



**Association of
American Medical Colleges**
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0400 F 202 828 1125
www.aamc.org

December 31, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Listening Session Comments on Hospital and Healthcare Acquired Conditions

Dear Mr. Weems,

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 130 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 125,000 faculty members, 70,000 medical students, and 104,000 resident physicians. We appreciate CMS' continued efforts in being transparent about their plans for Value Based Healthcare and conducting a listening Session on Hospital and Healthcare Acquired Conditions. We are pleased to have the opportunity to provide input and feedback.

The AAMC and its members are committed to providing high quality care and are supportive of strategies focused on eliminating harm and minimizing negative outcomes. Our members have been very active in implementing quality improvement strategies to reduce infections and eliminate serious reportable adverse events. We agree with CMS that hospitals need to do what they can to eliminate harm, however we do have concerns with the structure and implementation of the current Hospital Acquired Conditions and proposed Healthcare Acquired Conditions programs. Our comments and concerns re-iterate those already submitted through the inpatient and outpatient proposed rule comment periods.

Reasonably Preventable/Evidence-Based Guidelines/Risk Adjustment

The language in the Deficit Reduction Act requires that the conditions selected for the HAC program must be reasonably preventable and supported by evidence-based guidelines. Much has been debated about the definition of "reasonably preventable" as well as the amount of evidence supporting some of the selected conditions. To be reasonably preventable, there must be solid evidence, published in peer reviewed literature, that by engaging in a certain set of practices, clinicians can reduce the occurrence of an event to zero or near zero, among a typically broad and diverse patient population, including high risk patients. There is significant evidence that patient factors (co-morbidities, risk factors, etc.) have a great impact on the ability of hospitals to reduce the likelihood a patient would develop or contract a particular condition.

Aside from true Never Events, any condition selected should be supported by evidence-based guidelines that allow providers to achieve the near zero occurrence all of the time. An evaluation and assessment of the evidence supporting the guidelines should be conducted for potential and selected conditions and should be shared during rulemaking to allow for public comment.

Many of the selected conditions do not have guidelines that allow hospitals to reach the near zero occurrence, yet hospitals are still being held accountable. More specifically, teaching hospitals are at greater risk of being negatively impacted given they disproportionately treat complex and severely ill patients who often present with multiple co-morbidities and serious or rare complications of routine medical conditions. These patients are naturally more susceptible to complications and infections. As major referral centers, we are often the recipients of complex and high risk patients who are transferred from non-teaching hospitals. We fear that the incentives associated with this program may result in “cherry picking” and our members will see an increase in transfers beyond what is normal for complicated patients.

We appreciate CMS’ plans to evaluate new approaches for risk adjustment looking at population level adjustments which will help to achieve a level playing field amongst hospitals irrespective of the types of patients they treat.

Standard definitions

As CMS looks at potential conditions for future years, any condition must utilize a standardized definition where there is agreement in the clinical community around diagnosis. CMS needs to ensure that there is consistency in determining a particular condition exists. A widely known example where there is a lack of a standard definition and would be inappropriate to implement is Ventilator Associated Pneumonia (VAP). This problem is also an issue for coding where there are contradictories such as pyelonephritis and urethritis that are included in the coding for urinary track infections (UTIs), when, in fact, they may not have the associated UTI. Similarly, coding law requires that, if reported in the physician’s progress notes, 100,000 CFU of any single organism in a urine culture be coded as UTI, when, in fact, it may be colonization.

Promotion

We continue to have issue with the way this program has been promoted. In the media and popular press, this program is being referred to as the Never Events program which is an inaccurate representation. If that were the case then the only conditions that should be included in this program are the appropriate conditions from the list of serious reportable events endorsed by the NQF. While CMS has been careful to make the distinction now, the continued reference to this program as the Never Events program sets up false expectations amongst consumers and patients regarding their healthcare. In addition, we are concerned that the use of the Never Event term for this program in the legal arena will create a new minimum standard of care and may increase the liability of our members. This would hold our members responsible for an outcome that may not have been within their control or be misconstrued as somehow negligent. Many of these conditions are not preventable in complex patients even though evidence-based guidelines have been followed.

Documentation

The IOM points to team-based care as a measure of quality and yet this payment policy does not allow institutions to capitalize on the expertise of all providers on the care team. Nursing notes should be allowed for inclusion in the HAC policy beyond determination of staging for pressure ulcers. Nursing notes can be an integral part of identification of selected HACs and the use of their notes would eliminate the requirement for physicians to document what has already been captured in the nursing notes.

Education

Implementing a clinical program through an administrative policy presents significant challenges and obstacles including educating staff on the clinical and administrative program requirements. To that end, there is a significant need to provide a centralized resource aimed at education of providers, coders and quality management staff. We have fielded questions from our members looking for educational resources on coding, evidence-based guidelines and contacts for further information. At this time all of the necessary information is somewhat scattered and not in a user-friendly format which makes it more difficult for those institutions trying to be compliant with the requirements. We suggest that CMS work to develop a centralized resource with all of the appropriate federal and non-federal partners to facilitate the dissemination of up-to-date and complete information.

Evaluation

CMS has implemented the HAC program in the inpatient setting with eight conditions and added an additional three with very little notice just prior to full implementation. In order to fully implement the HAC program, Present on Admission (POA) coding was also initiated. CMS has moved very quickly to implement as well as expand this program over a very short period of time. At this point, CMS has not conducted any evaluation of the program's effectiveness or monitoring for unintended consequences. We believe that CMS should evaluate the HAC program, including the overall effectiveness, accuracy of POA coding, cost/benefit analysis and potential for unintended consequences, prior to any further expansion.

Healthcare Associated Conditions – Hospital Outpatient Setting

An HAC program should provide hospitals the tools and information they need to improve the quality of their care while minimizing harm. The program should align proposed and existing incentives so all providers are working together in the best interest of the patient. It's not clear that the proposed expansion of the HAC program would be able to accomplish that goal.

CMS has pointed out in the OPSS Proposed and Final Rules the many known challenges in implementing the HAC program in the hospital outpatient setting. The hospital outpatient setting has a different payment mechanism utilizing bundling of services and the ability to isolate particular services is much more complicated than in the inpatient setting. While many think of the hospital outpatient setting as the Emergency Room and Outpatient Surgery where an HAC

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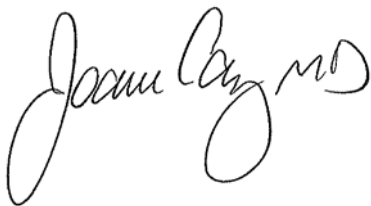
program may be easier to implement, for teaching hospitals many of our ambulatory clinics are paid under the OPSS system. Since a large portion of teaching hospital patients are receiving care from multiple providers, both within and external to the teaching hospital, it would be extremely complicated and resource intensive to develop a system that could determine what is present on admission, where an HAC may have occurred, who is responsible and whether it is really an HAC or rather a complication of their post treatment self care and maintenance. We are concerned that a lack of an appropriate risk adjustment methodology to account for these complex patients would result in teaching hospitals being impacted unfairly.

As we have already seen from the Hospital Outpatient Quality Reporting Program implementing an existing inpatient program in the outpatient setting can result in unexpected difficulties. Due to the difference in information systems, hospitals had difficulty in properly identifying the appropriate patient population for reporting. This highlights and reinforces how different the systems are between the inpatient and outpatient settings and the complexities that may arise that are above and beyond what is already known or expected.

As we have stated previously, we believe that until a full evaluation of the HAC program in the inpatient setting has been conducted as well as applying lessons learned from the unique outpatient issues from the outpatient reporting program, CMS should not move forward in expanding the HAC program to the outpatient setting.

If you have any questions, or require further information about the comments above, please contact Jennifer Faerberg at 202-862-6221 or jfaerberg@aamc.org

Sincerely,

A handwritten signature in black ink that reads "Joanne Conroy MD". The signature is written in a cursive, flowing style.

Joanne Conroy, M.D.
Chief Health Care Officer
Association of American Medical Colleges