CMS released a reliability report (described above) indicating that all of the mortality measures are unreliable.** The table below includes the data on the mortality measures from the study.

<table>
<thead>
<tr>
<th>Measure</th>
<th>6 Months</th>
<th>12 Months</th>
<th>18 Months</th>
<th>24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median* Reliability</td>
<td>% of Hospitals R ≥ 0.4**</td>
<td>Median* Reliability</td>
<td>% of Hospitals R ≥ 0.4**</td>
</tr>
<tr>
<td>AMI Mortality (R = 0.4 with 107 cases)</td>
<td>0.09</td>
<td>2</td>
<td>0.17</td>
<td>12</td>
</tr>
<tr>
<td>HF Mortality (R = 0.4 with 196 cases)</td>
<td>0.11</td>
<td>2</td>
<td>0.20</td>
<td>14</td>
</tr>
<tr>
<td>PN Mortality (R = 0.4 with 211 cases)</td>
<td>0.11</td>
<td>1</td>
<td>0.19</td>
<td>8</td>
</tr>
</tbody>
</table>

* Reliability of measure of hospital of median case size
**Proportion of hospitals with case size large enough that R ≥ 0.4

This illustrates that none of the three mortality measures, regardless of the time period used, have even what CMS considers to be the “lower limit of ‘moderate’ reliability,’’ equal to an R of 0.4. This is especially troubling considering CMS intends to use only a nine-month performance period for the mortality measures in FY 2014. **We do not support CMS’s proposal to codify the mortality measures for FY 2014. Further, we do not support CMS’s proposal to include the mortality measures in the FY 2015 program. We urge CMS to permanently remove the mortality measures from the VBP program due to their lack of reliability.**

**Measurement Domains.** CMS seeks comment on making the six measurement priority areas of the NQS the measurement domains for the FY 2016 VBP program. The six domains would be: patient and family engagement; care coordination; clinical processes; patient safety; efficiency; and population/public health. Though we agree that population/public health and care coordination are important goals of the NQS, we do not feel they are necessarily appropriate goals for a hospital VBP program at this time. However, these would be important goals for a program in which participants agree to take on full responsibility of patients, such as Accountable Care Organizations.

We also are concerned about into which priority areas each measure would be placed. In the proposed rule, CMS provides a crosswalk of all finalized and proposed measures to each of the six priority areas.
However, CMS states that many of the measures could potentially fit into multiple priority areas. We agree that measures may align with multiple priorities and it would be somewhat arbitrary to assign measures to only one.

- **Concerns with Previously Finalized Domains.** As previously stated, the mortality measures are unreliable and must be removed from the VBP program. However, CMS has finalized an outcomes domain, which contains only the mortality measures, for the FY 2014 VBP program. **Thus, we urge CMS to use a 0 percent weighting for the outcomes domain until appropriate, valid and reliable measures are available for inclusion in it.** For example, while we do not support the inclusion of CLABSI in the VBP program at this time due to a lack of validity testing, it is a type of quality measure that would be appropriate for inclusion in an outcomes domain in the future.

- **Administration of Statin upon Discharge for Heart Attack Patients.** The WHA supports CMS’s proposed performance period for the statin upon discharge measure for heart attack patients for the FY 2015 program. CMS proposes to use a nine-month performance period for this measure. Though we prefer a full calendar year of performance for this measure, we understand that CMS is limited to a nine-month period for FY 2015 due to the initial posting date of this measure on Hospital Compare. We urge CMS to use a 12-month period for this measure in the future.

- **CLABSI, PSI, MSPB, and Mortality Measures.** The WHA does not support CMS’s proposed performance period for the CLABSI, PSI, MSPB or mortality measures for the FY 2015 program. These measures have either been shown to be unreliable or have not undergone validity testing.

**Minimum Cases.** We do not support CMS’s proposals for the minimum number of cases for the mortality or MSPB measures. CMS proposes to increase the minimum case threshold for the mortality measures from 10 cases to 25. This does not increase the reliability of the measures sufficiently. As the CMS reliability study clearly illustrates, even if the minimum case count was 100 cases, the measures still would not achieve even the lower end of a moderate rate of reliability for the majority of hospitals. However, because CMS already has finalized the mortality measures for FY 2014, if the agency chooses to act against our recommendation and keep the mortality measures in the FY 2014 program, we urge CMS to increase the minimum case threshold to 25 cases.

CMS also proposes a minimum case count of 25 for the MSPB measure and seeks public comment on whether 50 cases are a more appropriate minimum for the MSPB measure. As stated above, we do not have sufficient information to make a meaningful comment on this proposal. CMS’s reliability for the mortality measures indicate that even a minimum of 100 cases does not produce reliable results for those measures. Since the MSPB measure is also a claims-based measure, it is highly probable that the same conclusion holds true. **To better understand how many cases are needed to generate reliable results**
for the MSPB, we urge CMS to include this measure in its reliability study and make the results publicly available.

Comparing a Hospital’s Performance When Moving from ICD-9-CM to ICD-10-CM/PCS Coding. WHA is concerned about how CMS’s measurement of hospital performance may change when ICD-10-CM/PCS codes begin to be used for claims-based measures. We urge CMS to compare baseline data to performance data using the same classification system. It would be unfair, and potentially impractical, to compare a hospital’s measurement results using ICD-9-CM in the baseline period and ICD-10-CM/PCS in the performance period. For calculation of the claims-based measures, we urge CMS to either re-run the baseline data using ICD-10-CM/PCS or re-run the performance data using ICD-9-CM. We cannot make a judgment in favor of either method without seeing the data. We urge CMS to test this concept both ways on a subset of hospitals and make the data publicly available.

4. Hospital Inpatient Quality Reporting (IQR) Program

Removal of Quality Measures. WHA supports CMS’s proposal to remove 17 measures from the IQR program. For all 17 measures, CMS proposes removal beginning with the FY 2015 IQR program.

We urge CMS to remove these measures for the FY 2013 and FY 2014 IQR program as well. Since CMS has concluded that these measures are unfit for the program, they should be removed as soon as possible. If CMS is unable to remove these measures before FY 2015 because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to remove these measures for the FY 2013 and 2014 IQR program. Further, we urge CMS to remove these measures from Hospital Compare as soon as possible.

- Removal of Claims-based Measures. CMS proposes to remove eight hospital-acquired conditions (HACs), five PSIs and three inpatient quality indicators (IQIs) from the IQR program. The WHA supports removal of the HAC, PSI and IQI measures from the IQR program. These measures have never been validated against medical records and the HACs are not endorsed by the NQF. The MAP also has recommended that the HACs be removed from the IQR program.

- Removal of Chart-abstracted Measure. CMS proposes to remove the Surgical Care Improvement Program (SCIP) measure for ordering recommended venous thromboembolism prophylaxis for surgical patients from the IQR program. The WHA supports removal of this SCIP measure from the IQR program. However, in the proposed rule, CMS failed to propose a date for when hospitals can cease submission of data for this measure. We urge CMS to finalize an end date for data submission of this measure that is effective immediately, or is effective on the date of publication of the FY 2013 inpatient PPS final rule. If CMS is unable to finalize an end date for data submission because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to propose a date by which hospitals can cease data submission for this SCIP measure.
FY 2015 Proposed Addition of New Quality Measures. The WHA supports the new HCAHPS, hip and knee complication and readmission measures. However, we do not support the all-cause, all-condition readmission and 39-week elective delivery measures.

- **HCAHPS Changes:** The CTM-3 measure is an important measure of a patient’s experience of care, and we support its inclusion in the HCAHPS survey that is required in the IQR program. CTM-3 is NQF-endorsed and was recommended by the MAP.

  CMS also proposes two new questions to be added to the HCAHPS survey in the “About You” section. The first question would require a beneficiary to declare whether he/she entered the hospital through the emergency department (ED). We agree with CMS that adding this question would enhance the HCAHPS survey and support the agency’s proposal.

  The second question CMS proposes to add would ask a beneficiary to rate his/her overall mental or emotional health on scale ranging from excellent to poor. CMS offers neither a rationale as to why it wants to add this question, nor a statement of what it will do with the data. In addition, CMS does not state whether it has pilot-tested this question with beneficiaries. We have several concerns about this question. First, we are concerned that patient characteristics, which are not adjusted for, may unduly influence how beneficiaries respond to this question. This could result in the potential unintended consequence of hospitals treating the most severely ill patients having systematically lower scores on this question, thereby unfairly disadvantaging these hospitals. In addition, we are concerned that beneficiaries may not feel comfortable answering this question and may perceive it as an invasion of privacy. Finally, we also are concerned that this type of self-diagnosing of psychiatric conditions may have potential unintended consequences for hospitals, such as increased liability risk.

  Because there are many unanswered questions and we are unsure of the state of pilot testing, we cannot support this proposal at this time.

- **Hip and Knee Arthroplasty Complications.** CMS proposes to add a measure to the IQR program that captures a composite of complications occurring after hip or knee arthroplasty procedures. This measure is NQF-endorsed and was recommended by the MAP. We support including this measure in the IQR program.

- **Hip and Knee Arthroplasty 30-day Readmissions.** CMS proposes to add a claims-based measure to capture all-cause readmissions within 30 days of discharge following hip or knee arthroplasty procedures to the IQR program. This hip and knee readmission measure is specified in a similar way to existing AMI, HF and PN readmissions measures. We do not support the addition of these readmission measures because they fail to:

  - differentiate between planned and unplanned readmissions;
  - differentiate between related and unrelated readmissions;
• exclude extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse); and
• properly adjust for patient characteristics (dual eligible status and race/ethnicity).

We urge CMS to make these changes to the hip and knee arthroplasty readmission measure, as well as to the AMI, HF and PN measures.

• Hospital-wide, All-cause, All-condition 30-day Readmissions. CMS proposes to add a claims-based measure to the IQR program that captures all-cause readmissions across all diagnoses within 30 days of discharge. The WHA does not support addition of this measure until the methodology is changed to include the following:
  • differentiation between related and unrelated readmissions;
  • exclusion of extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse); and
  • proper adjustment for patient characteristics (dual-eligible status and race/ethnicity).

FY 2016 Addition of New Quality Measures. The WHA does not support the safe surgery checklist measure CMS proposes for the FY 2016 IQR program. Though the use of a safe surgery checklist may lead to reduced surgical errors, the proposal is merely a concept that is not a fully developed measure. Therefore, it is not endorsed by the NQF, nor recommended by the MAP (although the MAP did support the general concept of the measure).

Data Submission. CMS makes two proposals concerning data submission changes. The first proposal addresses data submission for the 39-week elective delivery measure and the other proposal addresses reporting to the National Healthcare Safety Network (NHSN).

• 39-week Early-term Elective Delivery Data Reporting. The WHA supports CMS’s proposal to require aggregate data (numerator, denominator and exclusions) for the 39-week elective delivery measure.

• Exemptions for Reporting NHSN Data. The WHA supports CMS’s proposed exemption process for reporting of CLABSI, Catheter-Associated Urinary Tract Infections (CAUTI) and Surgical Site Infection (SSI) measures. Specifically, CMS proposes to exempt hospitals without an intensive care unit (ICU) from reporting of CLABSI and CAUTI. CMS also proposes to exempt hospitals with fewer than 10 combined cases of colon/abdominal hysterectomy procedures from reporting the SSI measure. Hospitals that do not have a relevant population for measure reporting should be exempt from applicable quality measure reporting.

Expansion of Infection Measures beyond the ICU. CMS seeks comment on whether the CLABSI and CAUTI measures should be expanded to all areas of the hospital, instead of applying only to the ICU. The WHA supports moving toward this goal in the long-term; however, expansion of these measures is currently inappropriate. A few more years of data collection and validation are needed to ensure
hospitals are properly and accurately capturing this infection data – display of CLABSI data on Hospital Compare only began in January 2012 and CAUTI reporting will begin in January 2013. We urge CMS to monitor reporting and validation progress on these measures and make a proposal for expansion only after hospitals have had a few years of data reporting experience.

5. Coding Adjustment

The proposed rule includes a permanent documentation and coding cut of -1.9 percent to eliminate what CMS claims is the effect of documentation and coding changes that occurred from FFY 2007 though 2009. In the rule, CMS proposes an additional cut of -0.8 percent as a prospective adjustment to correct for coding behavior in FFY 2010. CMS bases these reductions on the same methodology as was used for the FFY 2008 and 2009 adjustments. We strongly contest the CMS methodology in past years for determining the impact of coding behavior and the conclusions that have been drawn by CMS. We believe those conclusions to be overstated and we believe the methodology used by CMS to draw its conclusions to be flawed. We opposed the provision of the proposed rule, and recommend that CMS reverse its proposed adjustment for 2013.

6. Sole Community and Medicare-Dependent Hospitals

Regulations Regarding Duration of SCH Classification Period. Currently, a hospital’s SCH classification remains in effect without the need for re-approval unless there is a change in the circumstances under which the classification was approved. However, CMS states that these regulations do not explicitly address a situation where a hospital never met the requirements to be classified as an SCH to begin with, but was nonetheless granted such classification. CMS proposes to create a new requirement at §412.92 (b)(3)(iv) to state that an SCH must report to its fiscal intermediary (FI) or Medicare Administrative Contractor (MAC) any factor or information that could have affected its initial classification as an SCH. If it does not, CMS may cancel the hospital’s classification retroactive to when it was first granted. This proposal would require SCHs to monitor and have knowledge of any and all factors and information that could have affected their initial classification – and then potentially allow the retroactive cancellation of their classification if they do not do an adequate monitoring job. WHA strongly disagrees with this inappropriately punitive policy, which is inconsistent with existing regulations.

CMS cannot hold SCHs accountable for monitoring and having knowledge of any and all factors and information that could have affected their initial classification. Forcing them to do so would impose a tremendous administrative burden on these hospitals. We can envision many scenarios in which a hospital could have unintentionally obtained SCH status when it should not have, through absolutely no fault or knowledge of its own.

CMS does not simply take the hospital’s word that it qualifies as an SCH. The agency’s qualification criteria are complex; not only must the hospital demonstrate that it qualifies for SCH status, but both the
FI, acting as CMS’s representative, and CMS itself must review, agree as to the interpretation of the regulations, and approve the hospital’s SCH status. However, **CMS now seems to be proposing to require the SCH to continually monitor and verify whether CMS itself correctly interpreted its own regulations.** We also are concerned that this proposal puts SCHs at risk for a change in interpretation of the regulations, even after all parties involved have already agreed to the interpretation that led to the SCH’s classification. Such a proposal is unfair and inappropriate.

Further, **CMS’s proposal is inconsistent with other existing regulations.** We urge the agency to make three modifications to its proposal to rectify these inconsistencies and the inappropriately punitive nature of its proposal.

**First, we urge CMS to modify its proposed new requirement §412.92 (b)(3)(iv) so that it is consistent with its FY 2007 inpatient PPS final rule and the regulations at §412.92 (b)(3)(iii).** Specifically, the agency stated in its FY 2007 inpatient PPS final rule that “certain criteria may be excessively burdensome for a hospital to monitor” (71 Federal Register 48060). This recognition is why, in §412.92 (b)(3)(ii), a requirement similar to the one CMS proposes, the agency requires an SCH to monitor and report only certain changes in its circumstances, such as the opening of a new hospital in its service area. For other changes in circumstance, the agency requires the SCH to report only if it becomes aware of such a change. **Accordingly, we urge CMS to require that an SCH report to its FI or MAC if it becomes aware of one or more errors in its initial application that could have affected its initial classification.** Holding a hospital accountable for monitoring and having knowledge of any and all factors that could have affected its initial classification as an SCH, especially considering that this initial classification was granted more than 20 years ago for many hospitals, is inappropriate.

**Second, we urge the agency to modify the effective date of any SCH-status cancellations.** Specifically, CMS proposes that if a hospital does not report factors or information that could have affected its initial classification, the agency may cancel the hospital’s SCH classification effective the date the hospital failed to meet the criteria, which, by definition, is the date of the initial classification. However, §412.92 (b)(3)(iii), a regulation similar to the one CMS proposes, states that if CMS determines a hospital was aware of a change that affected its SCH status, but did not report it, CMS will cancel the classification effective on the date the hospital became aware of the change, consistent with the re-opening rules at §405.1885. Thus, to be consistent with its own regulations, we urge CMS to clarify that if a hospital is aware of, but does not report, factors or information that could have affected its initial classification, the agency may cancel the hospital’s classification effective on the date the hospital became aware of the factors or information. **A hospital should not be held accountable prior to the point at which it became aware of the problem.**

However, to also be consistent with the interpretation of these regulations as laid out in its FY 2007 inpatient PPS final rule (71 Federal Register 48061), **CMS should clarify that if the hospital is aware of, and does report, factors or information that could have affected its initial classification, the SCH status will instead be terminated 30 days after the Regional Office’s decision that the hospital no longer meets the SCH criteria.** We urge the agency to codify this effective date in the actual
regulations at §412.92 (b)(3)(ii), §412.92 (b)(3)(iii) and §412.92 (b)(3)(iv), instead of simply in the rule’s preamble, as has been done to date.

Third, as proposed, §412.92(b)(3)(iv) does not include a specific timeframe for the hospital to make a report. However, both §412.92(b)(3)(ii) and §412.92(b)(3)(iii) provide for reporting within a 30-day period. The proposed rule offers no explanation as to why the other provisions include a set timeframe for reporting, but §412.92(b)(3)(iv) does not. We believe that it is important for CMS to provide clarity on timeframes for reporting, and to give hospitals lead time between becoming aware of information that could trigger a requirement to report and when they must make a report. That lead time would allow hospitals time to assess whether the information warrants a report, for example. As such, we urge CMS to modify the proposed text of §412.92(b)(3)(iv) to indicate that hospitals must make a report within 30 days of becoming aware or any factor or information that could have affected the initial classification.

Consistent with other aspects of the rulemaking, we believe that the new reporting requirement under §412.92(b)(3)(iv) should not take effect until 60 days after the issuance of the final rule, and that also should be clarified in the final rule.

Medicare-dependent Hospitals (MDHs) Applying for SCH Status.

CMS states that it has become aware of a number of MDHs that intend to apply for SCH classification upon the expiration of the MDH program. To facilitate a seamless transition for those MDH hospitals that will qualify as SCHs, CMS proposes to add an exception to its SCH effective-date policy. Specifically, it proposes that, for any MDH that applies for SCH status by August 31, 2012, and requests that its SCH status be effective with the expiration of the MDH program, the effective date of the hospital’s SCH classification would be October 1, 2012. WHA supports and appreciates this policy change, which may be helpful to many MDHs.

However, the possibility remains that Congress may extend the MDH program retroactively, after it expires on October 1, 2012. To account for this distinct possibility, we ask that CMS provide hospitals with the ability to, in turn, rescind their new SCH status retroactively and reinstate their MDH status in a seamless manner, if a retroactive extension to the MDH program is made. Such an allowance would be extremely helpful for these hospitals, which are facing an unreasonably uncertain future of Medicare inpatient payments.

7. Graduate Medical Education

New Teaching Hospitals. WHA supports CMS’s proposal to increase the cap-building period for new teaching hospitals from three years to five years. However, WHA also believes CMS should give special consideration to hospitals that may have had a low number of rotations, but want to increase their residency capacity as a result of a new medical school, or expansion of an existing medical school. Such expansions may necessitate that hospitals increase the number of residents in existing programs.
WHA has been a leader in Wisconsin in developing a report citing the potential physician shortage in the state, and convening a graduate medical education task force to address the need to train new physicians. One of the state’s medical schools appears positioned to expand into at least one new area of the state. Hospitals wishing to expand their residency programs as a result of the new medical school capacity should be given special consideration and exemption from the cap.

Under current regulations, a hospital with a new resident training program is given a three-year period to grow its programs before CMS establishes the hospital’s permanent full-time equivalent (FTE) resident cap. CMS proposes to extend this window to five years for new programs beginning on or after October 1, 2012. CMS would also set a new teaching hospital’s resident cap at the end of the fifth program year of the first new program. Specifically, the FTE cap would be based on the product of: 1) the highest number of FTE residents training in any program year during the fifth year of the first program’s existence for all new residency training programs; and 2) the number of years in which residents are expected to complete the program. This cap would be permanent and take effect with the sixth program year of the first new program.

Given current accreditation requirements, three years is not sufficient to establish a new residency program. It is particularly challenging if a new teaching hospital chooses to establish more than one new residency program. The Accreditation Council for Graduate Medical Education (ACGME), for example, may require new residency training programs to pass through a three-year “initial” accreditation period before they can be granted “continued” accreditation. During this initial accreditation period, a hospital is not allowed to add any additional positions to its new program. Thus, even if a hospital has plans to expand its new training program beyond the number of positions for which it is initially accredited, it may not be possible to do so until this initial period has expired. In addition, some hospitals prefer to stagger the start dates of their new residency training programs to gain experience before beginning all of their new programs. These hospitals need much longer than three years before CMS sets their permanent resident cap.

WHA is pleased with CMS’s proposal to increase the cap-building period. The longer five year window should result in new teaching hospitals receiving a higher resident cap and one that is more reflective of the number of residents a hospital will actually train. However, as noted earlier, WHA also believes CMS should give special consideration to hospitals that may have had prior residency programs, but want to increase their residency programs as a result of a medical school expansion.

We also support CMS’s proposal to change how it calculates a new teaching hospital’s cap if the residents in the new program are training at more than one hospital. Specifically, the FTE cap would be based on the product of: 1) the highest total number of FTE residents training in any program year during the fifth academic year of the first new program’s existence at all participating hospitals; and 2) the number of years in which residents are expected to complete the program. CMS proposes to distribute the aggregate cap based on the percentage of resident time spent at each hospital over the course of the entire five-year period (rather than solely during the fifth academic year). WHA is pleased that CMS proposes to revise its methodology, which will allow new teaching hospitals to more appropriately count residents who spend a portion of their time training at another location.
Redistribution of Residency Positions under the ACA. WHA opposes CMS’s proposal to require hospitals to fill at least half of their new residency positions by the third year of the congressionally mandated five-year period. The ACA mandated a redistribution of unused residency positions to encourage increased training of primary care physicians and general surgeons. In awarding the slots, hospitals had to “demonstrate the likelihood” that they would fill the new positions within the first three cost-reporting periods beginning on or after July 1, 2011. In the rule, CMS proposes that a hospital must fill at least half of the redistributed slots (for purposes of both IME and direct graduate medical education (GME) payments) in the first, second and/or third cost-report periods of the five-year period. The agency argues that it is reasonable to expect that hospitals would begin to use their slots by the third year of the five-year period, given that hospitals needed to demonstrate the likelihood that they would be able to do so.

CMS’s proposal over-reaches. Congress imposed two precise requirements that hospitals must meet to keep their redistributed slots. First, for the five-year period beginning on July 1, 2011 (the date of the increase), hospitals must maintain at least their current level of primary care residents averaged over the three most recent years (referred to as the primary care average). Second, hospital must ensure at least 75 percent of the increased positions are designated for primary care or general surgery (referred to as the 75-percent threshold). Congress did not require hospitals to fill half their slots by the third year. Hospitals should have the full five-year period, or until June 30, 2016, to fill their new slots.

As previously stated, hospitals often need more than three years to grow a residency program. Accreditation rules make it difficult for hospitals to ramp up to full capacity in just three years. Hospitals that applied for the redistributed slots needed to do so by January 21, 2011. CMS gave its Medicare contractors until May 16, 2011 to estimate the number of slots for redistribution. By law, the slots were to be redistributed by July 1, 2011. Given the compressed timing, many hospitals did not know until late summer 2011 whether they would receive additional slots and thus failed to meet the August 2011 Electronic Residency Application Service deadline for the resident match. In addition, accreditation rules make it difficult for hospitals to ramp up to full capacity in just three years, especially for those teaching hospitals that are starting a new primary care program. These hospitals would need to recruit a program director, recruit faculty, and create and file a Program Information Form (PIF) with the ACGME. The ACGME would then need to review the PIF, schedule a site visit and provide final ACGME approval. ACGME accreditation requirements are lengthy and complex. The site visit along may take 12 to 18 months to complete. A three-year total timeframe is too short and will unjustly penalize hospitals that are building new primary care programs.

Additionally, the penalty is too harsh. Under CMS’s proposal, hospitals that did not fill at least half of their slots by the third year would lose all of their redistributed slots. For example, a hospital may fill a third of its slots by Year 3, two-thirds by Year 4, and all by Year 5. If this hospital received 30 total slots, 10 residents would be training in the facility. CMS’s proposal would result in eliminating these 10 occupied slots (as well as all 30 in the future). The hospital would either continue to train the resident without Medicare reimbursement, or terminate the residency position (and potentially the residency program altogether). This would result in significant disruption in training for these residents. Given the
shortage of primary care physicians, and the fact that 75 percent of these new slots are for primary care physicians or general surgeons, this could have devastating effects for the future supply of physicians. While the slot would be redistributed to another qualifying hospital, it could take that hospital a number of years to grow its residency program. The result is a delay in training physicians, which is in direct contrast to the goal of the ACA: to encourage increased training of primary care physicians and general surgeons.

8. **Hospital Services Furnished Under Arrangements**

In the FFY2012 Inpatient PPS final rule, CMS adopted a new policy to preclude a hospital from providing certain services to its patients “under arrangements” with another hospital. CMS delayed this effective date to October 1, 2012, and again proposed to delay the implementation date to October 1, 2013 in order to give hospitals additional time to comply with the new policy.

WHA appreciates CMS’s recognition of the need to delay the effective date of the policy for another, but believes that such a delay is not sufficient. Rather, CMS should rescind the revised policy, or at the very least, grandfather in hospitals that provided routine services under arrangements with other hospitals prior to FFY2012. CMS acknowledges that the new policy requires hospitals to “restructure existing arrangements and establish new operational protocols.” CMS has implicitly and explicitly recognized that this policy is not required by statute or regulations, nor has CMS provided any policy rationale to support it. In fact, the policy is both inconsistent with the agency’s increasing emphasis on the efficient delivery of care and unnecessary as a mechanism to guard against potential abuse of such arrangements. Thus, the costs hospitals will incur to comply with the policy is unnecessary and burdensome.

9. **Long Term Care Hospital Payments**

WHA is pleased to see the CMS’s proposal to delay full implementation of the 25% Rule for 12 months; however, we believe the delay should be effective for all LTCHs as is proposed. For LTCH referrals that exceed a specified threshold, the 25% Rule policy reduces the Medicare payment from the LTCH rate to a far lower amount equivalent to an inpatient PPS payment. With this policy, CMS seeks to reduce overall LTCH utilization by reducing LTCH admissions based on the origin of an LTCH referral. However, it completely disregards the patient’s medical necessity for LTCH services. In other words, the policy establishes an arbitrary threshold, beyond which LTCHs face a significant payment penalty for admitting patients from a particular referral hospital, regardless of the patient’s clinical characteristics. While the rule was intended to reduce “inappropriate” admissions to LTCHs, it does so by focusing on referral source rather than patient-level clinical criteria. This means that CMS would be reducing LTCH payments for medically appropriate care in the LTCH setting.

CMS explains that the proposed 12-month delay is intended to provide the agency with additional time to complete its research on an alternative to the 25% Rule. Accordingly, the proposed rule would allow two-thirds of the field to avoid temporarily transitioning their admissions and operational practices to comply
with the fully implemented 25% Rule, requiring modification of these protocols only once under the new, post-25% Rule policy framework to be developed by CMS. CMS’s efforts to smooth the transition from the 25% Rule to a new regulatory policy are commendable, and all LTCHs should benefit from the transition without having to fully implement the 25% rule.

The proposed rule includes a 3.75 percent **one-time budget neutrality cut** to ensure that any overpayment of LTCHs in FY 2003, the first year of the LTCH PPS, is not perpetuated in future years. CMS proposes to implement this 3.75 percent reduction of the LTCH standard rate over three years, beginning in FY 2013. We are concerned by the methodology CMS used to calculate FY 2003 overpayments and that this methodology has yielded an erroneous over correction; therefore, we urge CMS to modify its methodology to account for other payment policy changes that have been implemented since 2003. However, we are supportive and appreciate CMS’s proposal to phase-in cuts for the one-time budget neutrality adjustment over a three-year period.

Finally, we believe that moving to a **new LTCH-specific market basket**, as is proposed, will help align market-basket updates under the LTCH PPS with actual LTCH cost structures. We think this will help increase the accuracy of aggregate Medicare payments to LTCHs.

Thank you for the opportunity to comment on the proposed rule and on these critical issues affecting Wisconsin hospitals. If you have any questions, please contact Brian Potter, Senior Vice President, at 608-274-1820, or bpotter@wha.org.

Sincerely,

Stephen F. Brenton
President