

Public Comment Summary Report

Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

February 2014

Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (CORE)

Introduction

Dates of public comment period:

Monday, November 18, 2013 through Friday, December 6, 2013

Web site used:

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>

Methods used to notify stakeholders and general public of comment period:

- Email notification to the Centers for Medicare & Medicaid Services (CMS) listserv groups
- Email to relevant stakeholders and stakeholder organizations, including:
 - Business and consumer advocacy organizations
 - Colonoscopy-related registries
 - Electronic Health Record (EHR) vendors
 - Healthcare quality focused organizations
 - Insurance and purchaser organizations
 - Medical associations and societies
 - Research organizations
 - Topic knowledge-related organizations
- Posting on CMS Public Comment website

Volume of responses received:

We received comments from six commenters during the public comment period; specifically:

- Two professional societies (American College of Gastroenterology [ACG] and American Society for Gastrointestinal Endoscopy [ASGE])
- One ambulatory surgical center (ASC) quality organization (ASC Quality Collaboration [ASC QC])
- One EHR vendor (Epic)
- One hospital/health system (Cedars-Sinai Medical Center)
- One individual (Dr. Tim Carey)

Stakeholder Comments—General

Summary of general comments:

We received comments on various aspects of the measure of unplanned hospital visit rates after outpatient colonoscopy. Comments focused on the measure's objective; measure methodology, including the cohort, outcome, data sources, risk adjustment, level of reporting, and testing; Medicare's 3-day payment window policy; and the feasibility of using the measure for quality improvement purposes.

Several commenters were supportive of the measure's objective to measure risk-standardized, all-cause, unplanned hospital visits following an outpatient colonoscopy procedure. Four commenters expressed support for the focus of the proposed measure and its potential impact on health outcomes and quality improvement. However, five commenters conveyed concern about specific aspects of the measure methodology. One commenter conveyed concern over the impact of Medicare's 3-day payment window policy on the measure.

Proposed action(s):

See proposed action under the measure-specific comment summaries below.

Measure-Specific Comment Summaries

Measure name:

Hospital Visit Rate after Outpatient Colonoscopy

Summary of comments:

General comments

There were four general comments about the measure's focus.

- Four commenters expressed support for the measure's focus on evaluating unplanned hospital visits following outpatient colonoscopy and its potential impact on health outcomes and quality improvement.

Response: We appreciate the commenters' support for the measure's focus.

Cohort

Two comments addressed the cohort's inclusion and exclusion criteria and denominator time window.

- One commenter expressed support for the proposed exclusion of patients with a diagnosis of 'diverticulosis with hemorrhage.'

Response: We appreciate the commenter's support for the current approach.

- One commenter asked for clarification on how the exclusion of patients with a total colectomy will be captured for patients that received their colectomy before enrolling in Medicare.

Response: The exclusion will not identify these patients; rather, the goal of the exclusion is simply to remove claims data that clearly contain errors. Since colonoscopy is not possible in patients with a total colectomy (total colectomy removes the entire colon), we removed from the measure cohort colonoscopies for patients with documented prior total colectomy (~0.2% of colonoscopies). Since we are proposing to implement this measure with two years of Medicare data, we will not have pre-Medicare enrollment data available to assess for total colectomy performed pre-Medicare enrollment. We do not think linking to additional data for the purpose of identifying additional rare cases of this error is necessary.

Outcome

Nine comments addressed the outcome timeframe and outcome definition.

- Two commenters recommended refining the codes used to identify hospital visits for bleeding. One commenter recommended using gastrointestinal (GI) bleeding codes only, since the use of transfusion codes are too broad and may lead to the capture of bleeding events unrelated to the procedure. Another commenter recommended removing less specific bleeding codes (e.g., ICD-9-CM code 578.1 – *Blood in stool* and code 285.1 – *Acute posthemorrhagic anemia*) to make the outcome a more reliable indicator of bleeding complications from colonoscopy. This commenter noted that these bleeding codes may reflect the condition that led the patient to undergo the colonoscopy rather than reflecting a complication of the procedure.

Response: We used a definition of bleeding based on literature using claims data (Warren et al., *Ann Intern Med.* 2009; 150: 849-857) and based on clinical review. We included blood transfusions as an indicator of serious bleeding. We note that bleeding risk may not be limited to GI bleeding, as non-GI bleeding may occur due to peri-procedural management of anti-platelet and oral anticoagulation therapy. We also note that blood transfusion for non-acute presentations are identified by the measure as planned admissions and therefore are not counted as unplanned hospital visits in our outcome. However, we acknowledge the concern that the codes used to identify bleeding may be broad and capture bleeding events unrelated to the procedure.

We are currently reviewing the concerns raised about specific codes, seeking further technical expert panel (TEP) input on this issue, and reviewing options for refining the outcome definition.

- Three comments expressed concerns regarding the breadth of outcomes being measured (all-cause unplanned visits and bleeding-related visits), the range of outcome event acuity (e.g., emergency department (ED) visits and inpatient visits reflecting complications of varying severity), and the dual outcome timeframes (up to 7 days for all-cause unplanned hospital visits and between 8 and 14 days for bleeding visits). One commenter noted this broad definition of outcome may sacrifice usability because the facility will not be able to differentiate among patient outcomes in reviewing its performance. Another commenter recommended

standardizing the outcome timeframe by selecting either up to 7 days or up to 14 days and expressed a preference for the shorter timeframe in order to improve the probability that captured events are procedure related. Another commenter recommended reporting the results by the severity of the complication, by the type of visit (ED visits, observation stays, and hospital admissions), and separately for ASCs and hospital outpatient departments (HOPDs). The commenter also recommended providing detailed reports to facilities to increase the measure's usefulness for quality improvement purposes.

Response: We appreciate these comments that highlight how the measure outcome, as defined, captures a number of different types of events – admissions, observation stays, and ED visits. We understand that information about patients' specific types of hospital visits would assist with quality improvement. We have combined the three types of hospital visits together because any unplanned hospital visit (ED visit, observation stay, or an inpatient admission) is likely a quality issue from the patient's perspective. Further, separating the outcome into several measures by setting (ED visit/observation stay versus inpatient admission), outcome severity, or by outcome timeframe (7 days versus 8 to 14 days) reduces the outcome rate per facility and diminishes the statistical power to detect variation in quality between facilities. However, we agree that providing a detailed report of patient outcomes to facilities may be important for informing quality improvement. Therefore, CMS will consider making available to facilities patient-level data on all patients included in the measure score via a secure mechanism.

- One commenter recommended an outcome timeframe within 14 days (not just 7 days); the commenter's understanding was that the TEP could not reach consensus on the outcome timeframe for the numerator statement.

Response: The TEP debated the outcome timeframe and recommended all-cause, unplanned hospital visits within 7 days or unplanned hospital visits for bleeding within 8 to 14 days of an outpatient colonoscopy procedure as the optimal outcome timeframe. This timeframe captures delayed bleeding events post colonoscopy (an important clinical complication) between days 8 to 14 while minimizing capture of hospitalizations unrelated to the procedure during this time period. As noted above, we are currently reviewing this approach based on other comments received.

- One commenter expressed support of the proposed outcome timeframe.

Response: We appreciate the commenter's support for the current approach.

- One commenter requested clarification on the calculation of a 'score' as noted in the measure information form.

Response: The measure 'score' refers to the estimated facility-level, risk-standardized, unplanned hospital visit rate. We calculate a measure score for each outpatient facility by computing the ratio of the number of adjusted actual unplanned hospital visits to the number of expected unplanned hospital visits. The ratio is analogous to a ratio of observed to expected hospital visits. We multiply the ratio by the unadjusted overall unplanned hospital visit rate to transform the ratio into a rate for ease of interpretation. This approach conceptually allows for a comparison of a particular

facility's performance given its case mix to an average facility's performance with the same case mix.

The statistical model is detailed in the "Risk Adjustment or Stratification for Outcome or Resource Use Measures" section of the Measure Justification Form posted for public comment. Very briefly, we use hierarchical logistic regression to model the log-odds of the outcome from an outpatient colonoscopy procedure as a function of the patient demographic and clinical characteristics and a random outpatient facility-specific intercept. The hierarchical model accounts for within-facility clustering of observed outcomes and models the assumption that underlying difference in quality among outpatient facilities being evaluated lead to systematic difference in facility-level outcomes.

- One commenter noted that ASCs have unique challenges in determining patient outcomes following discharge. This commenter noted that ASCs cannot provide care beyond a length of stay of 24 hours or access clinical records of patients who receive subsequent post-procedural care in EDs or inpatient admissions at other hospitals.

Response: We acknowledge that patient follow-up is often difficult and that the scope of ASC practice is limited. However, the measure is designed to measure outcomes from the patient's perspective. Therefore, it is critical that this quality measure fully capture post-procedure outcomes across settings. It is well known that colonoscopy providers often under-report adverse outcomes of colonoscopy in part because they lack information about patients seeking follow-up care from other providers in settings such as a hospital ED – the measure seeks to address this gap in information.

We believe the proposed colonoscopy measure, which fully captures unplanned hospital visits following an outpatient colonoscopy, will facilitate quality improvement by helping fill this gap. Specifically, the measure will enable ASCs and HOPDs to (1) track adverse events after colonoscopy and thereby monitor the quality and safety of the care they provide; (2) understand their performance relative to other providers; and (3) identify opportunities that could lead to improvements and changes in patient care.

Medicare's 3-day payment window policy

- One commenter expressed concerns regarding the impact of Medicare's 3-day payment window policy on the measure. Under this policy, facility claims for colonoscopies that occur in a HOPD and result in a same-day admission or admission within three days of the initial colonoscopy at a facility wholly owned or wholly operated by the same hospital as the HOPD are bundled with the inpatient claim. The commenter asked how CORE will identify inpatient admissions that may have resulted from colonoscopies performed in the HOPD setting and pointed out that not including these colonoscopies may undercount the number of hospital admissions attributed to the outpatient setting and thus limit the comparability of the measure scores across types of settings (HOPDs versus ASCs). The commenter was concerned that this policy may have impacted the data used in analyses to establish the rationale for this measure.

Response: We agree that because of the 3-day payment window policy we may not be able to identify in the claims data all HOPD colonoscopies; in particular, we are at risk of not including in the measure those cases that lead to admissions for adverse events. We have developed and reviewed with CMS an alternative strategy for identifying and including HOPD colonoscopies for patients who are admitted within three days. Specifically, we will use Medicare Part B physician claims to identify the procedures affected by this policy and attribute the admission to the correct facility.

We are testing the following specific steps to identify and appropriately attribute HOPD colonoscopies affected by this policy:

1. Identify colonoscopies performed in the HOPD setting affected by the 3-day payment window policy.
 - a. Identify colonoscopies with Medicare Part B file physician claims for colonoscopy in the HOPD setting AND inpatient admissions within ≤ 3 days AND no corresponding HOPD facility claim.
2. Attribute the colonoscopies identified as affected by this policy to the appropriate HOPD facility using the facility's provider identification (ID) from the inpatient file. The physician claim cannot be used for this purpose as it only contains the physician's National Provider Identifier (NPI) and does not contain a facility ID.

Risk model

Two comments addressed risk model variables.

- One commenter expressed concern that the measure adjusts for screening colonoscopies performed in the elderly (aged >80 years); the commenter noted that these patients are at higher risk of complications and suggested that centers performing a high volume of colonoscopies on these patients raise a quality concern.

Response: We agree that performing screening colonoscopies on the very elderly may be inappropriate and may expose patients to unnecessary risk. However, we note that the measure is not limited to colonoscopies done exclusively for screening and recommend adjustment for increasing age ≥ 65 years for the following reasons:

1. Increasing age is associated with an increased risk of adverse events after colonoscopy.
 2. Increasing age is associated with an increased risk of hospitalization from any cause (irrespective of whether patient underwent colonoscopy procedure).
 3. Adjustment for age ensures that the measure score reflects quality of care rather than variation in the age profile of patients seen by the provider.
- One commenter expressed concern for variability among providers in the number of polyps removed during polypectomy procedures; he cautioned that adjusting for polypectomy may be adjusting for provider choice and financial incentives rather than procedure-related risk factor.

Response: We agree the removal of small polyps may be discretionary and vary across providers; however, we recommend adjustment for polypectomy at the time of the colonoscopy for the following reasons:

1. Polypectomy is associated with an increased risk of adverse events, especially bleeding; this risk rises with increasing polyp size, sessile morphology, and the number of polyps removed.
2. Failure to adjust for polypectomy may disadvantage providers who perform polypectomy in patients with an appropriate indication for polypectomy.

Note: We do not adjust for the procedural technique used for polypectomy since this is at the discretion of the provider.

Stratification

Three comments suggested we may need to stratify the measure cohort or take other steps to ensure the measure score reflects quality rather than difference in procedures or patient case mix.

- One commenter suggested that the measure be stratified by indication for colonoscopy (screening versus diagnostic) to increase usability for quality improvement. The commenter noted that this would allow hospitals to distinguish between hospital visits that are related to disease progression or treatment rather than hospital visits directly related to the procedure. A second commenter recommended we stratify the measure based on the difficulty of the procedure. A third stressed that some facilities serve sicker populations and raised concern that facilities that serve sicker patients will be inappropriately compared to facilities with a mix of healthier patients.

Response: We have considered these issues in designing the measure. We considered stratification by indication (screening versus diagnosis) but do not think this is necessary. The existing literature does not suggest a marked increase in risk for diagnostic versus screening colonoscopies. In contrast, an increase in risk is observed when therapeutic intervention (particularly polypectomy) occurs during colonoscopy.

To establish a clinically coherent cohort and address differences in procedural difficulty and patient comorbidities, we exclude high-risk procedures (rather than stratify procedures into two groups and report two measures scores), because we are primarily interested in evaluating widely-used lower risk procedures. In addition, we risk adjust for two procedural factors that increase the risk of hospital visits – polypectomy during the procedure and concomitant upper GI endoscopy. Further, we adjust for patient demographic and comorbidity risk factors. This approach to risk adjustment helps ensure that the variation in measure scores is due to variation in quality rather than patient or procedural factors. Finally, we do not adjust for the technical approach to the procedure as it is generally at the discretion of providers and can potentially influence patient outcomes.

Level of reporting

Two comments addressed the level of measure reporting.

- Two commenters supported reporting at the facility-level for ASCs, office settings, and hospital outpatient facilities as a unit measure; one of these commenters specified support for the facility level but not for physician-level quality reporting programs such as the Medicare Physician Quality Reporting System and Physician Value-Based Modifier programs.

Response: We appreciate the support for the current approach of reporting at the facility level.

- One commenter expressed concern for the denominator time window of “any colonoscopy procedures performed within a 1-year period” and the attribution of colonoscopies performed in non-hospital-affiliated ASCs and office-based settings to a specific hospital.

Response: The measure score will be reported for each outpatient facility, including HOPDs and ASCs. We use physician claims and facility claims to assign the procedure to specific facilities. We will provide additional details as we finalize the measure specifications.

Testing

- One commenter recommended that the measure undergo more testing, particularly for validity and reliability, stating that further testing can investigate the validity of the bleeding outcome as a quality signal and the impact of the 3-day payment window policy’s impact on the reliability of the measure score. Commenter recommended that the measure be assessed against the National Quality Forum’s (NQF’s) endorsement criteria for validity and reliability even though CMS does not require NQF approval for quality measures.

Response: This measure is not finalized and is presently undergoing testing as noted above. CMS generally seeks public comment during measure development to allow developers to address concerns or issues raised during the public comment period in the measure development and testing process.

Data source

Three comments addressed the data source and feasibility for EHR data entry.

- One commenter recommended collaborating with quality improvement registries such as GI Quality Improvement Consortium (GIQuIC) to support the use of the measure in quality improvement. Another commenter supported development of non-claims based measures (such as registry based) to track adverse events; the commenter suggested patient outreach as method of determining adverse events and whether events were attributable to the colonoscopy. A third commenter stated that EHR data entry for this measure’s specifications is feasible.

Response: CMS appreciates the opportunities registries present for incorporating clinical data into quality measurement. CORE has developed measures for CMS collaboratively with several widely-used hospital registries. In the short to medium term, however, claims data offers the best opportunity for national quality measurement of outpatient colonoscopy. Medicare claims data is available nationwide from every provider that performs colonoscopies in Medicare patients, is

highly feasible, and can be linked across care settings to assess outcomes. Clinical registries have an important role in measuring quality, and CMS welcomes further input from professional organizations on opportunities to collaborate on advancing quality measurement. We appreciate the commenter's support for EHR specification.

Correction

- One commenter brought to our attention our mischaracterization of CMS's use of the ASC QC's Hospital Transfer/Admission measure. The commenter noted that the measure is not included in the Hospital Outpatient Quality Reporting Program, rather it is one of four outcome measures currently reported under the ASC Quality Reporting Program.

Response: We misstated the CMS program that uses the ASC QC's Hospital Transfer/Admission measure and apologize for this error.

Clarification

- One commenter noted that the ASC QC's Hospital Transfer/Admission measure includes all ASC admissions, including all colonoscopies, and therefore CORE's claim that the proposed CMS measure captures a broader cohort of colonoscopy patients than the ASC measure is incorrect.

Response: Our assertion that the proposed measure has a broader cohort of patients was referring to the CMS measure's proposed use in both ASCs and HOPDs.

Proposed action(s):

We plan to incorporate the suggestions received during public comment into the development of our measure. Specifically:

- CORE and CMS will change the way we identify colonoscopies done at HOPDs to ensure those that are affected by the 3-day payment window policy are included in the measure.
- CORE will review in detail and with the TEP our approach to identifying hospital visits for bleeding in 8 to 14 days.
- CMS will consider making available to facilities patient-level data on all patients included in the measure score via a secure mechanism.
- CORE and CMS welcome further input from professional organizations on opportunities to collaborate on advancing quality measurement.

Overall Analysis of the Comments and Recommendations to CMS

The feedback on the measure focus and the measure's proposed use for facility-level reporting overall was positive. Commenters identified several technical issues that we will address through changes to the measure specifications.

Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Public Comment Verbatim Form

Date Posted	Text of comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
Nov. 18, 2013	<p>To CORE:</p> <p>I am submitting comments on behalf of Epic, the EHR vendor, on the draft specifications for this measure. I have reviewed this measure and find it to be very feasible from the perspective of EHR data entry. I can find no flaws in the measure from this perspective, and have no specific recommendations regarding any modifications that are needed.</p> <p>Sincerely: Howard Bregman</p>	<p>Howard Bregman, MD, MS, FAAP</p> <p>EPIC</p>	<p>Howard@epic.com</p>	<p>EHR Vendor</p>
Nov. 20, 2013	<p>Colleagues:</p> <p>Thanks for the opportunity to review the draft measure. Since I was specifically cc'ed, here goes. Overall, very impressive, and reflects a tremendous amount of work and thoughtfulness on the part of the team. This is a significant issue. Couple of specific comments that may require clarification.</p> <ol style="list-style-type: none"> 1. Agree with the two-week 'window' for admission or ED visit. 2. I agree with the TEP regarding concern about admission or visit after scope for 'diverticulosis with hemorrhage' on an outpatient basis. This is a common presentation. Elderly individual has bright red stool, and may or may not be hospitalized. Not tender, so not diverticulitis. Scope may show just diverticuli. These patients have a significant re-bleed rate, and interventions such as embolization can only occur when the patient is actively bleeding. So, the hospitalizations would be a mix of small numbers of complications (since they are generally not biopsied in this setting) and more natural hx of disease. I would favor exclusion. 	<p>Tim Carey, MD, MPH</p> <p>Professor of Medicine</p> <p>Director, Cecil G Sheps Center for Health Services Research UNC Chapel Hill</p>	<p>timothy_carey@med.unc.edu</p>	<p>Individual</p>

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	<p>3. Screening colonoscopy in the elderly (>80) has been demonstrated to be significantly higher risk, and centers that scope a large number of such patients will have higher complication rates. But.....should we adjust for this since scoping a 90 year old for to try to detect 2-3mm polyps may be a quality problem in its own right? I know this would add a level of complication, but worth considering and discussing, I didn't see it discussed in the TEP document. But I may have missed it.</p> <p>4. Polypectomy is associated with greater risk of problems, consistent with prior work. Currently polypectomy is considered a comorbidity- a characteristic of the patient. But....I suspect that the # of polyps removed may also be a characteristic of the provider. While all providers will remove larger polyps, there may be variability in the 'harvest rate' of smaller polyps. While clinical intuition tells me that removing a 3 mm polyp will have fewer complications than a 9mm polyp, I don't know that literature well. Providers working in an un-bundled environment may have incentives to remove more polyps, leading to more complications in total. Wanted to raise the issue. Could there be potential for over-adjustment?</p> <p>Many thanks Tim</p>			
Dec. 6, 2013	<p>CMS and CORE Project Teams:</p> <p>On behalf of the ASC Quality Collaboration (ASC QC), a cooperative effort of organizations and companies interested in ensuring ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding the draft measure of unplanned hospital visit rates after outpatient colonoscopy. The ASC QC's stakeholders include ASC corporations, ASC industry associations, physician and nursing professional societies, and accrediting bodies with an interest in ASCs. Please see Appendix A for a list of the ASC QC's participating organizations.</p> <p>The ASC QC strongly advocates quality reporting. This commitment is reflected in the steps we have taken independently to facilitate quality reporting by ASCs – all without federal</p>	<p>Donna Slosburg, BSN, LHRM, CASC</p> <p>Executive Director, ASC Quality Collaboration</p>	<p>donnaslosburg@ascquality.org</p>	<p>ASC Quality Organization</p>

Date Posted	Text of comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
	<p>incentive or penalty. This includes developing six ASC facility-level quality measures and securing the ongoing endorsement of the National Quality Forum (NQF) for each, as well as developing and publishing a quarterly public report of ASC quality data that is freely available online. These quarterly reports are made possible through the voluntary efforts of participants in the ASC QC and may be accessed at the ASC QC's website (http://www.ascquality.org/).</p> <p>We fully support the concept of developing standardized measures that may be used to assess the quality of care across settings providing identical services. We are pleased this project plans to address outcomes following colonoscopy in three settings - hospital outpatient departments (HOPDs), ASCs, and physician offices - increasing opportunities for consumers to make meaningful comparisons across outpatient settings offering colonoscopy. We appreciate the work CMS and the CORE measure development team have invested in developing draft measure specifications.</p> <p>With the goal of ensuring the measure produces valid, reliable, and actionable results across the spectrum of outpatient colonoscopy venues, we present several items for your consideration in the pages that follow the measure summary.</p> <p>A. Measure Background</p> <p>CMS has contracted CORE to develop a measure of hospital visits following an outpatient colonoscopy. The measure specifications have been developed around code-based data sets, using administrative claims and other administrative data as data sources. While administrative claims are a blunt instrument for assessing clinical quality, they do not impose any additional data collection or submission burdens on providers, which is a benefit. Key measure specifications are presented below:</p> <p><i>[Note: the following content has been reformatted from the original due to accessibility concerns.]</i></p>			

Date Posted	Text of comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
	<p><u>Hospital Visit Rate After Outpatient Colonoscopy</u></p> <ul style="list-style-type: none"> • Measure Intent <ul style="list-style-type: none"> ○ To measure the rate of risk-standardized, all-cause, unplanned hospital visits within 7 days or unplanned hospital visits for bleeding within 8-14 days of an outpatient colonoscopy procedure among Medicare fee-for-service (FFS) patients aged ≥65 years • Numerator <ul style="list-style-type: none"> ○ All-cause, unplanned hospital visits within 7 days or unplanned hospital visits for bleeding within 8-14 days of an outpatient colonoscopy procedure • Denominator <ul style="list-style-type: none"> ○ Colonoscopy procedures performed at hospital outpatient facilities, ASCs, or office settings, for patients aged ≥65 years enrolled in Medicare fee-for-service (FFS) over a one-year period • Denominator Exclusions <ul style="list-style-type: none"> ○ Procedures for patients who lack continuous enrollment in Medicare FFS parts A and B in the 12 months prior to the procedure and/or 1 month after the procedure ○ Procedures for patients with a history of total colectomy within the preceding 12 months* ○ Colonoscopy procedures that occur concurrently with high-risk upper GI endoscopy procedures* ○ Procedures for patients with a history of inflammatory bowel disease* ○ Procedures for patients with a history of diverticulitis* • Definitions <ul style="list-style-type: none"> ○ Bleeding: 285.1 – Acute post-hemorrhagic anemia, 569.3 – Hemorrhage of anus and rectum, 578.1 – Melena/blood in stool, 578.9 – Gastrointestinal hemorrhage, unspecified, 998.11 – Hemorrhage complicating a procedure; <i>OR</i> 99.03 – Other transfusion of whole blood, 99.04 – Transfusion(s) of packed 			

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	<p>red cells; <i>OR</i> HCPCS codes for whole blood or RBC products</p> <ul style="list-style-type: none"> ○ Colonoscopy: G0105, G0121, 45378, 45380, 45381, 45383, 45384, 45385 ○ Hospital Visit: any emergency department visit, observation stay, or unplanned inpatient admission* ○ Unplanned admission: any admission that is not deemed a planned admission by the measure’s adaptation of the CMS Planned Readmission Algorithm v2.1 <ul style="list-style-type: none"> ● Data Sources <ul style="list-style-type: none"> ○ Medicare FFS administrative claims and Medicare enrollment data ● Risk Adjustment <ul style="list-style-type: none"> ○ Statistical risk adjustment model is in development; risk adjustment look-back period is one year ● Stratification <ul style="list-style-type: none"> ○ None ● Measure Score <ul style="list-style-type: none"> ○ Rate of predicted versus expected unplanned admissions <p>*Defined by lists of ICD-9-CM, CPT, HCPCS and/or revenue codes.</p> <p>B. Concerns Regarding the Draft Measure</p> <p>1. Cross Setting Comparisons and the Medicare Three-Day Payment Window Policy</p> <p>As noted above, this project plans to address outcomes following colonoscopy in HOPDs, ASCs, and physician offices using administrative claims. However, we have been unable to determine how the measure will account for differences in Medicare billing policy across these three settings. We are particularly concerned about the impact of the Medicare three-day payment window policy, where certain hospital outpatient services are treated as inpatient. In accordance with Section 102 of Pub. L. 111-192, outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by a hospital (such as a hospital outpatient department, hospital emergency department, or a wholly owned physician practice) <i>on the date of a beneficiary’s inpatient admission</i> must be billed</p>			

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	<p>with the inpatient stay. In addition, outpatient services provided by a hospital (or any Part B entity wholly owned or wholly operated by the hospital) <i>on the first, second, and third calendar days preceding the date of a beneficiary's inpatient admission</i> are also deemed related to the admission, and must be billed with the inpatient stay. The three-day payment policy applies to all non-diagnostic services provided during the payment window unless the hospital attests that the services are clinically unrelated. Diagnostic services are always subject to the payment window, irrespective of whether they are considered clinically related. As a result of this policy, separate claims for many HOPD services that result in near-term complications requiring inpatient hospitalization are not generated.</p> <p>It is unclear how this measure will identify inpatient admissions that may have resulted from colonoscopies performed in the HOPD setting when those unplanned admissions occur on the date of the colonoscopy, or during the three days subsequent to the procedure. This missing data will skew the analysis by undercounting the number of hospital admissions attributed to the HOPD. Unless this can be overcome, measure scores will not be comparable across settings.</p> <p>This policy may have impacted the data used in the analyses performed to establish the rationale for this measure. These analyses estimated the measure score for both ASCs and HOPDs using 2010 Healthcare Cost and Utilization Project (HCUP) data, then separately calculated the measure score for HOPDs alone using 2010 data from the Chronic Conditions Data Warehouse (CCW). Both analyses found provider variability. It is unclear how much of this variability may have been a reflection of the three-day payment window policy, which was implemented for dates of service on or after June 25, 2010.</p> <p>2. Breadth of Outcomes Being Measured</p> <p>Outcomes for this measure include both bleeding and all-cause unplanned visits. The level of acuity ranges from issues that can be managed in the outpatient setting (ED visit), to problems that require inpatient treatment. Even the timeframe of outcomes varies from up</p>			

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	<p>to 7 days to between 8 and 14 days. From the standpoint of usability and actionability, there is significant benefit in measures that are focused on a clinically coherent topic. This measure attempts to cover the waterfront, and sacrifices usability and actionability in the process. We suggest the developers consider alternatives - such as creating two (or potentially more) separate measures - that more narrowly focus the outcomes. It would also be helpful to standardize the outcome timeframe by selecting either up to 7 days, or up to 14 days. The shorter 7-day timeframe would improve the probability that captured events are related to the index procedure.</p> <p>3. Actionability of Measure Results in the Absence of Stratification</p> <p>According to the Measure Justification Form, “[a] primary goal of the measure is to provide facilities with information necessary to implement focused quality improvement.” As currently specified, the measure result would be reported as a single rate for each facility. Assuming the measure can be re-specified to account for the three-day payment window policy, that rate would allow a facility to compare their rate to that of other facilities. However, without stratification or other changes in measure design, it is not sufficient for implementing focused quality improvement.</p> <p>ASCs face unique challenges in reliably determining patient outcomes following discharge. Per Federal regulation (see 42 CFR §416.2) an ASC is a “<i>distinct entity</i> that operates <i>exclusively</i> for the purpose of providing <i>surgical services</i> to patients...” [emphasis added]. ASCs function exclusively as a site for outpatient surgery, and - unlike other outpatient surgical settings, such as clinician offices, ambulatory clinics or hospital outpatient departments - <i>may not provide post-operative follow-up care after patient discharge</i>. As a result, the records detailing post-operative outcomes are generated in other settings. The ASC must rely on voluntary reports gathered by surveying physicians and making post-operative phone calls to patients to determine the occurrence of complications. In order to access medical records detailing complications, the ASC must request them from other providers (in the case of this measure, a hospital) after having obtained the patient’s</p>			

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	<p>consent.</p> <p>As a result of these constraints, an ASC presented with a single result for a complex measure such as this one would – although able to determine their overall performance relative to other providers - face challenges translating the result into a focused quality improvement effort. A single rate is useful for public reporting purposes, but the measure result should also be stratified to ensure actionability, particularly if the measure remains broadly construed. As currently structured, ASCs would not have even the most basic insight into the determinants of their overall score. For example, it would not be possible to determine the relative contribution of all-cause unplanned hospital visits during the first 7 days versus visits for bleeding in the subsequent 8 to 14 days; or the relative contribution of various condition or procedure categories to unplanned visits; or the relative frequency of ED visits, observation stays and hospital admissions.</p> <p>We believe providers affected by this measure should be able to gain insight from the vast amount of data that would be analyzed to support each provider-level measure result. If the measure were not stratified, a detailed report allowing the facility to drill down into its results would be essential to making the measure useful and actionable for quality improvement purposes.</p> <p>4. Definition of Bleeding</p> <p>For purposes of this measure, bleeding is defined by a series of ICD-9-CM diagnosis codes related to bleeding, ICD-9-CM procedure codes for receipt of a transfusion, and HCPCS Level II codes for whole blood or red blood cell products. The appearance of <i>any</i> of these codes anywhere on the claim is sufficient to cause the claim to be flagged as indicative of bleeding complicating a colonoscopy during the 8 to 14 day post-procedure period.</p> <p>Several of the diagnosis codes currently included in the definition are non-specific, which makes it difficult to use them as reliable indicators of bleeding complications from</p>			

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	<p>colonoscopy. One of the codes listed, diagnosis code 578.1 – <i>Blood in stool</i> is likely to be used to indicate the problem which led to the index colonoscopy, and unlikely to be used to indicate bleeding as a result of the procedure. Several of the ICD-9 diagnosis codes do not allow determination of the site of bleeding, which is problematic. For example, 578.9 – <i>Gastrointestinal hemorrhage, unspecified</i>, may be used to describe both gastric bleeding and intestinal bleeding, and “intestinal bleeding” is not limited to the colon. Diagnosis code 578.1 – <i>Blood in stool</i> is also non-specific as to the bleeding source. Code 285.1 – <i>Acute posthemorrhagic anemia</i> may be assigned to bleeding from any location in the body documented to have resulted in acute anemia, and is not limited to the gastrointestinal tract.</p> <p>The measure does not appear to require the codes for transfusion or blood products to be associated with a diagnosis of hemorrhage complicating a procedure, or even with a general diagnosis of gastrointestinal bleeding.</p> <p>The definition of bleeding should be refined. Some alternatives include removing codes such as 578.1 from the current ICD-9 diagnosis code set; requiring a diagnosis of gastrointestinal bleeding to appear concurrently on a claim with codes for transfusion and blood products; excluding patients with diagnoses indicating a potential source of upper gastrointestinal bleeding; or a combination of these or other approaches.</p> <p>5. Lack of Testing</p> <p>As presented, the measure is still in development, with key elements (a finalized risk adjustment algorithm) currently incomplete. Consequently, there is also a lack of testing for key measure attributes such as validity and reliability.</p> <p>The National Quality Forum (NQF) requires validity testing that demonstrates that the measure “correctly reflects the quality of care provided, adequately identifying differences in quality.” This measure has not been tested for either of these validity</p>			

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	<p>criteria. For example, in the absence of testing, it is unclear whether the measure algorithm for delayed bleeding can satisfactorily distinguish between hospital visits that are due to issues with procedural quality versus hospital visits that are due to an underlying illness that may have prompted the colonoscopy, or another unrelated or pre-existing condition. It is difficult to judge whether the measure results allow correct conclusions to be drawn about quality of care.</p> <p>To assure reliability, the NQF requires that the measure data elements are repeatable and produce the same results a high proportion of the time. Given the impact of the three-day payment rule on HOPD claims as discussed above, the measure data elements are not repeatable across settings. It is not clear that variations in the measure score reflect systematic differences in quality across the facilities offering outpatient colonoscopy, or reflect - at least in part - differences in billing requirements and other factors unrelated to quality.</p> <p>Although CMS measures are not required to be NQF endorsed, they should be subjected to the same reliability and validity testing to ensure that the agency is collecting scientifically sound measures that may be used to improve the quality of care. In the absence of this testing, we are unable to form any conclusions about the scientific acceptability of the measure. We look forward to learning more about how the measure performs when it is piloted and tested.</p> <p>C. Correction Regarding an ASC QC Measure</p> <p>Finally, we wish to draw your attention to erroneous information regarding the ASC QC's Hospital Transfer/Admission measure included in Section 5a.1. of the Measure Justification Form. First, this measure is characterized as the "only outcome measure currently used in a CMS program, the Hospital Outpatient Quality Reporting Program." The measure is not included in the Hospital Outpatient Quality Reporting Program. Rather it is one of four outcome measures currently reported under the ASC Quality</p>			

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	<p>Reporting Program. This measure includes all ASC admissions, and therefore the statement “our measure [<i>referring to the CORE measure under discussion here</i>] captures a broader cohort of the colonoscopy patients, including patients undergoing screening, diagnostic, and therapeutic colonoscopy procedures” is incorrect. All colonoscopies – including screening, diagnostic and therapeutic procedures – are included in the Hospital Transfer/Admission measure.</p> <p style="text-align: center;">***</p> <p>In summary, this measure addresses an important measurement topic and we support the effort to apply the measure across all settings that provide outpatient colonoscopy. The measure development project faces several challenges in meeting its key goals of allowing comparisons across settings and providing facilities with the information needed to implement focused quality improvement. These challenges include the CMS three-day payment window policy; limited usability and actionability resulting from the measure’s broad scope and lack of stratification; and issues with construct validity and reliability across measurement settings. It is our hope that the suggestions offered above would help remove some of these obstacles to success.</p> <p>Thank you for considering our comments. We would be happy to assist with questions or provide additional information at your request.</p> <p>Sincerely, Donna Slosburg</p> <p>Appendix A Current Participants in the Activities of the ASC Quality Collaboration</p> <p>Accreditation Association for Ambulatory HealthCare Ambulatory Surgery Foundation</p>			

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	<p>Ambulatory Surgical Centers of America American College of Surgeons American Osteopathic Association, Healthcare Facilities Accreditation Program AmSurg Association of periOperative Registered Nurses Florida Society of Ambulatory Surgery Centers Hospital Corporation of America, Ambulatory Surgery Division Nueterra Healthcare Outpatient Ophthalmic Surgery Society Surgery Partners Surgical Care Affiliates Symbion The Joint Commission United Surgical Partners International</p>			
Dec. 6, 2013	<p>Thank you for the opportunity to comment on this measure. On behalf of Cedars-Sinai Medical Center, I offer the following:</p> <ul style="list-style-type: none"> Quality measures must not only be relevant, but have significant impact on health outcomes, patient safety, or patient satisfaction. We welcome the focus on this topic, given the high volume of this procedure, as well as the wide variation in reported adverse outcomes, as demonstrated by the TEP's analysis of provide-level variation using data from the Healthcare Cost and Utilization Project (HCUP) and the Nationwide Hospital Outpatient Facilities Measures of quality and/or utilization should be structured to promote improvement. To that end, it would be helpful if this colonoscopy measure were stratified by the indication for colonoscopy: screening vs diagnostic. Such 	<p>Gail P Grant, MD, MPH, MBA</p> <p>Medical Director, Resource & Outcomes Management, Cedars-Sinai Medical Center</p>	<p>Gail.Grant@cshs.org</p>	<p>Hospital/ Health System</p>

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	<p>stratification would help hospitals distinguish between hospital visits and re-admissions that may be due to disease progression or treatment, versus those complications directly related to the procedure. In addition, rates of complications among these 2 clinical populations may vary markedly.</p> <ul style="list-style-type: none"> In the Measure Information Form (MIF) the denominator time window is specified as "Any colonoscopy procedures performed within a 1-year period". Given that colonoscopy procedures performed outside of the hospital setting are included in the denominator- as well as the primary data source of Medicare Part B claims - it is unclear how colonoscopies performed in non-hospital-affiliated ASCs and office-based settings will be attributed to a specific hospital. In particular, the attribution of office- or ASC-based procedures that are not followed by a subsequent hospital visit appears problematic. Additional detail on the methodology for hospital-specific attribution would be helpful. <p>Please feel free to contact me should you have questions or wish to respond to my comments directly.</p> <p>Respectfully submitted, Gail P Grant, MD, MPH, MBA</p>			
Dec. 6, 2013	<p>Dear CMS and CORE project team members:</p> <p>On behalf of the more than 12,000 members of the American Society for Gastrointestinal Endoscopy (ASGE), I thank you for the opportunity to provide comments on the draft administrative claims-based, risk-adjusted measure of hospital visits after colonoscopy procedures performed in the ambulatory care setting. Our society strongly supports the concept of this measure, as monitoring adverse events relative to colonoscopy procedures is an important activity to ensure high-quality endoscopy.</p> <p>MEASURE SPECIFICATIONS</p>	<p>Kenneth K Wang, MD, FASGE</p> <p>President, American Society for Gastrointestinal Endoscopy</p>	<p>Eessex@asge.org</p>	<p>Professional Society</p>

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	<p>ASGE applauds the efforts of the panel that developed this measure and looks forward to a performance target being set for the measure once a base rate of unplanned hospitalizations following colonoscopy can be determined. We offer to the measure developer and technical expert panel these recommendations and requests for clarification relative to the measure specifications as they continue to refine the measure.</p> <p>The numerator statement in the measure information form reads as follows.</p> <p><i>The outcome for this measure is all-cause, unplanned hospital visits within 7 days or unplanned hospital visits for bleeding within 8-14 days of an outpatient colonoscopy procedure. We define a hospital visit as any emergency department (ED) visit, observation stay, or unplanned inpatient admission.</i></p> <p>ASGE recommends confining the numerator to unplanned hospital visits and gastrointestinal (GI) bleeding codes only, as the use of non-specific bleeding codes is too broad and may lead to unintended consequences. For example, an endoscopist affiliated with a cancer center may have a relatively high percentage of patients who present regularly for blood transfusion as a sequela of bone marrow insufficiency. Such an endoscopist may therefore be incorrectly categorized as a lower quality provider than would be appropriate. Further, ASGE suggests the measure could be strengthened by stratifying adverse events based on their severity and the difficulty of the procedure. Stratification of adverse events based on their severity could be assessed by evaluating the impact (i.e., observation versus unplanned hospital admission versus surgery) as opposed to diagnosis.</p> <p>ASGE understands the technical expert panel could not reach consensus on the outcome timeframe for the numerator statement and agrees with the panel's majority opinion supporting a 14-day outcome timeframe. ASGE also supports capturing delayed adverse events leading to hospitalization occurring within 14 days (not just 7) of any endoscopic</p>			

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	<p>procedure.¹</p> <p>ASGE believes that attempts should be made to contact patients approximately 14 days after procedures to determine whether any adverse events had occurred and whether they were attributable to the procedure. As such, ASGE would support the development of non-claims-based measures to track delayed adverse events for use in registries and other mechanisms.</p> <p>The denominator statement in the measure information form reads as follows.</p> <p style="padding-left: 40px;"><i>Colonoscopy procedures performed at hospital outpatient facilities, ambulatory surgical centers (ASCs), or office settings for Medicare FFS patients aged ≥65 years.</i></p> <p>Among the denominator exclusions outlined in the measure information form are procedures for patients with a history of total colectomy (within the preceding 12 months). The rationale states that colonoscopy is not indicated for patients with a prior history of total colectomy. ASGE requests clarification on how the exclusion of patients with a total colectomy will be captured for patients that received their colectomy before enrolling in Medicare.</p> <p>As the calculation algorithm presented in Appendix C is under development, ASGE remains unclear if the risk model will stratify adverse event rates to account for patient comorbidities or if sicker patients will be excluded from the calculation. ASGE is concerned facilities with a larger population of sicker patients will be inappropriately compared to facilities with a mix of healthier patients. Further, with the numerator and denominator as defined and the risk model under development, ASGE requests clarification on the calculation of a “score” as noted in the measure information form.</p> <p>REPORTING AND INTERPRETATION OF THE DATA</p>			

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	<p>Given the low incidence of adverse events relative to colonoscopy, ASGE supports the measure primarily for measuring and reporting at the facility-level for ambulatory surgical centers, offices and hospital outpatient facilities. As a procedure-specific unit measure, it will encourage units to improve methods of capturing accurate data on adverse events.</p> <p>However, ASGE is concerned that the numbers will not be reliable and valid for reporting at the individual provider-level given the relative infrequency of these events. Further, the measure could inaccurately categorize therapeutic endoscopists who perform more challenging and complex procedures that may not be correctly accounted for simply by capturing billing or diagnostic codes. Therefore, ASGE supports this important measure for facility-level reporting via the Ambulatory Surgical Center Quality Reporting and Hospital Outpatient Reporting programs but not for physician level quality reporting programs such as the Medicare Physician Quality Reporting System and Physician Value-Based Modifier. Additionally, we do not believe that highlighting these measures on Physician Compare or the Physician Feedback/QRUR would be appropriate.</p> <p>Thank you for your consideration of these comments. Please direct any questions to Eden Essex, ASGE’s Manager of Quality and Health Policy, at Essex@asge.org or [phone number].</p> <p>Sincerely, Kenneth K. Wang</p> <p>¹ Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. <i>Gastrointest Endosc.</i> 2010 Mar;71(3):446-454.</p>			
Dec. 6, 2013	<p>The American College of Gastroenterology (ACG) appreciates the opportunity to provide comments in response to the development of colonoscopy ambulatory measures. ACG also appreciates the work of the Yale New Haven Health Services Corporation/Center for Outcome Research and Evaluation (CORE) to develop risk-</p>	<p>Brad Conway Vice President, Public Policy,</p>	<p>Bconway@gi.org</p>	<p>Professional Society</p>

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	<p>adjusted measures for ambulatory care.</p> <p>ACG is an organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, our organization currently numbers over 13,000 members. The primary activities of ACG have been, and continue to be, promoting evidence-based medicine and optimizing quality of patient care.</p> <p><u>Quality Improvement Registries: Linking Measure-Development and Measure-Adherence</u></p> <p>In an effort to work with our members to provide the highest quality of care to patients in gastroenterology, ACG and the American Society for Gastrointestinal Endoscopy (ASGE) created the “GI Quality Improvement Consortium” (GIQuIC), a specialty-specific clinical registry. This collaborative effort allows gastrointestinal (GI) specialists to submit data that is relevant to their specialty and receive feedback data that compares their performance with that of their peers. In July 2010, GIQuIC began collecting quality indicators for colonoscopy, as colonoscopy is by far the most common procedure in gastroenterology, especially within the Medicare program. ACG is very encouraged by the registry’s success to date. As of December 2013, GIQuIC has more than 1,500 physicians from more than 190 practice settings participating in the registry and more than 420,000 colonoscopy cases are in the database. All data in GIQuIC is encrypted and stripped of personally-identifiable patient information.</p> <p>ACG views the registry as the bridge between measure-development and measure-adherence. Thus, it is very important to consider clinical registries as the vehicle to collect measure developed by CORE.</p> <p><u>ACG Recommendations</u></p> <p>As the CORE technical expert panel (TEP) discussed in its report, there are well-documented pitfalls of relying on claims-based data when measuring patient outcomes. TEP members, for example, cited difficulty in determining why a patient had an</p>	<p>Coverage & Reimbursement, American College of Gastroenterology</p>		

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	<p>incomplete procedure or other complications from claim forms and codes. Indeed, members of the TEP noted that by relying on codes, measures may unintentionally exclude patients who should be included in the denominator.</p> <p>ACG recommends that CORE collaborate with registries such as GIQuIC as well as the national gastroenterological societies when finalizing these measures in order to successfully gather and collect outcome-based metrics that include all relevant patient populations.</p> <p>ACG also recommends CORE reach out to successful registries such as GIQuIC as these registries have already demonstrated a high uptake rate among gastrointestinal clinicians in just a few short years.</p> <p>Working with clinical registries will help incorporate these measures into clinical practice as well as streamline ongoing quality improvement efforts in the Medicare program.</p> <p><u>Conclusion</u></p> <p>ACG thanks CORE and the Centers for Medicare and Medicare Services (CMS). ACG is happy to provide physician-experts as needed and welcomes any opportunity to work with you to improve health outcomes and the Medicare system as a whole. Please contact Brad Conway, Vice President, Public Policy, Coverage & Reimbursement, at Bconway@gi.org or [phone number].</p>			