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Center for Clinical Standards and Quality
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***RE: Call for Public Comment, Reevaluation of Hospital-Acquired Condition Reduction Program Scoring Methodology by the Yale Center for Outcomes Research and Evaluation***

Dear Dr. Goodrich:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the re-evaluation of the Hospital-Acquired Condition (HAC) Reduction Program scoring methodology, developed by the Yale-New Haven Health Systems Corporation/Center for Outcomes Research and Evaluation (Yale).

While the AHA recognizes that the legislative mandate for HAC Reduction Program is very poorly designed, we applaud the Centers for Medicare & Medicaid Services' (CMS) willingness to reconsider aspects of its implementation. America's hospitals are deeply committed to reducing preventable patient harm, but are concerned that the HAC program fails to recognize hospitals for improvement and disproportionately penalizes hospitals caring for our nation's sickest patients. The HAC program's statutory requirements prevent CMS from using scoring approaches that recognize hospitals for significant performance improvement. However, we had hoped that CMS would direct Yale, and the technical expert panel (TEP) it convened, to assess a broad range of policy options within CMS's authority that would result in less biased HAC penalties.

**We are disappointed in the narrow scope defining this re-evaluation, which precluded Yale and the TEP from recommending changes that address the program's most significant shortcomings.** The public comment solicitation on CMS's website notes that the "reevaluation and/or alteration of the individual measures" in the HAC Reduction Program is outside the scope of the evaluation. Yet, individual measures are the HAC program's most significant problem that CMS has the authority to address. The failure to ask the TEP to evaluate such an important policy issue seems like an important missed opportunity. For example, numerous stakeholders have raised concerns about the low levels of accuracy of the patient safety indicator (PSI)

measure that comprises 35 percent of a hospital's HAC score. Others have urged CMS to consider updating the healthcare associated infection (HAI) measures – comprising 65 percent of a hospital's HAC score – so that hospitals are scored on total population at risk for infection, as opposed to the volume of central lines or urinary catheters. This is because many HAI reduction efforts correctly focus on reducing the use of unnecessary central lines and urinary catheters. As a result, a hospital's HAI rates could remain steady because the measure denominators (i.e., days that patients are on central lines and catheters) become smaller.

**Improving the HAC program's measures would result in a fairer program for all hospitals. Yet the sole policy recommendation in the draft report focuses on an issue that affects only six of the more than 3,300 hospitals eligible for the HAC Reduction Program.** Specifically, the draft report recommends that CMS, beginning with the fiscal year (FY) 2017 HAC Reduction Program, treat each measure in the HAI measure domain "independently." CMS would give hospitals the worst possible score of 10 points on each measure for which they fail to submit data submission waivers. Currently, hospitals are not penalized if they submit only one of the HAI measures in the domain and fail to provide a submission waiver for the other measures**.** The AHA agrees with this recommendation, but an issue affecting six hospitals does not seem to rise to the level of importance that would require advice from an esteemed group of experts.

**The AHA strongly urges CMS to address other more significant and meaningful issues in the HAC program.** We applaud the collaborative and transparent approach CMS has taken with the re-evaluation work so far by involving a TEP and providing an opportunity for public comment. We encourage CMS to continue using such an approach, but with a broad mandate to examine all aspects of the program. As a starting point, the agency could ask Yale and the TEP to consider the following ways to improve the program. These are described further in our comments (attached) on the FY 2015 inpatient prospective payment system proposed rule. CMS should:

- Eliminate the overlap in measures between the HAC and value-based purchasing programs.

- Identify and implement alternative measures to PSI 90 so that it can be phased out of the program as soon as possible. For example, the agency could explore the use of measures from the National Quality Forum portfolio of safety measures.

- Support innovative approaches to measuring patient safety events, including the work of organizations developing all-cause patient harm measures derived from electronic health records. The agency should consider how to incorporate these innovations into the program in future years.

We look forward to continuing to work with you to improve the HAC Reduction Program, and thank you for the opportunity to comment. If you have any questions, please feel free to contact me or Akin Demehin, senior associate director, policy, at (202) 626-2365 or ademehin@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President
Public Policy Analysis & Development

**Attachment:**
**AHA Comments on the Hospital Acquired Condition (HAC) Reduction Program**
**FY 2015 Inpatient Prospective Payment System Proposed Rule**
**June 26, 2014**

As mandated by the ACA, for FY 2015, CMS will implement the HAC Reduction Program, which imposes a 1 percent reduction to Medicare payments for hospitals in the top quartile of risk-adjusted national HAC rates. The basic payment adjustment approach, measures and scoring methodology used in the program were finalized in the FY 2014 inpatient PPS final rule, and the agency proposes largely non-substantive refinements for FY 2015. Hospital HAC rates are determined using three measures split into two measurement domains. One domain, which comprises 65 percent of a hospital's score, includes two healthcare-associated infection (HAI) measures – central line-associated blood stream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI). The other domain includes a Patient Safety Indicator composite measure (PSI 90) that combines performance on several safety indicators, such as pressure ulcers, post-operative hip fractures, and post-operative blood clots. For FY 2016, the agency proposes to place a greater weight on the HAI measure domain in determining a hospital's Total HAC Score.

**America's hospitals are deeply committed to reducing preventable patient harm, and support quality measurement and pay-for-performance programs that effectively promote improvements in patient safety. Our longstanding principle is to support value-based approaches that promote attainment and improvement. However, the AHA remains very concerned that the HAC policy is poorly designed.** We acknowledge that the HAC Reduction Program's statutory requirements prevent CMS from addressing some of the program's most important shortcomings. For example, even though it is arbitrary to do so, CMS must assess HAC penalties on 25 percent of hospitals each year, regardless of any significant improvements in a hospital's performance, whether there is a significant difference between its performance and that of the rest of the field, or the overall progress the field has made in improving performance on measures. Although we strongly believe this requirement fails to promote patient safety improvements, CMS has implemented as reasonable a scoring methodology as permitted by the statute.

In light of these constraints, we have urged CMS to adopt measures that accurately and fairly assess hospital performance on critically important and potentially preventable patient safety issues. CMS has indicated that the measures in the program allow for hospitals to be assessed on a variety of patient safety issues. The three measures in the FY 2015 HAC program also are used in the hospital value-based purchasing (VBP) program, and CMS suggests that the commonality of measures with the VBP program promotes alignment of quality improvement efforts.

**In practice, unfortunately, the overlap of measures between the HAC and the hospital VBP programs creates the potential for unfair double payment penalties, and could send conflicting signals about the true state of hospital performance. For example, a hospital could incur a penalty under the HAC program, signaling poor performance on the HAC measures, but receive an incentive under the VBP program, signaling good performance on**

**the VBP measures (including HACs). Moreover, the PSI 90 measure does not have a level of reliability or validity acceptable for measures in accountability applications. We also are deeply concerned that the current measures in the program disproportionately penalize teaching and large hospitals (more than 400 beds). Therefore, we urge CMS to adopt several changes to the HAC program that would more effectively promote hospital improvements in patient safety and improve the fairness of the program.** Specifically:

- CMS should eliminate the overlap in measures between the HAC Reduction Program and VBP program.

- CMS should identify and implement alternative measures to PSI 90 so that it can be phased out of the program as soon as possible. For example, the agency could explore the use of measures from the National Quality Forum (NQF) portfolio of safety measures.

- CMS should support innovative approaches to measuring patient safety events, including the work of organizations developing all-cause patient harm measures derived from electronic health records (EHRs). The agency should consider how to incorporate these innovations into the program in future years.

- CMS should adopt an exemption process for hospitals whose HAC Reduction Program performance may be affected by natural disasters or other extenuating circumstances beyond their control.

These recommendations are outlined in greater detail below.

**ELIMINATING THE MEASURE OVERLAP WITH VBP**

Many stakeholders, including CMS, have suggested that using the same measures in multiple programs is desirable because it aligns measures across programs and creates increased emphasis on a particular quality or safety issue. **However, the AHA does not support using the same measures in both the HAC Reduction Program and VBP program because the programs use disparate ways to identify good versus bad performance. This could lead to inappropriate and unfair double payment penalties, or worse, send conflicting signals about the true state of performance on these measures to hospitals and patients.**

As currently constructed, it is entirely possible that performance in the one program could appear acceptable or even good, but may lead to a payment penalty in the other program. As outlined in Table 1 below, the measurement and performance periods of the HAI measures and PSI 90 differ significantly. This alone may cause differences in measure performance.

**Table 1: Comparison of HAC Reduction and VBP Baseline and Performance Periods FY 2015**

| Measure | VBP Baseline Period | VBP Performance Period | HAC Measurement Period |
|---|---|---|---|
| HAI measures | Jan. 26, 2011 – Dec. 31, 2011 | Jan. 26, 2013 – Dec. 31, 2013 | Jan. 1, 2012 – Dec. 31, 2013 |
| PSI 90 | Oct. 15, 2010 – Jun. 30, 2011 | Oct. 15, 2012 – Jun. 30, 2013 | Jul. 1, 2011 – Jun. 30, 2013 |

Moreover, the scoring methodologies of the two programs are vastly different, which could lead to hospitals having disparate scores for the same measure, as well as disparate payment incentives. In the VBP program, a portion of hospital reimbursement is withheld, with hospitals having an opportunity to earn incentive payments back based either on how well they perform on certain quality measures or how much their performance improves from a baseline period. The HAC Reduction Program, by contrast, assesses penalties based on scoring in the top quartile of performance.

**Based on an analysis of estimated HAC penalties and VBP payments from data in the proposed rule, the AHA has identified indirect, but troubling, evidence that hospitals will experience disparate signals from the VBP and HAC programs.** Table 2 below categorizes hospitals by how they are projected to perform under both the HAC and VBP programs. Of the more than 3,300 hospitals potentially eligible for both programs, more than 1,100 hospitals, or 33 percent, will experience a loss under the VBP program, but not incur a HAC penalty. Moreover, 290 hospitals, or nearly 9 percent, will perform well on VBP by experiencing a gain, but also incur a HAC penalty. Thus, in FY 2015, nearly 42 percent of hospitals will have performance on the HAC and VBP program that is not directionally consistent.

**Table 2: Projected FY 2015 Hospital Performance on VBP and HACs**

| Projected FY 2015 Hospital Performance | Number of Hospitals | Percent of Hospitals |
|---|---|---|
| VBP Loss, No HAC Penalty | 1,113 | 33.05 % |
| VBP Gain, HAC Penalty | 290 | 8.61 % |
| VBP Gain, No HAC Penalty | 963 | 28.59 % |
| VBP Loss, HAC Penalty | 361 | 10.72 % |
| No VBP Gain or Loss*, HAC Penalty | 110 | 3.27 % |
| No VBP Gain or Loss*, No HAC Penalty | 531 | 15.77 % |
| Total | 3,368 | 100.00 % |

*These hospitals are ineligible for the VBP program due to insufficient data.

The AHA is conducting further analysis to determine the extent to which performance on the three measures common to both programs is driving the inconsistency in performance. Given that the VBP's outcome measure domain – which includes both PSI 90 and the two HAI measures – comprises 40 percent of a hospital's total VBP score, we believe that the differences in scoring approaches and data timeframes between the HAC and VBP programs may be contributing at least in part to differences in hospital performance.

The differences in measurement periods and scoring methodologies highlight important philosophical differences between the programs. VBP, we believe, is geared toward encouraging hospital improvement on measures where there is still variability and a gap in performance. The HAC program, by contrast, is a penalty program, plain and simple. Penalizing organizations because they have not achieved some level of performance without being able to demonstrate clear and achievable strategies in which that level of performance could be reached is both arbitrary and unreasonable. As noted above, the legislative mandate of the HAC program restricts CMS's ability to implement a fairer approach to scoring hospital performance, such as recognizing both improvement and achievement. We would welcome the opportunity to work with CMS to replace the HAC program with a more effective approach to encouraging hospital improvements in patient safety.

**Absent a legislative change to the HAC program, the AHA recommends that CMS consider all of its hospital pay-for-performance programs as being part of a comprehensive strategy in which measures are placed into programs using a staged approach.** We believe the measures selected for all of the pay-for-performance programs should be valid, reliable and important. The measures chosen for the IQR program, should be the basis for selection into the pay-for-performance programs. Those used in VBP should show variation in performance and some evidence of potentially effective strategies for improving performance. The ones chosen for the HAC program should have generally good, but not "topped out," performance, with a limited performance gap to close and a set of highly effective proven strategies that will lead to improved performance. This would indicate that the strategies for preventing the harm to patients were known, effective and able to be implemented in various hospitals. In such instances, failure to prevent such harm could represent a system failure for which a payment penalty would be a reasonable public policy option rather than an occurrence of patient harm that may not have been preventable. However, we continue to believe that the legislative mandate to penalize a quarter of hospitals each year regardless of improvement is misguided.

**For the reasons outlined above, we urge CMS to use measures in either the VBP or HAC program, not both.** We again recommend that CMS retain CLABSI and CAUTI in the HAC program, while retiring both measures from the VBP program. CLABSI and CAUTI are well-established HAI measures on which hospitals have been focused for several years. We also recommend that CMS use surgical site infection (SSI), *Methicilin-resistant Staphlococcus aureus* (MRSA) and *Clostridium Difficile (C. Difficile)*, which will be added to the HAC program in FY 2016 (SSI) and FY 2017 *(*MRSA and *C. Difficile)*, in the VBP program before putting them into the HAC program. The agency should monitor performance on these measures to determine when they should be transitioned to the HAC program. The rates of SSI have

declined, but there remains considerable variability in rates across surgical procedure types. Similarly, while hospitals have focused on reducing MRSA and *C. Difficile* rates, these measures were not part of federal quality reporting programs until they were finalized for the hospital IQR program for the FY 2015 payment determination. The public reporting of the measures began only in December 2013, meaning there has been limited experience with using the measure in a public reporting application.

**PSI-90 MEASURE ISSUES**

CMS proposes to change the weights assigned to the two domains of HAC measures. It would increase the weight of HAI measures from 65 percent to 75 percent, while lowering the weight of the PSI-90 composite from 35 percent to 25 percent. CMS indicates that this change is appropriate because several stakeholders have indicated support for reducing the weight of PSI measures, and because the SSI measure will become part of the HAI measure domain.

**The AHA appreciates CMS's responsiveness to stakeholder views about PSI 90 and we support this proposal. However, we continue to have significant concerns about the use of PSI 90 in the HAC Reduction Program because it fails to accurately and meaningfully reflect hospital performance. Therefore, we urge the agency to develop a plan to phase out the PSI measure from future years of the HAC program, and replace it with a more reliable and valid measure or small set of measures.**

PSIs use hospital claims data to identify patients that have potentially experienced a safety event. However, claims data do not fully reflect the details of a patient's history, course of care and clinical risk factors. As a result, the rates derived from the measures are highly inexact. PSI data may assist hospitals in identifying patients whose particular cases merit deeper investigation with the benefit of the full medical record. But, the measures are poorly suited to drawing definitive conclusions about hospital performance. For example, a recent study that validated the results generated by PSI 3 (pressure ulcer rates) using direct patient surveillance found that PSI 3 frequently misclassified hospital performance.[i] This finding is consistent with a CMS-commissioned study showing that many of the individual components of PSI-90 have low levels of reliability.[ii] Adequate measure reliability is critical to ensuring that differences in performance scores across hospitals are, in fact, due to underlying differences in quality and not just random variations in patient populations or in how hospitals capture clinical information and code it into claims.

**A recent review of PSI 90 by the patient safety measure review committee of the NQF revealed additional concerns about the reliability and validity of the measure.[iii] In fact, the committee did not recommend the measure, as currently constructed, for continued NQF endorsement.** PSI 90 is comprised of individual PSIs reflecting different patient safety issues, and each component PSI is assigned a weight towards calculating the total measure score. The committee noted that the weights assigned to each component may not reflect the relative importance or preventability of each component. For example, the committee expressed concern that PSI 15, which reflects the rates of accidental punctures or lacerations during surgery, has too high a weight. The committee also recommended that the weighting used more explicitly

consider "the degree of preventability or actionability by a healthsystem [sic] to reduce it."[iv] Lastly, the committee "expressed apprehension about the use of the measure in payment applications."[v] In response, the measure developer has indicated that the measure will be revised and re-submitted to the committee for review.

**The AHA strongly supports the use of NQF-endorsed measures in federal quality reporting and pay-for-performance programs, including the HAC Reduction Program**. The NQF endorsement process is designed to bring together multiple stakeholders to assess whether measures are important, scientifically sound, useable and feasible to collect. The fact that the NQF Patient Safety Committee suggests that PSI 90 will require significant changes in order to be suitable for continued endorsement is a strong indication that the measure is inappropriate for the HAC program.

**The AHA also is concerned that PSI 90 focuses predominantly on surgical issues, which may contribute to the fact that large hospitals and teaching hospitals bear the brunt of penalties.** For example, retained foreign objects (PSI 5), post-operative metabolic derangement (PSI 10), post-operative deep vein thrombosis (DVT) (PSI 12), and accidental puncture/laceration (PSI 15) are all more likely to occur in the context of surgical care. We agree that improving surgical safety is a laudable and important goal for hospitals. However, hospitals with a range of clinical services will be subject to the HAC program, and some may have significantly higher surgical volumes than others. Large hospitals and teaching hospitals offer an array of services, and often care for the most medically complex patients. Such hospitals are often referral centers, and are more likely to have a higher volume of surgical procedures. We believe that because the PSI measures are biased toward surgical procedures, hospitals that have higher volumes of such procedures are more likely to receive penalties.

**ALTERNATIVES TO PSI 90**

**For the reasons described above, we urge CMS to identify alternative measures that could be used in the HAC Reduction Program in place of PSI 90.** In identifying alternative measures for the HAC program, we recommend that the agency use the following guiding principles:

- CMS should identify measures that address a variety of quality and safety issues relevant to a broadest possible range of hospitals. This will help ensure that hospitals do not experience HAC penalties simply because of the types of patients they treat.

- CMS should use only NQF-endorsed measures in the HAC Reduction Program.

- Before proposing measures for the HAC program, the agency should use the formal pre-rulemaking process of the Measure Applications Partnership (MAP). The ACA requires that measures for most CMS quality reporting and payment programs be reviewed by the multi-stakeholder MAP before they are proposed for programs. While the HAC program does not specifically require MAP review, we believe the MAP's perspective is critical to

facilitating agreement among all stakeholders about which measures are the most important for national quality efforts.

- CMS should report measures publicly for at least one year before incorporating them into the HAC Reduction Program so that any unintended consequences of measurement and reporting can be addressed. Further, if the safety issue addressed by the measure is important, but it is unclear whether effective strategies exist through which a hospital could effectively reduce the incidence of harm, CMS should consider including the measure in the VBP program before moving it to the HAC program.

One potential source of stronger measures in the short term is the portfolio of NQF-endorsed measures. While not all NQF-endorsed measures are suitable for a pay-for-performance application, CMS should review the NQF portfolio to identify measures it could substitute for the existing PSI measures. The MAP provided another useful reference by assembling a patient safety "Family of Measures" that identifies suitable measures for possible use in federal programs.[vi] For example, there is an NQF-endorsed pressure ulcer prevalence measure (NQF #0201) in which hospitals conduct quarterly, one-day studies of the number of patients with pressure ulcers in their facilities. While this measure is not perfect, we believe it is better than PSI 3, which is a component measure of PSI 90. As noted above, CMS should seek formal MAP pre-rulemaking review of NQF #0201 and any other measure it identifies through this review process.

**USE OF EHR-BASED ALL-CAUSE HARM MEASURES**

The AHA also acknowledges that CMS may need to embark on longer-term efforts to either re-tool or develop new measures that better address important patient safety topics. In the proposed rule, CMS solicits comment on whether it should use a standardized, EHR-based composite measure of all-cause harm in future years of the HAC Reduction Program. The agency's interest in such a measure stems from the early work of some hospitals that are using EHRs to proactively identify potential and actual harm across their patient populations.

**The AHA believes that EHR-enabled approaches to measuring preventable adverse events hold considerable promise for the future, and we strongly encourage CMS to support those hospitals that are engaging in innovation and experimentation in this area.** If appropriately designed, EHR-derived measures of adverse events would result in significantly more reliable and valid data than the use of claims data. Such measures also could require significantly less effort to collect and report than measures manually abstracted from patient charts. Several AHA members are participating in efforts to use EHR-derived measures of all-cause adverse events and have reported considerable success in proactively identifying and reducing adverse events.

These exciting efforts are still under development, and not all hospitals have the capacity to deploy all-cause adverse event measures. For this reason, it would be premature to propose a "date certain" for using such a measure for all hospitals. However, we encourage CMS to use its Innovation Center to work with hospitals using such innovative approaches to gain an appreciation for what it would take to scale up such a measure more broadly. The agency also

should consider using its authority to test innovative approaches to improving care and reducing cost by providing alternative mechanisms to participate in the HAC program for hospitals that use EHR-based all-cause adverse event measures.

**DISASTER/EXTRAORDINARY CIRCUMSTANCES WAIVER**

**The AHA commends CMS for soliciting input on whether it should adopt a waiver process for hospitals that face natural disasters or other extraordinary circumstances. We are eager to work with the agency to develop fair, consistent waiver processes for all of its quality reporting and pay-for-performance programs.** Natural disasters and other circumstances have a profound impact on both hospitals' ability to collect measure data and their performance on those measures. As we noted in a letter to the agency on May 20, 2013, hospitals affected by Superstorm Sandy in October 2012 experienced meaningful differences in their performance on a variety of quality measures. Without a waiver mechanism, we are concerned that hospitals will face an undue burden of data reporting and collection, as well as the potential for their performance to be unfairly reported and penalized.

The AHA was pleased that the agency adopted a waiver process for the VBP program in the FY 2014 inpatient PPS final rule. The agency could consider adopting several aspects of that process for the HAC program. For example, hospitals could submit waiver requests to CMS describing how their performance on HAC measures was adversely affected within 60 days of the occurrence of the extraordinary circumstance. This would ensure that hospitals do not seek an advantage on their HAC scores long after a disaster period has ended. We also encourage the agency to develop a mechanism to waive program requirements for an area – such as federally declared disaster areas – when a natural disaster or other extraordinary circumstance affects a region or locale.

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[i] Meddings JA et al. Hospital Report Cards for Hospital-Acquired Pressure Ulcers: How Good are the Grades. Annals of Internal Medicine. 519(8):505-13. October 2013.

[ii] See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

[iii] See National Quality Forum, *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at http://www.qualityforum.org

[iv] See National Quality Forum, *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at http://www.qualityforum.org , page 55.

[v] See National Quality Forum, *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at http://www.qualityforum.org , page 56.

[vi] See National Quality Forum, *MAP Families of Measures: Safety, Care Coordination, Cardiovascular Conditions, Diabetes*, available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72021