Consumer-Purchaser
DISCLOSURE
PROJECT
Improving Health Care Quality through Public Reporting of Performance

March 18, 2011

Donald Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

File Code: **CMS-2400-P: Medicaid Program: Payment Adjustment for Provider-Preventable Conditions Including Health Care Acquired Conditions**

Dear Dr. Berwick:

The Consumer-Purchaser Disclosure Project, representing consumer, labor union, and purchaser interests, is pleased to have the opportunity to comment on CMS' proposal to prohibit payment for provider-preventable conditions (PPCs) and health care acquired conditions (HCACs) in the Medicaid program, as required by Section 2702 of the Affordable Care Act (ACA).

In today's health care system, millions of Americans find themselves vulnerable to conditions and situations – such as infections, medical errors, and trauma – that are often serious, sometimes deadly, and mostly preventable. This is unacceptable. No one should leave a hospital sicker than when they were admitted. In the past, we strongly supported imposing the risk of financial penalty as one tool to encourage hospitals to engage in better care practices. With the upcoming implementation of Section 2702, we are pleased to see CMS providing states with the flexibility to expand upon the current Medicare HAC non-payment program in a way that recognizes that a patient's care does not begin and end in the hospital, but typically is received in multiple settings, all of which have responsibility to reduce health care acquired conditions.

For this reason, we support establishment of the terms: 1) *Provider Preventable Condition* as an umbrella for all preventable conditions across all care settings; and 2) *Health Care Acquired Conditions* that refers to hospital conditions beyond the inpatient setting, that are distinguishable from the established set of ten Medicare HACs. Regardless of the terminology, non-payment is a powerful reform strategy; it targets not only several of the priorities identified by the National Priorities Partnership[1], including patient safety, care coordination, population health, and overuse, but also helps fulfill CMS' "three-part aim" of creating a health care system that provides better care for individuals, better health for the population, and lower cost through improvement.

The cost of these patient safety lapses – both in terms of human suffering and in financial resources – is unsustainable. We believe that this program will address the fact that approximately 1 in 20 patients gets an infection each year while receiving medical care.[2] Further, nearly 2 million health care associated infections occur in hospitals, leading to about 100,000 deaths.[3] In addition to the human cost are billions in wasted dollars. Current estimates of the health care dollars spent on treating hospital acquired infections alone range from $7 billion to over $30 billion annually – dollars that could be put to better use by improving access to and quality of health care for all consumers.

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[1] More information on the National Priorities Partnership can be found at www.nationalprioritiespartnership.org

[2] *Making Health Care Safer: Reducing Bloodstream Infections*. CDC Vital Signs report, March 2011. http://www.cdc.gov/vitalsigns

[3] National Healthcare Quality Report, 2009. P. 108.

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As the proposed regulation notes, the mandate requires that states implement non-payment for the ten existing Medicare HACs and the three "never events." Our comments reflect our belief that states should also look beyond those conditions/events and include additional HCACs and PPCs that cut across multiple care settings. The following comments address:

- Suggestions for additional conditions and measures to include in the program;
- The need for a payment methodology that does not impede access to care;
- The importance of creating a public reporting framework for these data in order to expand the impact of this initiative; and
- Considerations for the future evolution of the program.

Expanding Beyond the Medicare HACs

Hospital-Level Expansion: We support the direction taken in the proposed rule that calls for states to view the Medicare HACs as a floor, and not a ceiling, and to consider additional conditions and measures in their non-payment programs. We suggest adding the following additional HCACs, all of which meet the CMS criteria of being high cost and/or high volume, reasonably preventable through application of evidence-based guidelines, and applicable to the hospital setting:

- *Surgical Site Infections (SSI) Following a) Total Knee Replacement and b) Device Procedure:* We urge CMS to add both total knee replacement, and device insertion, to the list of procedures for which hospitals will be responsible for reducing the incidence of surgical site infection. In the case of total knee replacement, incidence of deep vein thrombosis/pulmonary embolism related to this procedure is already included in the HAC list, so we see adding it to the SSI list as promoting alignment within the program.
- *Failure to Rescue*: This AHRQ Patient Safety Indicator is an important measure of quality and safety of hospital care and should be included, with the application of the exclusion for patients who have documented Do Not Resuscitate (DNR) orders in place.
- *Death or Disability Associated with Drugs, Devices or Biologics:* As these events are becoming more commonly reported at the state level, states are garnering experience with collecting and reporting these data, which have the potential for wide-reaching impact on patient safety and outcomes.
- *Iatrogenic Pneumothorax:* The breadth of procedures in which Iatrogenic Pneumothorax may possibly occur makes it an appropriate candidate for non-payment, given the broad implications for patient safety and outcomes. We do suggest, however, if this is included in the final rule, that there be specific reference to the exclusions listed in the AHRQ patient safety indicator that pertains to this condition.
- *Ventilator Associated Pneumonia (VAP)*: Complications due to VAP are serious, relatively frequent, preventable, and add significantly to the cost of care.
- *Additional Measures of Hospital-acquired Infections (HAI)*: In addition to the infections already included in the Medicare HAC list, we urge CMS to consider, concurrent with their implementation in the Medicare program, adding the following HAIs to the proposed list for payment reduction. These HAIs were identified by the Secretary in the Department of Health and Human Services *Action Plan to Prevent HAIs.* ACA requires that HHS include these in the Medicare Hospital Value-Based Purchasing Program, and we believe that they should be applied across all public sector programs whose goals are to improve patient safety:
  - Central line-associated blood stream infection (CLABSI)
  - Central Line Bundle Compliance
  - Clostridium Difficile 1 and Clostridium Difficile 2
  - MRSA 1 (incidence rate per 100,000 persons of invasive MRSA infection)
  - MRSA 2 (related to facility-wide healthcare facility-onset MRSA)

  We are in support of strategies that will increase the monitoring and prevention of MRSA, and adding it to the list of HACs for non-payment is one such important strategy. However, we acknowledge that this will not be possible until coding is available to monitor its occurrence accurately. Thus we urge improved coding be rapidly implemented to meet this need. MRSA poses a significant threat to those receiving inpatient care, and reducing its occurrence should be actively pursued by hospitals. While it is true that many individuals are carriers of a latent form of MRSA, the percentage of individuals with active cases is

much smaller, and there are actions that can be carried out within the hospital setting to prevent it from spreading.

Expansion to Non-Hospital Settings

We strongly support aligning non-payment for hospitals **and** other providers. If only hospitals are penalized, the system will not change. The non-payment policy must cut across, and bring into alignment, the full range of providers and settings. We therefore support the inclusion in the program of provider-preventable conditions (PPC), defined as occurring "in any health care setting."

We encourage CMS to provide significantly more guidance to states on how such an expansion would be operationalized without negatively affecting access to care. For example, which entity would be penalized in the case of a patient whose primary care provider did not "catch" a sign of a pending complication which resulted in the patient's preventable use of the hospital emergency department? The obvious answer is that the primary care provider would face the penalty, but how would it be calculated? And would this result in providers refusing to care for Medicaid patients with chronic conditions? These are all questions that should be addressed if payment policies are to be equitable. We strongly suggest that the proposed methodologies for operationalizing the expansion of the program to non-hospital settings be made available for public comment.

In terms of PPCs, we urge CMS to consider the following:

- *Death or Disability due to Drug Events*: Adverse drug events that take place in the outpatient and ambulatory care environment are high volume, high cost, and exact an extremely high price on the patient population. They are also highly preventable.
- *Incidence of dialysis-related infection:* The volume of dialysis procedures done, coupled with the high rate of infections stemming from these procedures, makes this PPC an important addition to the program.

Finally, we urge CMS, together with the states, to explore the potential for implementation of NQF Measure #OT2-022-09, *Proportion of patients with a chronic condition that have a potentially avoidable complication during a calendar year*: This measure quantifies the percent of adults aged 18 – 65 with at least one of six chronic conditions (Diabetes Mellitus, Congestive Heart Failure, Coronary Artery Disease, Hypertension, Chronic Obstructive Pulmonary Disease, or Asthma) who had one or more potentially avoidable complications (PACs) in a calendar year. The measure defines a "Potentially Avoidable Complication" as any event that negatively impacts the patient and is potentially controllable by the physicians and hospitals that manage and co-manage the patient. We believe it would be an appropriate measure of physician-preventable conditions, as it measures hospitalizations due to the anchor condition or comorbidities, or hospitalizations that reflect patient safety failures such as infections, DVT, and adverse drug events.

Establishing a Rational Payment Adjustment Mechanism

As with the Medicare HAC nonpayment program, we urge CMS to take all necessary steps to ensure that this program does not result in any loss or reduction of access to care for beneficiaries due to providers turning away patients who may be more susceptible to HCACs or PPCs. One suggestion for addressing this concern is for CMS to apply proper risk assessment and adjustment methodologies to each of the HCACs and PPCs.

Unlike "never events," HCACs and PPCs are largely, but not 100 percent, preventable. For those conditions and events that are not entirely preventable, we believe that providers and hospitals should not have to bear complete risk. We strongly urge CMS to institute a payment reduction methodology that is based on the relative risk-adjusted rates of the complication. The criteria for determining this calculation should reflect the language in the preamble of the proposed rule, including: 1) the ability of the hospital and/or provider to prevent the event; 2) the ability to validly collect data on the incidence of the events; and 3) that coding and data collection issues are addressed. It is imperative that implementation of the program meet the patient safety goals in a way that is both fair and clinically sound. CMS is well-positioned to take on this task, and can leverage what it has learned over the past two years through the Medicare HAC non-payment program to further refine the concept of non-payment versus a risk-adjusted payment reduction.

In regard to providers' role in not restricting access, we strongly support the idea outlined in the preamble that states should be able to reinvest any savings achieved from PPC-related payment adjustments into provider rate improvements to further prevent access problems.

Finally, we strongly encourage CMS to closely monitor the program to assess the impact of the payment adjustments, and publicly report the results of the assessment. When the Medicare program changed the way physicians were paid – moving to the resource-based relative value scale – a similar monitoring system was created to detect any changes in beneficiary access to physician services. A monitoring system acts as a bellweather and detects changes in enrollee access before problems become extensive.

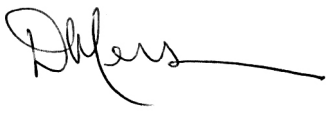
Public Reporting and Transparency

The proposed rule notes the importance of including a mandatory public reporting element to this program, in order to give providers the incentive to report conditions and adverse events. While we agree that *Hospital Compare* in its current format would not be the most feasible site for states to report their PPC and HCAC data, we urge CMS to develop a strategy for making these data transparent not only to states, providers, and CMS, but also to consumers. The preamble states that CMS "proposes a requirement that existing claims systems be used as a platform for provider self-reporting," but that requirement alone will not necessarily translate into the formation of a consumer-friendly public reporting mechanism. We urge CMS to ensure that the publicly reported data will be displayed in a way that is accessible, understandable, and usable by consumers. We suggest that CMS work with consumers via focus groups, listening sessions, and other venues, in order to determine how best to structure the reporting element of this program.

Future Considerations

As this program is implemented and subsequently evolves to meet the needs of Medicaid beneficiaries, states, and other stakeholders, we strongly encourage CMS to study Maryland's experience with implementing a HAC reduction initiative. Instead of adopting a case-specific reduction in payment policy, the Maryland Health Services Cost Review Commission has moved to a system of rewards and penalties for hospital HAC performance (See http://hscrc.state.md.us/init_qi_MHAC_cfm). A hospital's annual performance on a selected list of preventable conditions is compared to a statewide target; good performers receive an uptick in their annual update factor, poorer performers a reduction. We believe that innovative state efforts such as this one can provide important lessons to CMS and to other states as this program matures. In that spirit, we suggest that CMS go beyond publishing states' policies as a learning tool, and more aggressively assist states in information sharing. CMS can facilitate programs, teleconferences, and other learning opportunities where states can share information about other identified HCACs and learn from other states about what is or is not working in their particular environment.

On behalf of consumers and purchasers across the country, we thank you for your efforts and your responsiveness to our comments. If you have any questions, please contact either of the Disclosure Project's co-chairs, Bill Kramer, Executive Director for National Health Policy at the Pacific Business Group on Health, or Debra L. Ness, President of the National Partnership for Women & Families.



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