

August 30, 2011

The Honorable Max Baucus
Chairman, Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Orrin G. Hatch
Ranking Member, Committee on Finance
U.S. Senate
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Fred Upton
Chairman, Committee on Energy and
Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member, Committee on Energy and
Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Dave Camp
Chairman, Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Sander M. Levin
Ranking Member, Committee on Ways and Means
U.S. House of Representatives
1139E Longworth House Office Building
Washington, DC 20515

RE: Department of Health and Human Services *Report to Congress: Medicare ambulatory surgical center value-based purchasing implementation plan*

Dear Chairmen and Ranking Members:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on the Department of Health and Human Services' *Report to Congress: Medicare ambulatory surgical center value-based purchasing implementation plan*. The Patient Protection and Affordable Care Act (PPACA) requires the Secretary of Health and Human Services to develop a plan to implement a value-based purchasing program for ambulatory surgical centers (ASCs). MedPAC supports using Medicare payment policy to reward improvements in quality made by ASCs. This letter provides specific comments to help the Congress and CMS develop a VBP plan for ASCs. The Commission believes that the VBP program should include a relatively small set of measures that are primarily focused on clinical outcomes, with some process, structural, and patient experience measures.

The report discusses key issues that would be involved in designing a VBP program for ASCs; however, it does not lay out a timeframe for implementing such a program, identify which measures would be used, or propose how measures would be scored. Although CMS has statutory authority to require ASCs to submit quality data and to reduce the annual update for ASCs that fail to do so, the agency lacks the authority to adjust payments based on ASCs' performance. Therefore, the Congress would need to grant CMS such authority before Medicare could adopt a VBP program for ASCs.

In the Commission's March 2011 Report to the Congress, we recommended that the Congress require ASCs to submit cost and quality data to CMS; ASCs have never been required to submit quality data to Medicare. Quality data would enable CMS to assess ASCs' performance and allow beneficiaries to compare providers on the basis of quality. A quality reporting program could also become the foundation for a VBP program, which was the case for the Medicare hospital inpatient VBP program. We are encouraged that CMS has recently proposed an ASC quality measure reporting program in the 2012 proposed rule for the ASC payment system and hospital outpatient prospective payment system (OPPS).

The Commission has outlined the following general criteria for measures that apply to VBP programs across all types of providers and settings:

- Measures should be well-accepted and evidence-based, and should be familiar to providers.
- Collecting and analyzing measurement data should not be unduly burdensome for either the provider or the Medicare program.
- Incentives should not discourage providers from taking riskier or more complex patients.
- Most providers should be able to improve on the available measures. Aspects of care being measured should be within the control of the provider, there should be room for improvement in the quality of care being measured, and the measure set should include measures that apply to all patients, such as safe practices and patient perceptions of care.
- The performance measures selected for all of Medicare's VBP programs should send consistent signals about Medicare's expectations for quality and efficiency across different types of providers and care settings. To that end, quality measures should be aligned across settings such as ASCs, hospital outpatient departments, and physician offices for services that are performed in all of those settings.

In the following sections, we highlight two key principles for a VBP program for ASCs:

- the program should reward ASCs based on both improving care and exceeding certain benchmarks, and
- the program should include a relatively small set of measures that are primarily focused on clinical outcomes.

VBP program for ASCs should reward providers based on both improving care and exceeding certain benchmarks

Summary of Secretary's report: The report states that an ASC VBP program could measure ASCs' performance relative to a national benchmark and their improvement over time. As in the

inpatient hospital VBP model, an ASC's performance on each measure could be based on the higher of an attainment score or an improvement score. However, the report does not propose a clear plan for how CMS would assess and reward ASCs' performance.

Comment: The goal of a VBP program is to improve care for as many beneficiaries as possible. Thus, it is important to reward providers who attain certain thresholds of quality as well as lower-performing providers who improve their quality over time. Consistent with MedPAC's design criteria for VBP programs and the inpatient hospital VBP program, ASCs should be rewarded either for attaining high thresholds of quality performance or for making significant improvements over their own prior-year performance.¹ It is reasonable to expect that, over time, these thresholds will converge as more facilities raise their performance to the national attainment benchmark.

VBP program for ASCs should include a small set of measures primarily focused on clinical outcomes

Summary of Secretary's report: The report does not specify which measures CMS would use for an ASC VBP program, but does list ten measures that CMS has proposed for the ASC quality reporting program in the 2011 proposed rule for the ASC payment system and hospital OPSS:

1. Patient fall in the ASC
2. Patient burn
3. Wrong site, wrong side, wrong patient, wrong procedure, wrong implant
4. Prophylactic intravenous (IV) antibiotic timing
5. Hospital transfer or admission upon discharge from the ASC
6. Appropriate surgical site hair removal
7. Surgical site infection
8. Medication administration variance
9. Medication reconciliation
10. Venous thromboembolism measures: Outcome/assessment/prophylaxis.

The report also says that CMS intends to explore developing new measures with high incidence rates that capture multiple domains of quality, such as clinical processes, outcomes, and patient experience. Although ASCs do not currently collect Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data to determine patients' perspectives on their experience, the report notes that a survey instrument could be developed to measure patient experience. The report states that outcomes and patient experience measures should be adjusted for patient risk or provider characteristics. CMS emphasizes that ASC quality measures should be aligned across care delivery settings (e.g., ASCs and hospital outpatient departments) and across Medicare quality reporting programs (e.g., the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS)).

¹ In MedPAC's March 2005 and June 2007 Reports to the Congress, we laid out several design criteria for Medicare VBP programs (which we also refer to as pay-for-performance programs).

Comments:

The Commission believes that the ASC VBP program should include a relatively small set of measures to reduce the burden on ASCs and CMS, and the measure set should primarily focus on clinical outcomes because Medicare's central concern should be improving outcomes across all ASCs and over time. The program should also include some clinical process, structural, and patient experience measures.

CMS should incorporate the following outcomes and process measures into the ASC VBP program:

1. Patient fall in the ASC (outcome)
2. Patient burn (outcome)
3. Wrong site, wrong side, wrong patient, wrong procedure, wrong implant (outcome)
4. Prophylactic IV antibiotic timing (process)
5. Hospital transfer or admission after an ASC procedure, whether the patient is transferred directly to the hospital from the ASC or admitted to the hospital after returning home from the ASC procedure (outcome)
6. Surgical site infection (outcome)
7. Selection of prophylactic antibiotic: First or second generation cephalosporin (process)

CMS should not adopt the proposed measure of appropriate surgical site hair removal for the ASC VBP program because the agency has decided to suspend data collection for this measure under the hospital inpatient quality reporting program. CMS suspended data collection for this measure because it has a high level of adherence nationwide, with little variability among hospitals, and doing so will reduce the data collection burden for hospitals (76 FR 51610–51611). In addition, this measure is not included in the hospital outpatient quality reporting program. CMS also should not adopt the medication administration variance, medication reconciliation, and venous thromboembolism measures because these are primarily process indicators that use data extracted from samples of patient medical charts; the VBP program should include a relatively small set of measures that focus mainly on clinical outcomes and minimize the data collection burden for providers.

As noted in the CMS report, a study from the *Journal of the American Medical Association* (JAMA) found that lapses in infection control were common among a sample of ASCs in three states.² In light of these findings, CMS should hold ASCs accountable for surgical site infections (SSIs) by adopting measures that apply to the most frequent ASC procedures that involve incisions. In particular, CMS should consider how Medicare can use the same measures to track infection rates for surgeries across hospital inpatient, hospital outpatient, and ASC settings. Measuring surgical site infection rates could be a way to encourage providers to collaborate and better coordinate care for ambulatory surgery patients. Because surgical site infections often do not appear until after a patient has been discharged from an ASC, and ASCs typically do not have an ongoing relationship with patients, it may be difficult for them to identify SSIs. Therefore, CMS should instruct ASCs to conduct a follow-up phone call with patients, their

² Schaefer, M.K., M. Jung, M. Dahl, et al. 2010. Infection control assessment of ambulatory surgical centers. *Journal of the American Medical Association* 303, no. 22 (June 9): 2273–2279.

caregivers, or their physicians within 30 days after the procedure to identify patients who have developed SSIs. ASCs should include this information in the patient's medical record and submit it to CMS.

CMS proposes to use a measure that tracks ASC patients who are transferred or admitted directly to a hospital (including a hospital emergency room) upon discharge from an ASC. This measure should be expanded to include patients who return home after the ASC procedure but are then admitted to a hospital shortly thereafter due to a problem related to the procedure. Including these patients in the measure would enable CMS to better track patients who experience serious complications or medical errors related to an ASC procedure. Because some patients are admitted to the hospital after returning home from an ASC, CMS should consider creative methods to track these adverse outcomes. For example, CMS could analyze claims data to look for patterns of hospital admissions that occur within a certain number of days of an ASC procedure, specifically focused on admissions for complications that are associated with the ASC procedure that was performed.

The other three outcomes measures (patient fall; patient burn; wrong site, wrong side, wrong patient, wrong procedure, wrong implant) are patient safety indicators identified by the National Quality Forum (NQF) as "serious reportable events," which are defined as errors in medical care that are clearly identifiable and measurable, usually preventable, serious in their consequences for patients, and that indicate a problem in a health care facility's safety systems. These patient-safety indicators were developed by the industry-sponsored ASC Quality Collaboration and have been endorsed by the NQF. Given that these measures were developed by an ASC industry coalition, it should be technically feasible for ASCs to report these indicators without an undue administrative burden.

In addition to outcome measures, the VBP program should also initially include infection control process measures such as prophylactic IV antibiotic timing and selection of prophylactic antibiotic: First or second generation cephalosporin. Prophylactic IV antibiotic timing assesses the rate of ASC patients who received IV antibiotics to prevent surgical site infection on time (within one or two hours prior to the incision). Selection of prophylactic antibiotic assesses the rate of patients with indications for a first or second generation cephalosporin prophylactic antibiotic who had an order for such an antibiotic; guidelines indicate that these antibiotics are effective for prevention of surgical site infections in most cases. These indicators are similar to measures that have been included in the Quality Reporting Programs for hospital inpatient and outpatient settings and the physician quality reporting system (PQRS). Requiring the reporting of these measures by ASCs would harmonize use of these measures across four settings of care, a small but important step toward the goal of consistent quality measures across care settings. The VBP program should eventually phase out infection control process measures as it adopts outcome measures that apply to the majority of ASC procedures.

The VBP program should also include a structural measure based on ASCs' use of a safe surgery checklist. A safe surgery checklist would help ensure that safe practices are performed prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room.

Measures of patient experience in ASCs are also important and the Commission supports the development of a survey to measure patients' perceptions of their ASC care. Such a survey could be modeled after the existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians and groups and the CAHPS Surgical Care Survey.

We also have comments on two other measurement issues:

- CMS should consider incorporating quality measures that use data from patient registries and electronic health records (EHRs), and
- CMS should address the “small numbers issue” for individual performance measures and low-volume ASCs.

Adding measures that use clinical registry and EHR data over time

The Commission has found that claims-based process measures provide important, if limited, information about quality of care and are the least burdensome approach to collecting quality information. We also have discussed the quality improvement value of patient registries that can aggregate and report data from a provider's entire patient population. Registries also can be used to analyze providers' adherence to evidence-based process measures and track patients' health outcomes over time. Providers can use registries to track patients who are treated with a particular drug or device, information that could be used for post-market surveillance of clinical outcomes associated with the use of that product. For these reasons, we urge CMS to consider incorporating quality measures that use data from registries into the ASC VBP program over time, when it is clinically appropriate and administratively feasible to do so.

The Commission also strongly supports the use of EHRs and other health information technology, such as computerized provider order entry and clinical decision support, as tools that can improve the quality and reduce the cost of care. We have specifically recommended that CMS should include measures of functions supported by the use of information technology (as opposed to simply having the technology) in Medicare initiatives to financially reward providers on the basis of quality. EHRs may reduce the administrative burden of collecting and reporting clinical data that are not readily available from claims, such as diagnostic test results. As EHRs become more widespread, CMS may wish to consider adding more clinically detailed measures to the ASC VBP program, as well as using EHR data to refine risk adjustment methods for outcome measures.

Addressing “small numbers issue” for individual performance measures and low-volume ASCs

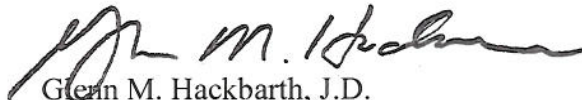
Certain ASCs—including those with relatively low volumes of Medicare patients—may report small numbers of cases for the calculation of some performance measures, especially measures of low-frequency and high-cost events such as serious reportable events and other patient safety incidents. This phenomenon means that the rates reported for these providers could vary substantially from one observation period to the next solely based on random statistical variation, which in effect would reward or penalize the provider for fluctuations in their performance scores that are unrelated to their actual quality of care.

To address these cases, CMS could consider the use of composite measures that would aggregate the rates for several measures of rare events into a single rate, or using alternative ways of calculating scores on these kinds of measures, such as using performance data from multiple years. The trade-off for the increased statistical reliability in both of these approaches is that the reported rates become less actionable for providers. In the case of a composite measure, the result is the sum or average of several different measures that may have varying rates of performance, making it hard for a provider to know where to focus quality improvement efforts. In the case of a multi-year measure, the results may reflect performance from past years that no longer reflect current practices, making it difficult to show improvement quickly and create momentum for more rapid change. CMS will need to keep this trade-off in mind as it balances the need for statistically reliable measures that also yield actionable quality information for providers and beneficiaries.

Conclusion

MedPAC appreciates the opportunity to comment on this important report to the Congress. If you have questions or would like clarification of our comments, please feel free to contact Mark E. Miller, MedPAC's Executive Director.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth".

Glenn M. Hackbarth, J.D.
Chairman

GMH/aw/w