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Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS–1525–P, Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements; (Vol. 76, No.137), July 18, 2011.***

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the hospital value-based purchasing (VBP) portion of the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (PPS) proposed rule for calendar year (CY) 2012. We are submitting comments separately on CMS's proposed changes to the outpatient PPS.

The *Patient Protection and Affordable Care Act of 2010* (ACA) established a Medicare inpatient hospital VBP program to pay hospitals for their performance on quality measures beginning in fiscal year (FY) 2013. The ACA also set forth detailed requirements regarding implementation of the VBP program, including the timing of measure introduction and selection. **Despite the law's specificity, CMS has not met its requirements with respect to certain measures. This failure will unfairly and adversely impact the hospital field and even undermine the intent of the law, which is to provide opportunities for hospitals to improve their performance.** In this year's inpatient PPS and VBP rulemaking cycles, the agency failed to appropriately acknowledge or address our concerns. This failure is exacerbated in the outpatient PPS rulemaking cycle because it builds on policies that fail to comply with the law's requirements

Our detailed comments on the entire VBP program are included below.



## TIME REQUIREMENT FOR PRIOR REPORTING AND NOTICE

The ACA states that:

**(i) TIME REQUIREMENT FOR PRIOR REPORTING AND NOTICE - The Secretary may not select a measure under subparagraph (A) for use under the Program with respect to a performance period for a fiscal year (as established under paragraph (4)) unless such measure has been specified under subsection (b)(3)(B)(viii) [the inpatient quality reporting (IQR) program] and included on the Hospital Compare Internet website for at least 1 year prior to the beginning of such performance period. (Emphasis added.)**

Specification. The ACA requires that, to be included in the VBP program, measures must first be *specified* under the IQR program. The IQR program has been operating since FY 2004. Since that time, many stakeholders, including CMS, AHA and the National Quality Forum (NQF), have agreed on what constitutes specification under the IQR program. This specification process has been promulgated in every inpatient PPS rulemaking cycle since FY 2005 (69 FR 49078 through 69 FR 49082).

Specification consists of releasing a publicly available document that clearly defines the denominator of cases that should be included, the numerator of results, any exclusions that should be removed from the denominator and any risk adjustment that should be applied to guarantee fair and accurate performance. Further, the ACA explicitly references the IQR program (subsection (b)(3)(B)(viii)); therefore, specification also must include the process that measures undergo in the IQR program. That is, when the Secretary of the Department of Health and Human Services (HHS) calculates measures, each hospital is given the opportunity to review its performance, request changes and attest to the accuracy of each calculated measure.

Hospital Compare. In addition to being specified under the IQR program, measures must have their data displayed on the *Hospital Compare* website for a year prior to their inclusion in the VBP program. The inclusion of these requirements in this section of the ACA is absolutely essential to the integrity and equity of the VBP program. The law requires that hospitals whose payments will be affected by these measures, clinicians whose performance will be judged by these measures, and patients whose care will be affected by these measures have the opportunity to know precisely what CMS is measuring, their current level of performance and have an opportunity to improve on measures prior to their inclusion in the VBP program.

Review of the measures and the data displayed on *Hospital Compare* over the past decade has been essential to identifying problems with the data collection, potential unintended consequences of measures and simple errors in data collection. Further, the ACA requirement around *Hospital Compare* posting is critical because it allows hospitals the opportunity to view their performance in advance of actually being measured on that performance. To the extent necessary, hospitals can use the required one-year viewing period to improve their performance. Since performance improvement is the goal of the program, this is a highly desirable outcome.

In pursuit of this performance improvement goal, the legislation was crafted to ensure that participants know the full details of how the measures are to be calculated, have the opportunity to review and comment on those specifications, and then have the opportunity to look at a year's worth of data to more fully understand each measure, its effect and its potential unintended consequences, and to improve performance.

## **FAILURE TO COMPLY WITH CLEAR CONGRESSIONAL DIRECTION**

In the FY 2012 inpatient PPS final rule, CMS finalized a policy stating that, beginning with the Medicare spending per beneficiary measure, it will generally add measures to the VBP program at the same time it adds them to the IQR program. **This is inconsistent with the law.** Until a measure is included in the IQR program, CMS will not have measure data to post on *Hospital Compare*. Thus, if a measure enters both the IQR and VBP programs in the same year, CMS will not have data available to satisfy the statutory requirement that the measure be included on *Hospital Compare* for at least one year prior to the beginning of its performance period.

Hospitals need to see the data in advance and have a reasonable opportunity to address concerns. Hospitals should not have to face the prospect of immediate financial penalties because they are not able to review their relative performance and make improvements. This is not what the law requires or intended.

At this writing, CMS has failed to meet the statutory *Hospital Compare* posting requirement with respect to the Medicare spending per beneficiary measure, the hospital-acquired conditions (HACs) and the Agency for Healthcare Research and Quality (AHRQ) composite measures that it has included in the VBP program. **By failing to post these measures on *Hospital Compare* for a minimum of one year prior to the start of these measures' performance periods, CMS is not complying with the law.**

Medicare Spending Per Beneficiary. The ACA directed CMS to include a Medicare spending per beneficiary measure in the VBP program in FY 2014 *or a subsequent fiscal year*. In the FY 2012 inpatient PPS final rule, CMS finalized the inclusion of such a measure in the VBP program in FY 2014. **However, CMS has not met the statutory specification requirement with respect to the Medicare spending per beneficiary measure.** Specifically, CMS has never released a publicly available specification document for the measure. This measure is a completely new type of quality measure for hospitals in which they will be held accountable for patient care provided by external and likely unaffiliated providers through 30 days post-discharge. Because it is CMS's first foray into efficiency measurement, it is even more critical to follow the specification process in detail. Thus, the specifications of this measure will be especially illuminating for hospitals. However, because of CMS's failure to comply with the law, hospitals do not know:

- What defines the denominator of cases that are included;
- What defines the numerator of cases that are included;
- Which exclusions are to be removed from the denominator; or

- How the measure is risk adjusted.

In addition, CMS has never made the measure results for the Medicare spending per beneficiary measure available to hospitals. Thus, hospitals have never:

- Been given the opportunity to review their performance on the Medicare spending per beneficiary measure;
- Been given the opportunity to request changes; or
- Attested to the accuracy of the calculated measure.

CMS finalized a performance period for the Medicare spending per beneficiary measure that begins on May 15, 2012, stating that the measure was posted on *Hospital Compare* on April 21, 2011. This is not accurate. The Medicare spending per beneficiary measure data were not posted on that date and are still not posted as of the date of this letter. CMS's assertion that the data were posted in April is even contradicted by other sections of the FY 2012 inpatient PPS final rule (76 FR 51622) that state:

The data for the Medicare spending per beneficiary measure *will be posted on Hospital Compare*, along with the other hospital quality measure data available on that Web site. *We will also provide explanatory language*, in order to assist beneficiaries in interpreting the Medicare spending per beneficiary measure data. (Emphasis added.)

While there is a vague reference to the Medicare spending per beneficiary concept in the *Hospital Compare* "Glossary," this is not sufficient to satisfy the statutory requirement that measures be specified under the IQR program and posted on *Hospital Compare*. **Thus, in order to comply with the law, CMS cannot begin the performance period for the Medicare spending per beneficiary measure on May 15, 2012.**

Hospital-acquired Conditions (HAC). In the hospital inpatient VBP final rule, CMS finalized a general policy starting a measure's performance period one year after it was first displayed on *Hospital Compare*. In accordance with its finalized policy, CMS stated it would begin the performance period for the HAC measures on March 3, 2012. **However, the HAC measures were not posted directly on *Hospital Compare* one year prior to this date, as required by law, and are still not posted as of the date of this letter.** Instead, the HAC measures were displayed as a downloadable spreadsheet on the CMS website ([www.cms.gov](http://www.cms.gov)) on March 31, 2011. Including HAC measures in a spreadsheet does not comply with the statutory requirement for them to be included on the *Hospital Compare* website.

This legal requirement has a sound practical basis. The HAC data are difficult to interpret accurately and including the data on *Hospital Compare* (rather than simply posting all measures in a downloadable spreadsheet) provides context and allows performance to be more readily and accurately understood and improved upon. CMS invests substantial resources in testing how to display data on *Hospital Compare* when new measures are added precisely so that interested persons can more readily interpret them. Consequently, CMS's failure to adhere to this

requirement adversely impacts hospitals' ability to interpret the data and make whatever improvements are required before penalties are potentially attached.

We work with CMS through the Hospital Quality Alliance (HQA) partnership. It was the HQA that first told CMS that posting HACs in a downloadable spreadsheet on the agency's website was not an adequate substitute for meeting the law's requirements. In response to the HQA's concerns, CMS attempted to rectify the situation by posting a link from *Hospital Compare* to the CMS website containing the spreadsheet on April 21, 2011. Posting a link on *Hospital Compare* to an external website containing a spreadsheet with HAC data also fails to meet the statutory requirement. **In order to comply with the law, CMS cannot begin the HAC performance period on March 3, 2012.**

AHRQ Composite Measures. In accordance with CMS's general policy of beginning a measure's performance period one year after it was first displayed on *Hospital Compare*, the agency stated it also would begin the performance period for the AHRQ composite measures on March 3, 2012. **However, the AHRQ composite measures were not displayed on *Hospital Compare* one year prior to this date, as required by law.** In fact, CMS's contractor has notified hospitals that these measures will not be displayed on *Hospital Compare* until mid-October 2011.<sup>1</sup> **Thus, in order to comply with the law, CMS cannot begin the AHRQ composite measure performance period on March 3, 2012.**

## NQF ENDORSEMENT

The ACA states:

**'(IX)(aa) Subject to item (bb), effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a).**

**(bb) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.**

The ACA requires that measures included in the VBP program be endorsed by the NQF. In the case that there is no NQF-endorsed measure, CMS may use a non-endorsed measure as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the HHS Secretary. **However, CMS is not meeting this statutory requirement with respect to the Medicare spending per beneficiary measure.** This measure has not gone through the NQF endorsement process, although CMS has had ample time to

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<sup>1</sup><http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=OnetPublic%2FPPage%2FOnetTier2&cid=1228695321101>

submit it. Further, although it has done so in the past when using other non-endorsed measures, the agency neither provided justification for using the non-NQF-endorsed Medicare spending per beneficiary measure nor gave any consideration to measures that have been endorsed or adopted by a consensus organization identified by the HHS Secretary. **Thus, by including this measure in the VBP program, CMS is not complying with the law.**

NQF endorsement ensures that measures are reliable, valid and relevant. When CMS circumvents the NQF process, as well as the process of other consensus organizations, hospitals are not guaranteed that measures are reliable, valid and relevant. Thus, hospitals are subject to lowered Medicare payments because measures may not, for example, be statistically accurate.

## **VBP PROPOSALS INCLUDED IN THE OUTPATIENT PPS**

We understand that CMS is under tremendous pressure to implement many ACA provisions within a short timeframe. However, we are concerned about how the agency has handled the notice and comment process for the hospital VBP program. CMS made significant changes to this program in three separate regulations. It has been very difficult to track all of the moving pieces associated with these multiple regulations. Further, CMS has created timing issues, both for itself and the public, around outpatient proposals that were reliant on inpatient proposals that were not finalized until well into the outpatient comment period. To the greatest extent possible, we urge CMS to select one regulation in which it will make any future changes to the hospital VBP program.

Proposed Performance Periods and Baseline Periods for FY 2014 Measures. For FY 2014, for both the clinical process and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures, CMS proposes a nine-month baseline period of April 1, 2010 through December 31, 2010, and a nine-month performance period of April 1, 2012 through December 31, 2012. **The AHA supports these proposed baseline and performance periods.** We also support CMS's proposal to notify hospitals of their final FY 2014 performance scores by the beginning of that fiscal year, as well as to select CY 2013 as the performance period for the FY 2015 VBP program.

The ACA directed CMS to include a Medicare spending per beneficiary, or efficiency, measure in the VBP program in FY 2014 *or a subsequent fiscal year*. In the FY 2012 inpatient PPS final rule, CMS finalized a policy to include such a measure in the program beginning in FY 2014. It also finalized a nine-month performance period from May 15, 2012 through February 14, 2013. **However, as noted above, the Medicare spending per beneficiary measure is still not posted on *Hospital Compare*. Thus, in order to comply with the law, CMS cannot begin this measure's performance period on May 15, 2012.**

Even if CMS posts the Medicare spending per beneficiary measure immediately after this comment letter is submitted, it would not be able to begin the performance period until one year later, or the end of August 2012. Since the performance period must end by February 14, 2013,

this would lead to a period of less than six months. This is not acceptable. CMS stated in the January 2011 VBP proposed rule, and we agree, that “a one or two quarter performance period would provide lower data accuracy for scoring hospitals and adjusting their payments.” **Thus, we urge the agency to implement a proper performance period for this measure, which necessitates delaying its introduction into the VBP program until after FY 2014.**

Regarding HACs, CMS proposes a nearly seven-month performance period of March 3, 2012 through September 30, 2012. CMS states that it proposes a September 30, 2012 end date because the performance period needs to end by the fourth quarter of FY 2012 in order to be able to score these measures in time for the FY 2014 VBP program. In addition, CMS states that the performance period start date of March 3, 2012 is one year after the date the HACs were first included on *Hospital Compare*, as is required by statute. **However, as noted above, these HAC measures are still not posted directly on *Hospital Compare*. Thus, in order to comply with the law, CMS cannot begin the HAC performance period on March 3, 2012.**

Even if the agency were to post the HAC measures immediately after our comment letter is submitted, it would not be able to begin the performance period until the end of August 2012. Since the performance period for FY 2014 must end by September 30, 2012, a start date of August 2012 means the period would be about one month long. A one-month performance period is not acceptable. **We remain strongly opposed to the inclusion of the HAC measures in both the VBP program and the HAC policy because they are not NQF-endorsed and hospitals could be penalized twice on the same measures. If, however, the agency still decides to include them, it must implement a proper performance period, which necessitates delaying their introduction into the VBP program until after FY 2014.**

Finally, CMS also proposes a performance period of March 3, 2012 through September 30, 2012 for the AHRQ composite measures. **However, the AHRQ composite measures were not displayed on *Hospital Compare* on March 3, 2011, as is required in order to have a performance period beginning March 3, 2012.** As noted above, CMS’s contractor has notified hospitals that these measures will not be displayed on *Hospital Compare* until mid-October 2011. Thus, in order to comply with the law, the earliest a performance period could begin is October 2012. Since the performance period needs to end by September 30, 2012 in order to be able to score these measures in time for the FY 2014 VBP program, they cannot be included in FY 2014. **We urge the agency to implement a proper performance period for these measures, which necessitates delaying their introduction into the VBP program until after FY 2014.**

**Finally, we strongly urge CMS to use consistent performance periods across measures when at all feasible.** Having different performance periods of differing lengths for many measures, even those within a given domain, is extremely confusing and burdensome to hospitals and other stakeholders. A more streamlined policy is desirable.

Proposed Domain Weighting for FY 2014. To determine a hospital’s total performance score, CMS must combine its scores from the different domains. For FY 2013, the clinical process of

care domain will account for 70 percent of a hospital's total performance score, while the patient experience of care domain will account for the remaining 30 percent. However, for FY 2014, CMS states that this weighting must be revised, as the agency is adding an outcomes domain and an efficiency of care domain. Accordingly, CMS proposes to weight the domains as follows: clinical process of care domain – 20 percent; patient experience of care domain – 30 percent; outcomes domain – 30 percent; and efficiency domain – 20 percent.

**We urge CMS to delay finalizing the outcomes domain.** As noted above, we do not believe that either the HACs or AHRQ composite measures that are part of the outcomes domain can be included in the FY 2014 program due to statutory violations. Therefore, only the three mortality measures potentially remain in the outcomes domain. **However, as we outlined in greater detail in our comments on the January 2011 VBP proposed rule, while we would like to see greater incorporation of outcomes measures into the VBP program, the mortality measures should not be included until the risk-adjustment methodology is further refined.**

Further, we urged CMS to inform the public about how it intends to harmonize the current performance information for the mortality measures on *Hospital Compare* with how the measures will be scored in hospital VBP. Currently, hospitals receive a performance rating of below, at or above the national average compared to the national mortality measure benchmarks. However, CMS has not indicated that it will use this categorization in the scoring methodology for the mortality measures in hospital VBP program. We do not understand how this scoring will translate to a point system. In addition, if CMS intends to use a hospital's point estimate on the mortality measures, we do not understand how it will use the current confidence intervals to differentiate performance beyond the current three categories. It would be inappropriate to use the current point estimate with the current confidence intervals in a scoring methodology.

**It is inappropriate to base an entire domain on only three measures that have serious methodological flaws. Therefore, we strongly urge CMS to delay introducing the entire outcomes domain into the VBP program until after FY 2014.** We reluctantly make this recommendation because, although it is critical to include outcomes measures in VBP, CMS's failure to plan appropriately when measures are posted on *Hospital Compare* has led to conflicts with the statute.

**In addition, we urge CMS to delay finalizing the efficiency domain.** As noted above, we do not believe that the Medicare spending per beneficiary measure, which is the sole measure in the efficiency domain, can be included in the FY 2014 program due to statutory violations.

**Therefore, we strongly urge CMS to delay introducing the efficiency domain into the VBP program until after FY 2014.** We reluctantly make this recommendation because, although efficiency measures can be very valuable, CMS's failure to work with a measure developer and pursue NQF endorsement, as well as its failure to post measures on *Hospital Compare* in a timely and appropriate manner, has led to conflicts with the statute. We urge CMS to devote the necessary resources to the ongoing management of the hospital VBP program to avoid these missteps in the future.

**Thus, we urge CMS to include only the clinical process of care domain and the patient experience of care domain in the VBP program in FY 2014. In addition, the agency should reduce the weighting of the patient experience of care domain to 15 percent.** We believe a weighting of 15 percent strikes a balance between the importance of including a measure of patient experience in the VBP program and the concerns we have about potential biases present in the survey, as outlined in greater detail in our comments on the January 2011 VBP proposed rule. The clinical process domain should accordingly be weighted at 85 percent.

**If, however, CMS ignores our concerns about the small number of measures in the outcomes domain and chooses to include it in the FY 2014 program, we urge it to weight the outcomes at 15 percent.** This weighting would more appropriately reflect the methodological weaknesses that exist with the mortality measures, as well as the limited number of measures the domain includes. We believe that, in general, there should be a connection between the weighting of a domain and the number of measures it includes.

The clinical process domain should then be weighted at 70 percent and the patient experience with care domain at 15 percent. In addition, we note that if CMS chooses to include a three-measure outcomes domain in the FY 2014 program, it will need to re-evaluate the minimum number of measures required for a hospital to be eligible for the domain. We urge CMS to articulate its vision on what number of measures is appropriate to constitute an entire measurement domain and how it empirically derives what weight should be placed on each domain. In order to lend creditability to the empirical basis of weighting measure domains, we urge CMS to consult a technical expert panel.

Additional FY 2014 Hospital VBP Measures. Of the 10 Surgical Care Improvement Project (SCIP) measures that are reported in the IQR program, eight were selected for hospital VBP for the FY 2013 update and beyond. CMS proposes one of the two remaining SCIP measures (SCIP-Inf-9: postoperative urinary catheter removal on postoperative day 1 or 2) for the FY 2014 hospital VBP program. This is an important process of care measure that is closely linked to outcomes; **we therefore support the incorporation of the SCIP-Inf-9 measure into the hospital VBP program for FY 2014.**

Minimum Numbers of Cases and Measures for Outcome Domain for FY 2014. The ACA requires the HHS Secretary to conduct an independent analysis for establishing minimum thresholds. CMS previously finalized that an outcomes domain would begin in FY 2014 and consist of three mortality measures, two AHRQ composite measures, and eight HACs, but it did not set minimums for these measures. According to the proposed rule, CMS contracted for independent analyses to be conducted by Brandeis University and Mathematica Policy Research to determine the minimum number of cases per measure and the minimum number of measures per hospital required to derive reliable performance scores. CMS proposes that a hospital would need 10 cases to be eligible for a mortality measure and three cases to be eligible for an AHRQ composite measure. In addition, CMS proposes that all hospitals that submit at least one Medicare claim during the performance period will be eligible for all HACs except “Foreign

Object Retained After Surgery.” The agency notes that the Foreign Object HAC will not apply to all hospitals.

As discussed above, in order to comply with statutory timelines, we urge CMS to delay introducing the entire outcomes domain into the VBP program until FY 2015. Nonetheless, minimums will eventually need to be set for the domain. **Most importantly, in the interest of transparency, we urge CMS to make public the results of the Brandeis and Mathematica analyses so that all stakeholders may evaluate the results of the study.** We previously requested this in our comments on the January 2011 VBP program proposed rule. The agency responded that to the extent that these analyses were not subject to privilege, it would “make available additional information, including the study results and methods, and [would] inform the public when such information is available.” **Now these studies are being used as the basis for another VBP proposal, yet they still have not been released. It is inappropriate for CMS to continue to make such proposals when the studies are not available to the public for a full and thorough evaluation.** In future rulemaking, we urge CMS to simultaneously make the results of the independent analysis publicly available; propose a minimum threshold for each measure in the regulatory process and justify any changes made from the recommendation of the independent analysis; solicit public comment; and finalize an appropriate applicable minimum threshold for each measure.

**We urge CMS to provide empirical justification, by publicly releasing analytic results, for the minimum threshold of cases needed to derive a consistent rate of reliability for all measures used in VBP programs.** In the proposed rule, CMS states that it includes an efficiency measure in both the group practice and individual reports if the measure is able to be populated for 30 or more patients. CMS also states that: “this threshold is commonly used for attribution purposes.”

It is incumbent upon CMS to harmonize methodologies, such as the establishment of minimum thresholds, across its various VBP programs. One way in which CMS can do this is to establish a rate of reliability that a measure must achieve in order to ensure the measure is statistically accurate. There is a variety of conflicting research on what rate of reliability is needed. Therefore, it is incumbent upon CMS to consult experts and then obtain comment from the public prior to finalizing a rate of reliability. Once a rate is established, then CMS must conduct further research on what minimum threshold of cases (whether it be patients or claims) is appropriate in order to attain the rate. **It is incumbent upon CMS to make all of this research available to the public for review.** Currently, CMS has established the following minimum thresholds for measures used in its VBP programs:

- 30 patients for efficiency measures in the physician feedback program;
- 25 patients for the public reporting of quality measures reported on *Hospital Compare*;
- 11 patients for the ESRD Quality Incentive Program (*proposed*);
- 10 patients for clinical process of care measures in hospital VBP;
- Three patients for the patient safety composites in hospital VBP (*proposed*);
- One claim for the hospital-acquired conditions rates in hospital VBP (*proposed*).

While these measures are currently tied to payment or soon will be, CMS has not done its due diligence to ensure these measures are producing statistically reliable information. CMS must rectify this immediately. In the absence of disclosing its research results on reliability rates, we are unable to assess the appropriate number for a minimum sample of patients for the HACs and AHRQ composite measures. **Further, we believe that the case minimum for the AHRQ measures should apply to each individual measure within the AHRQ composite.**

CMS proposes that all hospitals that submit at least one Medicare claim during the performance period will be eligible for all HACs except “Foreign Object Retained After Surgery.” The agency notes that the Foreign Object HAC will not apply to all hospitals, but does not state how it will determine whether a hospital is eligible for this condition. In the proposed rule, CMS states that Mathematica “examined the minimum number of cases a hospital would need to report in order to receive a reliable score on each HAC measure.” Yet, the agency also states that Mathematica took into account CMS’s view that “the incidence of HACs raises significant safety and quality concerns for patients and for the Medicare program,” and that “a hospital should be held accountable when HACs occur in all instances in order to protect and promote patient safety.” CMS already has a policy in place that achieves this goal. This policy, which was enacted in the *Deficit Reduction Act*, does not permit a hospital to be paid at a higher diagnosis-related group rate for diagnoses arising from a HAC.

Mathematica’s conclusion (and CMS’s proposal) that one claim is sufficient for eligibility seems to be based primarily on this philosophical view, not on the empirical analysis it conducted. This is inappropriate and unresponsive to the statutory mandate. We agree with CMS that rigorous efforts need to be made to protect every patient from harm, which is not the critical question in implementing the HACs as part of VBP. In making HACs part of VBP, CMS must be able to answer the question, “Which hospitals’ performances are sufficiently better than a threshold level or have improved sufficiently from the base line period to warrant reward?” Valid answers to this question require that there be a sufficient number of cases in the calculation of a hospital’s performance rate that one can make reliable and fair comparisons among hospitals and between the base year and the performance year. That is a matter of math and statistics, not philosophy. Further, without the results of Mathematica’s study, the public cannot fully weigh the merits and tradeoffs between a philosophical and empirical basis for the proposal. **We again urge CMS to make the results of the Brandeis and Mathematica analyses available to the public so that all stakeholders may evaluate the results of the study.**

**In the meantime, however, we disagree with CMS’s proposal that all hospitals submitting at least one Medicare claim during the performance period be eligible for all HACs except “Foreign Object Retained After Surgery.”** The occurrence of a HAC is a rare event, as evidenced by the fact that at least half of hospitals did not have an occurrence of six of the eight HACs, and that the proposed achievement threshold for the HACs is 0.00109 and the proposed benchmark for the HACs is 0.0000. Because of this rarity, it is inappropriate for the minimum sample size to be one Medicare claim. The sample must be increased in order to improve statistical reliability. Further, because the sample size of the HACs is based on all Medicare claims, not only the Medicare claims for a specific condition, increasing it appreciably would not

exclude many hospitals. **Because, as we describe below, we do not believe the HACs can be included in the FY 2014 VBP program, we urge CMS not to finalize HAC minimums at this time. The agency should reconsider its proposal and, concurrent with or after it releases the Brandeis and Mathematica analyses, make a new HAC minimum proposal.** At that time, we suggest the agency also propose the method it will use to determine whether a hospital is eligible for the “Foreign Object Retained After Surgery” HAC, as it did not do so in this rule.

In addition, CMS proposes to exclude from the VBP program any hospitals for which fewer than 10 of the 13 outcomes measures apply. These 10 measures would need to include at least seven of the eight HACs and three additional outcomes measures. However, as discussed above, in order to comply with statutory timelines, we believe that CMS can introduce only the three mortality measures into the outcomes domain in FY 2014. Because it is inappropriate to base an entire domain on such a small number of measures, we urge CMS to delay introducing the entire outcomes domain into the VBP program. **However, if CMS ignores our concerns about the small number of measures in the outcomes domain and chooses to include it in the FY 2014 program, it should exclude from the VBP program any hospital for which fewer than all three of the outcomes measures apply.**

**Finally, the AHA supports CMS’s proposal to exclude from the VBP program any hospital that does not have enough cases and measures to receive scores on all finalized domains.**

Proposed Performance Standards for FY 2014. **We do not support CMS’s proposal that its “topped-out” measure policy not apply to the HACs.** We do not see any difference that would justify a difference in policy for the HACs measures compared to the clinical process measures and urge CMS to articulate its reasons for treating the HACs differently. If CMS is considering this “topped-out” policy for HACs because some HACs are rare events, it raises the issue of whether inclusion in the hospital VBP program is appropriate for HACs. We do not believe HACs should be included in the hospital VBP program and urge CMS to do extensive stakeholder engagement on this issue. At a minimum, CMS should host a technical expert panel to seek feedback on which program (HAC diagnosis-related group policy, hospital VBP or section 3008 of the ACA) is appropriate for each individual HAC.

Proposed Scoring Methodology for FY 2014. CMS proposes to use the same scoring methodology for the FY 2014 VBP program that it used for the FY 2013 program, with certain modifications for HAC scoring. Specifically, the agency will calculate a score for each domain by adding the individual measure scores within that domain, weighting each measure equally. The score for each domain will be based only on the measures that apply to that hospital. The hospital’s total points for the domain will then be divided by that hospital’s total points possible. CMS proposes to treat the individual HACs as a single aggregate condition for purposes of setting performance standards and scoring. Though we do not support the use of HACs in hospital VBP, because they are not NQF-endorsed, **we have no objections to the HAC scoring proposals.**

Ensuring HAC Reporting Accuracy. CMS articulates several concerns with the accuracy of HAC reporting through Medicare fee-for-service claims data. Specifically, CMS states that it believes HAC claims data are underreported. We also have concerns about using claims data to determine rates of HACs and have repeatedly brought this to CMS's attention. Alternative sources, such as medical record abstraction, may be a much better source of calculating HAC rates. We have repeatedly urged CMS to develop actual HAC measures with specific numerators and denominators for recognizing HACs that go well beyond the unacceptable claims-based rates that CMS uses. **Such a step is necessary under the statute, as noted above.** Further, we have urged CMS to submit the HAC rates to the NQF for measure endorsement. Though CMS's assumptions about the reporting of HACs may be valid, the first step in attaining more accurate data to recognize HACs is to move away from flawed claims data.

Proposed Review and Corrections Process under the VBP Program. CMS makes two proposals regarding the timeframes that hospitals will have for reviewing their data prior to their use in the calculation: one for the data submitted to the Quality Improvement Organization (QIO) clinical data warehouse (process of care measures) and one for submission of HCAHPS data. **We support CMS's proposal to use the timeframe for submission and review of the clinical process measures in the QIO data warehouse for the hospital VBP program.** The process in place for submission and review of the process measures for the IQR program is working and does not need to be altered for the hospital VBP program. However, we do not support the proposal to reduce the HCAHPS timeframe of submission from 14 weeks to 13 weeks in order to allow hospitals one week to review their data. We note that CMS made a similar proposal for HCAHPS in the FY 2012 inpatient PPS proposed rule for the IQR program; however, CMS did not finalize this proposal HCAHPS proposal. Since this change was not finalized for the IQR program, we do not support its inclusion in to the hospital VBP program. Further, we note that allowing hospitals only one week to review their performance data is not enough time. We urge CMS to consider a minimum of two weeks for review of HCAHPS data.

We note that CMS did not include any proposals for review of claims-based data by hospitals before they are used in the hospital VBP program. The ACA requires the HHS Secretary to provide a hospital with an opportunity to appeal the validation of measures reported by such hospital. We urge CMS to propose timeframes for the review of the mortality, AHRQ composites and HAC data in future rulemaking. Further, hospitals have never seen their performance on the Medicare spending per beneficiary measure. **We urge CMS to rectify this immediately.**

Beyond explicitly creating an appeals process, hospitals should be afforded the opportunity to pursue an external validation of the measures that CMS calculates. In order to facilitate external validation, **we urge CMS to make available a database including all of the data used to calculate the hospital VBP measures.** CMS must provide the data in a format that is consistent with the time periods used for the baseline and performance data. Until this resource is made available, hospitals have not been given the right of appeal that was afforded in the ACA.

Donald M. Berwick, M.D., M.P.P.

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If you have any questions, please feel free to contact me or Lisa Grabert and Joanna Hiatt Kim, senior associate directors for policy, at (202) 626-2305 and (202) 626-2340, respectively.

Sincerely,

/s/

Rick Pollack

Executive Vice President

Cc: Janice Hoffman, General Counsel, CMS

Jonathan Blum, Deputy Administrator, Center for Medicare

Patrick Conway, Director, Office of Clinical Standards and Quality