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August 30, 2011

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

File code: **CMS-1525-P**

RE: **Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program: Comments from National Consumer, Labor, and Employer Organizations**

Dear Dr. Berwick:

The 28 undersigned organizations representing consumer, labor and employer interests appreciate the opportunity to comment on the proposed rule pertaining to the Hospital Outpatient Prospective Payment System, Ambulatory Surgical Center (ASC) Payment, and the Hospital Value-Based Purchasing Program.

Overall, the proposed rule reflects CMS' continued efforts to drive payment based on quality and value, versus volume. It also aligns with the many quality and safety initiatives included in the *Affordable Care Act (ACA),* the Meaningful Use of Health IT incentive program, pre-ACA initiatives such as the Inpatient Quality Reporting Program (IQR), the themes of the *National Quality Strategy,* and the goals of the new HHS patient safety initiative, the *Partnership for Patients.*

We are particularly pleased to see the initial set of measures that will populate the new Ambulatory Surgical Center quality reporting program (ASC QR). The rule makes clear that CMS is committed to implementing quality reporting programs to assure that the measures are meaningful to consumers and purchasers and include information on patient safety, overuse, and outcomes. As this and other quality measurement-based programs continue to evolve, we look forward to working with CMS – both directly and through our members' participation in multi-stakeholder consensus efforts such as the *Measures Application Partnership* – to further these efforts and drive toward a patient-centered system of care that is HIT-enabled and uses robust measures of performance to promote transparency, accountability, and value-based payment for care.

Our comments pertain to issues raised in Sections XIV and XVI of the proposed rule:

- **Overall, we support the proposed OQR measures.** We are pleased to see a strong focus on measures of patient safety that are closely linked to outcomes. These measures will not only complement the efforts of the *Partnership for Patients* initiative, but ultimately can be harmonized with measures in the Inpatient Quality Reporting Program, the ASC Quality Reporting Program, the Meaningful Use program, and other initiatives that include performance measurement.

- **We have significant concerns about the proposed *Electronic Pilot* for reporting clinical quality measures for the OQR, IQR and Meaningful Use programs.** There are a number of components of this pilot which we believe would have unintended consequences, not just for the specific data collection goals of the above-mentioned programs, but for patient protection, and for DHHS' over-arching goals of better health, better care, and lower cost as outlined in the *National Quality Strategy.* We do not feel that this pilot is ready for implementation without major adjustments.

- **We strongly support the launch of the ASC quality reporting program.** We believe that the focus on patient safety and harmonization with the Inpatient and Outpatient quality reporting programs is an appropriate starting point. However, we urge CMS to populate this program with process measures that are closely linked to outcomes rather than process measures whose relationship to the outcome are not closely linked. Measures of outcomes, functional status, and patient experience specified for use in this setting are sorely needed, and we ask CMS to take a leadership role in filling these gaps. The majority of procedures performed in ASC settings tend to be straightforward surgeries that lend themselves especially well to use of patient-reported outcomes measures.

- **Across both the OQR and the ACS programs, we urge CMS to identify a tool for measuring patients' experience of care and require that it be reported to qualify for the annual payment update.** We note with concern that – with the exception of the HCAPHS survey requirement for the IQR – there is a glaring lack of patient experience measures proposed for implementation among CMS' pay-for-reporting initiatives. Patient-reported data on the patient and family caregiver's experiences are invaluable to understanding the effectiveness of care coordination, care transitions, and medication safety efforts. Given the paucity of "good" outcome measures, it is especially important that CMS take advantage of existing patient experience survey instruments that can shed light on patients' experience of care in outpatient and ACS facilities. We urge CMS to implement an appropriate version of the current CAHPS instruments in the OQR and ACS programs, and concurrently, lead the way in improving these tools to include questions specific to care coordination and outcomes so that they can be even more effective at collecting critical patient-reported data.

- **We support most of the recommendations made regarding the Hospital VBP program.** In particular, we applaud CMS' proposed weighting of the domains: 30 percent to the patient experience domain; 30 percent to the outcomes domain; and 20 percent to the efficiency domain, all in FY 2014. The emphasis on outcome and patient experience measures – and reduced reliance on process measures – to determine hospital value payments is consistent with the goals of the *National Quality Strategy* to promote better health, better care, and more affordable care.

Section XIV: Hospital OQR Updates and ASC Quality Reporting Program

OQR: Proposed New Measures for CY 2014

We support the majority of measures CMS proposes to add to the OQR for FY 2014, including the following:

- Surgical Site Infection
- Five diabetes care measures
- Use of the Safe Surgery Checklist
- Procedure volume *for procedures that have a demonstrated volume-outcome linkage.*

Measuring Surgical Site Infection is foundational to building a core set of patient safety measures in this program. Adding this measure to the OQR will bring the outpatient setting in line with the recommendations made in the January 2009 Department of Health and Human Services report, "Action Plan to Prevent Healthcare-Associated Infections." This report includes a number of additional hospital-acquired infection measures that are crucial to reducing infection rates and improving patient safety and outcomes. We urge CMS to use this report as a roadmap for selecting additional patient safety metrics as the OQR evolves, including the immediate addition of a measure of central line-associated blood stream infection (CLABSI). Central lines are commonly used in the outpatient setting, particularly in the delivery of chemotherapy protocols, making this measure extremely relevant to the OQR. We also urge CMS to build a core patient safety measure set that includes Central Line Bundle Compliance, c-difficile, catheter-associated urinary tract infection (CAUTI), and MRSA. These measures are all either currently, or soon to be, implemented in the IQR, and corresponding, harmonized measures should be required in the OQR.

There are five discrete diabetes process measures proposed for CY 2014, all of which were introduced in last year's proposed rule but did not get implemented in the final rule. Given that a significant percentage of primary care services are provided in the hospital outpatient clinic setting, we presume there will be future proposed rules in which CMS will seek to apply Physician Quality Reporting System (PQRS) or other physician-specified measures to the hospital outpatient setting. This would be appropriate, and addresses our continued calls for harmonization across settings and the need for the silos of care to be eliminated. We suggest that CMS more clearly articulate how this would occur, in practical terms, since we do see the value in applying these measures to the hospital outpatient setting. For patients with diabetes who are treated in a hospital outpatient department, having information on the quality of care provided at the hospital level – while not as useful as having individual physician-level reporting – would be meaningful and allow for more informed decision-making. Although the issue of how these measures are reported on *Hospital Compare* is not addressed in this proposed rule, it will be critical to consumer usability that these diabetes measures be reported as a single composite measure of quality of diabetes care, with the ability for providers and purchasers to drill down into the data to make decisions regarding quality improvement.

There is broad agreement that use of a Safe Surgery Checklist is closely linked to successful outcomes and we appreciate CMS' discussion in the proposed rule of the recognized value of a checklist by a wide range of professional societies. We believe that adding an element to the OQR that asks hospitals whether they use a Safe Surgery Checklist adds to the core of patient safety-oriented elements in the program. However, when considering a hospital's safety record and making choices using *Hospital Compare,* consumers want and need to know that they are making apples-to-apples comparisons. Thus, in the interest of comparability across hospitals, and in the absence of a specific *Safe Surgery Checklist* measure, we suggest that CMS put in the final rule a "short list" of checklists that will satisfy this data request. This may include the World Health Organization's checklist, described in detail in the proposed rule, which has been adopted as a standard of practice by the World Federation of Societies of Anesthesiologists, along with others that meet the criteria for good checklists as outlined in the rule. Simply giving broad outlines for what a safe surgery checklist should include may not guarantee that all of those elements are in use in a given hospital.

Finally, we fully support requiring reporting data on volume of procedures, but only in cases where there is evidence that higher volume is linked to better outcomes. While there is a perception that the link between volume and quality is a constant, the evidence does not support this, and currently there are only a small number of conditions/procedures for which the evidence does indicate a clear link. In the absence of this straightforward evidence, we would caution CMS against publicly reporting information that may lead consumers to believe that a low volume rate automatically leads to a poorer outcome. It is clearly an area for additional research; this research could also provide critical information needed to develop measures of appropriateness and overuse, allowing stakeholders to better understand costs associated with high volume that points to potential overuse of certain procedures. In lieu of these volume measures, we suggest that CMS implement a structural measure of whether a hospital outpatient department participates in a surgical outcomes registry, to build the evidence base in this area.

Out of the list of proposed measures for CY 2014, we do **not** support the implementation of the measure *Cardiac Rehabilitation Patient Referral from an Outpatient Setting.* We are strong advocates for care transition approaches that improve outcomes and reduce preventable hospital readmissions. However, we have multiple concerns with this particular measure. Primarily, we are concerned that it falls into the "check the box" category. In addition, we believe that making a referral to cardiac rehab is something that should be considered a standard of practice. For accountability, quality improvement, and payment purposes, our goal should be to have a measure that does not just record whether a referral was made, but documents in a meaningful way whether or not communication took place among the referring physician, the rehabilitation facility, and the patient, to ensure that the rehabilitation protocol was completed. We expressed these concerns to the Physician Consortium for Performance Improvement during the measure development process, and to the National Quality Forum during the measure endorsement process. We believe that this measure falls short and is not a meaningful care transition measure that will tell consumers if better care resulted from the referral.

OQR: Proposed New Measures for CY 2015

We fully support the implementation of the measure *Influenza Vaccine for Healthcare Personnel* in the OQR, to further harmonize this program with the IQR. This measure also addresses the population health goals of the *National Quality Strategy.*

Possible Measures and Measure Topics for Future Inclusion in the OQR

In general, we commend CMS for citing a focus on outcomes, efficiency and patient experience as criteria for selecting proposed measures for the OQR. However, a number of gaps still remain in the program. Below are measures that we believe would help fill those gaps, and for which we urge CMS to consider for implementation for the payment determination period, include:

- *Patient experience*: Currently hospitals are required to report their HCAHPS data to CMS in order to receive their full inpatient payment update. We strongly urge CMS to add a requirement to field and report the results of a patient experience survey for patients receiving care in the outpatient setting as well. While there is no CAHPS version specifically tailored to the outpatient setting, we suggest that CMS look into ways that HCAHPS, the Clinician/Group CAHPS, or the CAHPS Surgical Care Survey could be specified for the outpatient arena. As noted earlier, we urge CMS to implement one of the above CAHPS tools in the OQR as quickly as possible, and at the same time, work with AHRQ to add measures specifically related to outcomes and care coordination. We appreciate that CMS has listed the CAHPS tool as a measure under consideration, and we would strongly suggest making it a top priority.

- *Emergency Department non-mortality outcome measures*: There are several NQF-endorsed ED outcome measures that we have suggested for implementation in the past. These include the Severe Sepsis and Septic Shock Management Bundle, and Confirmation of Endotracheal Tube Placement.

We also appreciate the opportunity to comment on the measures and measure topics that CMS put forward for future consideration.

Of the 11 heart failure measures, seven of them are currently being reported in the IQR program. We do appreciate the need for harmonization between the two hospital settings, and the need for quality improvement in the outpatient environment. Thus, we support the addition of these measures, but urge CMS to report the data on *Hospital Compare* as a Heart Failure Quality of Care composite, in order to make the information more useful and meaningful to consumers.

Regarding symptom management, symptom and activity assessment, patient education, and end-of-life-planning for Heart Failure patients, we believe these are extremely important areas to measure, and subsequently be included in the OQR (as well as harmonized with measures in the IQR). We strongly urge CMS, when seeking development of these types of measures, to ensure the data collected are meaningful and accurate. Unfortunately, these are the types of activities for which it is easy to just “check the box” that such functions as management, education, and planning were conducted, without knowing whether they affected the outcome. Thus we suggest that CMS develop companion measures that evaluate patients’ experiences with care to get at whether patients felt their symptoms were being managed, they received the education they needed, and were provided support and assistance in developing an end-of-life plan.

We support the two heart failure measures “overuse of echocardiography” and “post-discharge appointment for heart failure patients.” In the past we have called upon CMS to implement more cardiac imaging overuse measures, and we have expressed in this letter the need for additional care transition measures.

As for the other proposed future measures, we support all except "Needle Biopsy to Establish Diagnosis of Cancer Preceding Surgical Excision/Resection." This measure quantifies a procedure that should be a standard of practice, and is not a quality measure that should relate to payment policy.

Finally, regarding the list of topics for future measure development, we would prioritize the areas of chemotherapy, post-discharge follow-up, post-discharge ED visit within 72 hours, and the Health Care Provider Immunization Refusal Rate.

The measurement topic areas listed above are critically needed to assess performance in the hospital outpatient setting. All of these topics address clinical and/or cross-cutting areas that would affect a high volume of patients and have the potential to improve outcomes and reduce costs.

2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

The proposed rule outlines a pilot to allow hospitals participating in the Meaningful Use (MU) program to meet the MU quality reporting requirements through a single submission for the IQR, OQR and MU programs. While we strongly support the advancement and use of e-measures, as well as pilot programs to advance the use of electronic capabilities in reporting quality measures, we have concerns about the proposed pilot.

1. The pilot would require eligible hospitals to submit patient-level clinical quality measure (CQM) data. We have long advocated for using health IT to streamline the data collection and submission process for quality measures included in various CMS-administered programs, and being careful with how individual beneficiary-level data is shared. The proposed approach would be inconsistent with the Meaningful Use program, which requires reporting summary-level data. Therefore, we strongly support relying on summary data only and urge CMS to make changes to this pilot program in order to make it consistent with the Meaningful Use Incentive Program.

2. The proposed Electronic Reporting Pilot would require the submission of Medicare data only. Considering that hospitals have been required to submit all-payer quality data to CMS for almost a decade, this would be a significant step backward and would delay expanded use of all-payer data bases. The availability of patient data, regardless of payer, is instrumental to meeting the goals outlined in the *National Quality Strategy* and the *Partnership for Patients* initiative. Further, the lack of all-payer data could erode the utility of the *Hospital Compare* website, which now reports all-payer data for a majority of measures. Finally, reporting should be consistent with the Meaningful Use program, which requires reporting of all-payer data. It will be counter-productive to implement two different reporting methodologies for these programs.

Proposed ASC Quality Reporting Program

According to a survey by the National Association of Health Data Organizations (NAHDO), more than 35 states are currently collecting and using ASC data. Given the growing reliance on ASC's, we are extremely pleased to see the ASC Quality Reporting Program come to fruition. For the most part, we support the measures proposed for implementation, including:

- Patient burns
- Patient falls
- Wrong site, wrong side, wrong patient, wrong procedure, wrong implant
- Hospital transfer/admission
- 1st or 2nd generation cephalosporin use
- Surgical site infection

The above measures address issues of patient safety (burns, falls, wrong site, etc., and surgical site infection); outcomes (hospital transfer/admission); and population health (1st or 2nd generation cephalosporin use). Several of these measures are in the IQR program, which supports alignment across programs. However, we do not feel that the measures 1) *Prophylactic IV Antibiotic Timing;* and 2) *Appropriate Method of Hair Removal* will add value to the program.

Prophylactic IV Antibiotic Timing is a process measure that will not provide meaningful information to consumers or purchasers. Ultimately, consumers and purchasers (as well as providers and payers) want to know what the rate of infection is in the patient population. Timing of IV antibiotics is but one step in a series of processes meant to lead to a safe and effective outcome and it is those outcome measures that we want to see included in this program. However, we believe that by including the *Surgical Site Infection* measure, CMS is moving in the right direction in this regard, and we would hope to see additional hospital-acquired infection measures added to the program in the future, rather than crowding the program with surgical process measures.

Appropriate Method of Hair Removal has been identified for retirement from the Inpatient Quality Reporting Program, and we feel it sends a confusing signal to hospitals, as well as to consumers and purchasers, to call for retiring it in one hospital setting but implementing it in another setting. Again, this is a process measure that is not closely linked to outcomes, and evidence shows that a very high number of patients are already receiving appropriate hair removal for relevant procedures.

We urge CMS to build on the lessons learned from the IQR and OQR programs by populating this program from the beginning with measures of outcomes, patient safety, functional status, and patient experience, and limiting process measures to those that have a very direct, evidence-based link to outcomes. We understand that there are many measurement gaps in these areas, particularly when it comes to measures specified and tailored for use in the ASC. Thus we urge CMS to take a leadership role in working with measure developers to leverage measures already in existence and in use in the IQR that address these broad areas, and harmonize them for use in the ASC.

Section XVI: Additional Proposals for the Hospital VBP Program

We have a number of comments pertaining to the additional proposals for the HVBP program. Overall, we support the following:

- CMS' proposal for how the domains of clinical processes of care, patient experience, outcomes, and efficiency will be weighted in the total performance score. We were strong advocates for assigning significant weight to the patient experience domain and are very pleased to see it retained at 30 percent for FY 2013 and 2014. We are also pleased to see that the weighting of the outcome measures will also be placed at 30 percent, with a subsequent reduction in weight given to the clinical process measures. Finally, we support the 20 percent weighting of the efficiency domain, which we hope will be populated more fully in future rulemaking to go beyond the Medicare cost per beneficiary measure. CMS' proposed weighting scheme places the appropriate emphasis on the areas that are most important to transforming our current dysfunctional health care delivery system into one that is patient-centered and puts a priority on outcomes, patient experience, and efficiency.

- Continuous monitoring of the measures implemented in the program to ensure that they remain relevant, reliable, and indicate variation in performance.

- Allowing hospitals with as few as one documented case per a given hospital-acquired condition (HAC) to include that HAC among the measures used in their performance score. The research conducted by Mathematica Policy Research and other supporting research by Brandeis University, provides evidence that having one case will neither invalidate the measure's accuracy, nor the overall performance score. However, CMS will need to develop a way to display these data on *Hospital Compare* in a way that clearly conveys the incidence of HACs in a given hospital.

- Keeping HACs in the program even if they become "topped out," given that the goal is to drive HAC rates to as close to zero as possible, and to continuously keep the incidence extremely low or non-existent.

- CMS' proposed threshold and benchmark designations for the measures to be implemented in FY 2013 and 2014.

Our one point of concern is CMS' proposal to add the measure *Post-operative Urinary Catheter Removal on Post-operation Day 1 or Day 2* to the program in FY 2013. A more meaningful measure for holding hospitals accountable for providing high quality care is incidence of Catheter-Associated Urinary Tract Infection (CAUTI), which was recently endorsed by the National Quality Forum and slated for implementation in the Inpatient Quality Reporting Program. The proposed rule notes that the process measure of post-operative urinary catheter removal is important because it can reduce CAUTI, but what consumers and purchasers want to know is the rate of CAUTI in the hospital. Therefore, we strongly urge that if the catheter removal measure is implemented in the final rule, that it be paired with the complimentary CAUTI rate measure once that has been reported on *Hospital Compare* for the requisite 12 months and thus eligible for use in the HVBP.

On behalf of the millions of Americans represented by the undersigned organizations, we appreciate the opportunity to provide comments on the proposed regulations related to the Outpatient and Ambulatory Surgical Center Quality Reporting Programs, and the Hospital Value-Based Purchasing Program. If you have any questions, please contact either of the Consumer-Purchaser Disclosure Project's co-chairs, Debra L. Ness, President of the National Partnership for Women & Families, or Bill Kramer, Executive Director for National Health Policy at the Pacific Business Group on Health.

Sincerely,

AARP
American Benefits Council
American Federation of State, County, & Municipal Employees (AFSCME)
Center for Medical Consumers
Childbirth Connection
Dallas-Fort Worth Business Group on Health
Employers' Coalition on Health
Employers Health Coalition, Inc.
Employers Health Purchasing Corporation
The Empowered Patient Coalition
HealthCare 21 Business Coalition
Health Policy Corporation of Iowa
HR Policy Association
Iowa Health Buyers' Alliance
Indiana Employers Quality Health Alliance
Massachusetts Group Insurance Commission
Midwest Business Group on Health
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Pacific Business Group on Health
PULSE of America
Puget Sound Health Alliance
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The Alliance
The Leapfrog Group
Virginia Business Coalition on Health