



February 6, 2015

To: Consensus Standards Approval Committee (CSAC)

From: NQF Staff

Re: Appeal for All-Cause Admissions and Readmissions Measure #2539: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

In accordance with the NQF Consensus Development Process (CDP), the 17 measures recommended by the All-Cause Admissions and Readmissions Standing Committee were released for a 30-day appeals period. On January 28, 2015, the 30-day appeals period for the readmissions and admissions measures closed and NQF received two appeals. The Ambulatory Surgery Center Quality Collaboration (ASC-QC) submitted an appeal for Measure #2539: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy developed by CMS/Yale.

Accompanying this memo are the following documents:

- [ASC-QC letter of appeal for Measure #2539](#)
- Response to the appeal from the CMS/Yale measure developers, including Attachment 79 FR 66948-66956 [HOQR], 66970-66985 [ASCQR]

CSAC ACTION REQUIRED

The CSAC will review the letter of appeal, the response submitted by the developers, and this memo in consideration of the appeal. The CSAC will determine whether to uphold the endorsement decision or uphold the appeal for #2539: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (CMS/Yale).

Background

Measure #2539 is a new submission to NQF and was developed under stewardship of The Centers for Medicare and Medicaid Services (CMS) (see [full measure specifications](#)). During the Admissions/Readmissions Standing Committee in-person meeting on May 5-6, 2014, the measure passed each of the criteria – importance to measure, scientific acceptability, usability, and feasibility. Overall, the Committee was supportive of the measure but did discuss the completeness of the risk adjustment model and measure exclusions during their review of the validity of the measure. In particular, the Committee questioned why polypectomy was included in the risk adjustment model, since polypectomy could cause a readmission, and inclusion in the model would negate that effect. As such, the Committee recommended that this measure should be used in conjunction with other measures of polypectomy rates or adenoma detection rates. Ultimately, the Committee agreed that the measure was usable for quality improvement and accountability purposes, and voted to recommend the measure for

endorsement. CMS plans to publicly report the measure in the Hospital Outpatient Quality Reporting Program and/or Ambulatory Surgery Center Quality Reporting Program. Commenters were supportive of increased focus on the quality of colonoscopy and the development of this measure. Concern was raised that the planned readmission exclusions and risk adjustment variables included in this measure are not sufficient for the clinical condition and may result in reluctance of endoscopists to scope patients with significant comorbidities.

The measure was subsequently advanced to a NQF member vote which opened on September 10 and closed September 24, 2015. No measure was approved by the membership during Member vote, and the voting results were shared with the CSAC during their October 2014 Conference Call. In an attempt to understand the consensus issues across stakeholders, the CSAC instructed NQF to move forward with additional consensus building, specifically, an all-Member web-meeting to better understand concerns surrounding these measures

On October 20, 2014, NQF held an All-Member Web-Meeting, inviting all member stakeholders to participate in a discussion about the measures under review. The call provided an opportunity for NQF Members to voice their concerns and provide feedback for the CSAC's consideration.

During their November 2014 Conference Call the CSAC moved to make an endorsement decision after reviewing all of the Admissions/Readmissions Standing Committee's deliberations, the public and member comments, member voting results, and the all-Member call feedback. The CSAC approved Measure #2539 for endorsement. On December 22, 2014, the NQF Board Executive Committee unanimously ratified the CSAC's recommendation to endorse the slate of admission and readmission measures, only with the following conditions:

1. The Admissions/Readmissions Standing Committee will determine which measures must enter the trial period for consideration of SDS.
2. One-year look-back assessment of unintended consequences. NQF staff will work with Admissions/Readmissions Standing Committee and CMS to determine a plan for assessing potential unintended consequences. The evaluation of unintended consequences will be initiated within approximately one year and possible changes to the measures based on these data will be discussed at that time.

NQF staff is in the process of developing plans to operationalize and address these conditions.

Summary of Issues Raised in Appeal

NQF staff has reviewed the appeal and has outlined the issues raised by the appellant below:

- A. Lack of validity testing in the settings of care measured: the appellant notes that the testing of this measure is based on administrative claims for inpatient settings, rather than outpatient settings for which the measure is specified. Hospital Outpatient Departments (HOPD) and Ambulatory Surgical Centers (ASC) claims differ from inpatient claims; as such it is unclear how valid the measure and its risk adjustment approach would be without testing the measure using administrative claims from the appropriate settings.
- B. The measure is not valid due to systematic undercounting of HOPD events when there is an inpatient admission: the appellant notes that the measure systematically undercounts

- hospital visit rates following HOPD care due to Medicare’s three day payment window policy. This policy limits the ability to identify index HOPD visits, and subsequent hospital visits related to HOPD care.
- C. Measure rationale and the three-day payment window policy: the three-day payment policy window implemented in 2010 may limit the observed performance gap for the measure demonstrated using 2010 data.
 - D. Issues with the reliability of the measure: the appellant raises two areas of concern about the reliability of the measure. Specifically, the interclass correlation coefficient (ICC) measure reliability statistic was calculated by excluding providers with less than 400 cases, and using three-years of data. The appellant notes that the measure specifications doesn’t exclude providers with less than 400 cases, nor is it clear in the specifications that the measure score would be calculated using three years of data.
 - E. The measure score suffers from a lack of actionability in ASCs. The appellant notes that the measure doesn’t provide information to drive quality improvement beside the facility’s rate of hospital visits compare to the expected rate. These facilities do not have basic information about the patient affected, the number of ED visits, observations stays, or inpatient admissions, or why a subsequent visit occurred. There is limited actionable data for providers to use to drive quality improvement.
 - F. Very limited ability to make distinctions among facilities: the appellant notes that there is limited discriminatory power in the measure. Specifically, only 0.4 percent of facilities would be identified as underperforming.
 - G. The data collection period is too long: the data collection period is three years which may mean the measure score does not reflect current, or recent, performance.
 - H. Incomplete adaptation to the outpatient setting. The appellant notes that the measure continues to include inappropriate inpatient condition categories (CCs) in the risk-adjustment model and the measure needs to be reviewed more thoroughly before being endorsed for the outpatient settings identified in the measure specifications.

Standing Committee Voting Results for Measure #2539 during Standing Committee In-Person Meeting May 5-6, 2014

Importance to Measure and Report	1a. Evidence: Y-14; N-4; 1b. Performance Gap: H-7; M-11; L-0; I-0; 1c. Impact: H-12; M-6; L-0; I-0
Scientific Acceptability of Measure Properties	2a. Reliability: H-1; M-17; L-0; I-0 2b. Validity: H-0; M-18; L-0; I-0
Feasibility	H-14; M-4; L-0; I-0
Use and Usability	H-1; M-16; L-1; I-0

Appendix A: Measure Evaluation Summary Table for NQF #2539

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

2539 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
Submission Specifications
<p>Description: Rate of risk-standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare fee-for-service (FFS) patients aged 65 years and older.</p> <p>Numerator Statement: The outcome for this measure is all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy. We define a hospital visit as any emergency department (ED) visit, observation stay, or unplanned inpatient admission.</p> <p>Denominator Statement: Colonoscopies performed at hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) for Medicare FFS patients aged 65 years and older.</p> <p>Exclusions: We established the following exclusion criteria after reviewing the literature, examining existing measures, and discussing alternatives with the working group and technical expert panel (TEP) members. The goal was to be as inclusive as possible; we excluded only those high-risk procedures and patient groups for which risk adjustment would not be adequate or for which hospital visits were not typically a quality signal. The exclusions, based on clinical rationales, prevent unfair distortion of performance results.</p> <p>1) Colonoscopies for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 1 month after the procedure. Rationale: We exclude these patients to ensure full data availability for outcome assessment.</p> <p>2) Colonoscopies that occur concurrently with high-risk upper gastrointestinal (GI) endoscopy procedures. Rationale: Patients undergoing concurrent high-risk upper GI endoscopy procedures, such as upper GI endoscopy procedures for the control of bleeding or treatment of esophageal varices, are often unwell and have a higher risk profile than typical colonoscopy patients. Therefore these patients have a disproportionately higher risk for the outcome.</p> <p>3) Colonoscopies for patients with a history of inflammatory bowel disease (IBD). Rationale: We exclude these patients because: -IBD is a chronic condition; patients with IBD undergo colonoscopy for both surveillance due to increased cancer risk and for evaluation of acute symptoms. IBD is likely to be coded as the primary diagnosis prompting the procedure irrespective of whether the patients are undergoing a screening procedure or a diagnostic procedure in the setting of an acute exacerbation of IBD. Therefore, we may not be able to adequately risk adjust for these patients as we cannot identify relatively well versus acutely unwell patients among visits coded as IBD. -Our aim is to capture hospital visits which reflect the quality of care. Admissions for acutely ill IBD patients who are evaluated with an outpatient colonoscopy and are subsequently admitted for medical treatment of an IBD flare do not reflect the quality of the colonoscopy. In our 2010 Medicare 20% FFS Full Development Sample (see Measure Testing Form Section 1.2 and 1.7 for full description of the dataset), more than one third of IBD patients admitted to the hospital with colonoscopy had a discharge diagnosis of IBD, indicating their admission was for medical treatment of their IBD. We therefore excluded this group so that providers who treat a disproportionate number of IBD patients will not be disadvantaged in the measure.</p> <p>4) Colonoscopies for patients with a history of diverticulitis. Rationale: We exclude these patients because: -It is unclear what the health status is of patients coded with a history of diverticulitis, making it difficult to fully risk adjust for patients' health. Colonoscopies performed on patients with a history of diverticulitis are likely to be coded as diverticulitis as the primary diagnosis irrespective of whether the patients are undergoing a screening procedure or a diagnostic procedure (i.e., are acutely unwell with</p>

2539 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

active disease). Furthermore, the codes for diverticulitis and diverticulosis may not be consistently used; patients with diverticulosis may be erroneously coded as diverticulitis. Therefore, we may not be able to adequately risk adjust as we cannot identify relatively well versus acutely unwell patients among visits coded as diverticulitis.

-Admissions for acutely ill patients with a history of diverticulitis who are evaluated with an outpatient colonoscopy and are subsequently admitted for medical treatment of do not reflect the quality of the colonoscopy. In our 2010 Medicare 20% FFS Full Development Sample (see Measure Testing Form Section 1.2 and 1.7 for full description of the dataset) more than one quarter of patients with a history of diverticulitis admitted to the hospital post colonoscopy had a discharge diagnosis of diverticulitis, indicating they were admitted for medical treatment of the condition. These admissions are likely unrelated to the quality of the colonoscopy. We therefore excluded this group so that providers who treat a disproportionate number of diverticulitis patients will not be disadvantaged in the measure.

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: The Centers for Medicare & Medicaid Services (CMS)

STANDING COMMITTEE MEETING [05/05/2014-05/06/2014]**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-14; N-4**; 1b. Performance Gap: **H-7; M-11; L-0; I-0**; 1c. Impact: **H-12; M-6; L-0; I-0**

Rationale:

- The Committee noted that colonoscopy is the most common procedure performed in the outpatient or ASC setting.
- The Committee noted that there is significant variation from 8.3 to 20.1 per 1,000 beneficiaries and agreed there is opportunity for improvement.
- The Committee agreed with the evidence in support of the rationale. They noted that most patients return to the hospital with potentially preventable complications (e.g., abdominal pain, bleeding, perforation, aspiration because of the anesthesia).
 - The developer further stressed there is rationale suggesting that providers in the outpatient setting are unaware of these events, citing a study which suggested that in about 80 percent of readmissions the provider is unaware of any complication. The developer suggested that there are legal limitations around follow-up care by ambulatory surgical centers.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1; M-17; L-0; I-0** 2b. Validity: **H-0; M-18; L-0; I-0**

Rationale:

- The Committee noted, that the interclass correlation coefficient (ICC) provided by the

2539 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

developer (0.335, interpreted as “fair agreement”) was comparable to other outcome measures of quality. The developer noted, that the split sample which was used to conduct reliability testing contained 2-years of data, rather than 3-years (as the measure is specified), as such when extrapolating the data to 3-years the ICC increased to 0.43, interpreted as “moderate agreement”.

- The Committee agreed the systematic face validity testing provided by the developer demonstrated the TEP agreed with overall validity of the measure as specified, concluding the measure could be used to distinguish quality.
- The Committee noted that the model has is able to discriminate between high and low performers, with a C-statistic of 0.67, when the development sample was compared to the validation sample.
- The Committee questioned why polypectomy was included in the risk adjustment model. The developers explained that polypectomy was included in the model because while polypectomy is a risk factor for GI bleeding, removal is discretionary the developers did not want to penalize providers who excised polyps during colonoscopy.
 - Committee members warned that was possible then that the polypectomy could cause the readmission and that the model might adjust that away. The Committee further recommended that this measure should be compared to another measure of polypectomy rates or adenoma detection rates.
- The Committee questioned the 7-day time window and asked the developer to provide insight as to why they chose that time period. The developer explained that while there is a range of side effects that could occur after a colonoscopy, the literature suggests that a majority of complications or adverse events occur within 7 days. The developers empirically tested this looking at the number of hospital visit per each day post procedure, and noticed the number of visits levels off to after about 7 days.
- The Committee questioned whether there was any other measure in use that would be able to externally validate this quality measure (i.e., looking at volume or detection of abnormalities). The developer noted that finding other measures to validate against was difficult as there are not many outcome measures for ASC.
- Some Committee Members noted similar issues with Measure 2496: Standardized Readmission Ratio (SRR) for dialysis facilities, where the skill of the provider is not easily distinguished from the facility, while other Committee members noted the measure was well specified and precise in determining a linkage between the physician doing the colonoscopy, the procedure, and the outcome.
 - The developer explained that the reason the measure is specified at the facility level is because the measure is dependent on the number of cases in order to get a reliable estimate, but also that there is a component of facility care that the developers think contributes to the outcome such as anesthesia care, post-op care, and discharge.

3. Feasibility: H-14; M-4; L-0; I-0

2539 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy <i>(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified 3d. Data collection strategy can be implemented)</i> <u>Rationale:</u> <ul style="list-style-type: none"> All data elements are in defined fields in electronic claims and that these data are routinely collected as part of the billing process.
4. Use and Usability: H-1; M-16; L-1; I-0 <i>(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)</i> <u>Rationale:</u> <ul style="list-style-type: none"> The Committee noted that the measure developers acknowledge that there are many situations where a component of primary care or first contact care can happen someplace besides a primary care clinician's practice, such as an ED, and cautioned against potential unintended consequences of using this measure as a metric for ED visits. The Committee warned against potential misattribution of risk if the ASC is one where a single provider in a small group is driving poor outcomes; there is a potential for the ASC to become an outlier. The developers noted that CMS is considering use of this measure in public reporting in the Hospital Outpatient Quality Reporting Program and/or Ambulatory Surgery Center Quality Reporting Program. During workgroup discussion of this measure the Committee cautioned that overlap of this measure within two programs could cause "double jeopardy."
5. Related and Competing Measures <ul style="list-style-type: none"> No related or competing measures noted.
Standing Committee Recommendation for Endorsement: Y-17; N-1
6. Member and Public Comment <ul style="list-style-type: none"> NQF received four comments on Measure 2539. Commenters were supportive of the increased focus on the quality of colonoscopy and the development of this measure concept. Concern was raised that the planned readmission exclusions and risk adjustment variables included in this measure are not sufficient for the clinical condition and may result in reluctance of endoscopists to scope patients with significant comorbidities. One commenter argued that the intraclass correlation coefficient of 0.355 suggested a low level of reliability.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-13; N-1
8. Board of Directors Vote: Ratified; December 22, 2014
9. Appeals

Appendix B: Comments Received on NQF #2539

Submitted by Dr. Allison L. Jones, MD	Help me understand this. A patient has a screening colonoscopy planned. The physician tells the patient that there is a risk of death, perforation, bleeding, etc. The procedure is performed skillfully, and because of biologic variability the patient winds up with post-polypectomy syndrome, which is a common recognized complication for this procedure, which the patient has accepted. Look at the possible downside of this measure. Lesions which are difficult to remove, or are in tough anatomical positions, will the proceduralist given this measure, remove the lesion or not?? I think a wiser position on this would be to make sure that the patient is appropriately advised of the possible risks.
GI Endoscopy Physician Experts BJC Clinical Expert Council, BJC Healthcare; Submitted by Dr. Bruce L. Hall, MD, MBA, PhD	<p>The nominated endoscopic clinical experts of the BJC Healthcare System have read and reviewed this proposed metric with interest.</p> <p>We believe strongly in the need to measure the quality of colonoscopy, and applaud the efforts of the NQF to develop new metrics which will serve this purpose. However, we have several brief concerns regarding this metric and offer the following comments:</p> <p>Reasons for unplanned admission that are not related to the colonoscopy procedure are included, which could have the unintended consequence of increasing the reluctance of endoscopists to scope patients with significant co-morbidities.</p> <p>While certain conditions such as IBD are considered “high risk”, and are excluded from the denominator of this metric, there are other clinical indications for colonoscopy such as diarrhea that might also be associated with higher risk for admission unrelated to the endoscopist or facility treatment. One potential short-term step would be to start by collecting this data in the context of “screening” or “surveillance” exams only.</p> <p>To prevent postpolypectomy bleeding and unplanned visits, we worry that some endoscopists might start placing clips on every patient, thus significantly increasing the cost of the procedure and adding an unnecessary medical intervention.</p> <p>On behalf of BJC Healthcare, we thank you for the opportunity to offer our brief comments and look forward to seeing the final metric.</p>
AHIP; Submitted by Ms. Lauren M. McKown	We recommend that the developer further examine measure exclusions, as patients who have had multiple biopsies are included in this measure despite their higher risk of perforation than excluded conditions such as inflammatory bowel disease (IBD) and diverticulitis. Further, we recommend that patients with conditions such as IBD and

	diverticulitis be included in this measure and that appropriate risk adjustment be applied. Additionally, given the extremely low rates of 7-day post colonoscopy hospital visit rate, this measure may not be usable due to small numbers.
Donna Slosburg, ASC Quality Collaboration; Submitted by Dr. Kim Wood	<p>Part 1 of 2</p> <p>We are pleased by the improvements that have been made to this measure since it was submitted to the MAP in December 2013, and appreciate this opportunity to briefly summarize our current concerns.</p> <p>It appears that colonoscopies for Medicare patients who do not have continuous enrollment in Medicare FFS Parts A and B in the 1-year period prior to the procedure are effectively excluded by the risk adjustment criteria. It is not clear why the measure no longer excludes this population from the denominator, as it did when presented to the MAP in 2013.</p> <p>Certain CCs are not included in risk adjustment if they are only recorded at the time of the colonoscopy, as they are considered to be possible adverse outcomes. The list of CCs does not appear to have been fully adapted for an outpatient episode of care. For example, ESRD would not be a complication of colonoscopy diagnosed and recorded at the time of the procedure.</p> <p>Validity testing relies in part on work the developer did in the past using inpatient claims. Given the different claims structures for inpatient versus outpatient claims, the inpatient results should not be assumed to apply to the outpatient setting. Further, HOPDs and ASCs do not use the same claim format, and the impact of these differences must be systematically assessed to assure the measure results are attributable to differences in quality rather than differences in claims and coding practices. The measure score should be directly validated against outpatient medical records.</p> <p>We are struck by the low reliability results for this measure despite testing having been limited to facilities with relatively high volume. Even so, the ICC was, on average, 0.335, which according to conventional interpretation is “fair”. The developer has since recalculated the results using the Spearman-Brown prophecy formula, resulting in a higher score of 0.43. After reviewing the available literature, we believe this is a non-standard application of the Spearman-Brown formula, which is typically used when test items (as opposed to the test sample) are split. Further, we believe the reliability for a measure intended for public reporting and accountability purposes should be significantly higher.</p>

	<p>The feasibility of this measure is significantly impacted by Medicare billing policies affecting HOPD claims. Specifically, as a result of the three-day payment window policy, separate claims for many HOPD services that result in near-term complications requiring hospitalization are not generated. Attempting to work around this, the measure uses physician claims for colonoscopy indicating an HOPD place of service (POS) that had an inpatient admission within 3 days and lack a corresponding HOPD claim. However, HHS OIG audits regarding physician POS coding consistently demonstrate high error rates, which would adversely impact the integrity of the data. See, as one example of many, report A-01-10-00516 of September 2011. (cont)</p>
<p>Donna Slosburg, ASC Quality Collaboration; Submitted by Dr. Kim Wood</p>	<p>Part 2 of 2</p> <p>In addition, it is not clear what methods would be used to identify ED visits and observation stays following HOPD services. If the measure scores are to be compared across settings, complete data is needed. Given the impact of Medicare billing policy, this cannot be assumed and should be tested.</p> <p>The outcomes measured are uncommon, and as a result the measure has been specified in ways that generate large case volumes, but that diminish its usefulness. Specifically, the need for volume prevents stratification, requires the use of long data collection periods (2-3 years), has resulted in the inclusion of physician claims in the denominator of what is characterized as a facility-level measure, and has also resulted in the inclusion of low volume facilities although their measure score would be unreliable despite the collection of multiple years of data. In addition, it is not clear what steps have been taken to ensure the professional and facility claims included in the denominator are not duplicative.</p> <p>As noted above, the measure result is not stratified and would be reported as a single rate for each facility. This presents challenges for actionability given the range of outcomes being measured. Even if a facility-specific report were generated, as is done for inpatient readmissions, ASCs would have to obtain the patient's consent to request medical records from other providers in order to understand and use the results of the measure.</p> <p>In addition to significant lag time from the generation of claims to the reporting of results, the measure's extended data collection timeframe means that past performance continues to impact the measure score for each facility for a long time. The measure score would not be a reflection of current, or even recent, performance. In fact, the score could obscure either significant improvement or significant deterioration in recent performance. As a result, consumers could be</p>

	<p>misled by the lack of timely data.</p> <p>While administrative claims do not impose additional data collection or submission burdens on providers, they are blunt instruments for assessing quality. Using the standard 95 percent interval estimate to report the measure score, the developers indicate 99.5% of facilities would be classified as no different than expected, 0.4% of facilities as worse than expected, and 0.1% of facilities as better than expected. Thus it would be uncommon for a consumer to be able to discriminate among facilities using the results of the measure. In addition, the number of facilities that could use the data to improve their results to “as expected” would be miniscule. While the developers state there is variability in performance, as a practical matter the risk standardized results indicate little room for improvement.</p> <p>Thank you for this opportunity to share our concerns regarding this measure’s shortcomings with respect to endorsement criteria.</p>
Submitted by Dr. Thomas James, III, MD	<p>We support this measure but would ask the developer to reconsider the exclusions. If IBD and diverticulosis are indications for exclusion then so should patients who have had multiple biopsies as they also have higher risk of perforation. Preferred would to have a better risk adjuster and include these conditions.</p>

MEMORANDUM

TO: National Quality Forum (NQF) Admissions and Readmissions Standing Committee
FROM: Elizabeth Drye, MD, Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE)
THROUGH: The Centers for Medicare and Medicaid Services (CMS)
Lein Han, PhD, and Vinitha Meyyur, PhD
DATE: Thursday, February 5, 2015
SUBJECT: Response to ASC QC letter appealing NQF approval of NQF# 2539: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; Submitted January 29, 2015

1. Introduction to Response

The Ambulatory Surgical Center Quality Collaboration (ASC QC) raises a number of objections to the colonoscopy measure in its appeal letter, summarized below. The Centers for Medicare & Medicaid Services (CMS) and the measure developer, Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE), have previously addressed the major points raised during the National Quality Forum’s (NQF’s) review. In addition, CMS addressed these issues in detail in the rulemaking process that incorporated the measure into the Hospital Outpatient Quality Reporting (HOQR) and Ambulatory Surgery Center Quality Reporting (ASCQR) programs for first use in calendar year 2018. We briefly address the main points here for ease of review and attach the rule language for reference (79 FR 66948-66956 [HOQR], 66970-66985 [ASCQR]).

An overarching assertion in the ASC QC’s letter is that we have not completed the testing necessary for NQF approval. We disagree; the testing and results fulfill NQF criteria as previously determined during the NQF review process. As finalized in rulemaking, CMS will conduct a national “dry run” of the measure (confidential reporting to all facilities) in 2015 (79 FR 66975). The dry run is an opportunity for facilities to learn about the measure and for CMS to test the measure nationally. CMS is committed to informing the public and NQF about the results of the dry run, including further examination of several of the issues raised by the ASC QC, as indicated below. However, CORE and CMS disagree with the ASC QC that NQF approval should be withheld pending the dry run’s completion.

Finally, although CMS’s policy plans for the measure are not directly relevant to NQF review criteria, we wanted to share that, per the recent final rule, CMS will first use the measure in its outpatient quality reporting programs in calendar year 2018 (79 FR 66979). Hence, CMS will have ample time to make any technical revisions to the measure that might be needed prior to its use in reporting or accountability programs, and to submit any substantial changes to NQF for further review.

2. Specific ASC QC Points and Responses

A. Lack of validity testing in the settings of care measured

The ASC QC letter:

1. Argues CMS inappropriately cites as evidence of data element validity a chart validation study of claims-based hospital quality measures. Notes:
 - a. Ambulatory Surgery Center (ASC) coding does not require diagnosis codes not explicitly linked to service, and
 - b. ASCs use CMS-1500 and hospital outpatient departments (HOPDs) use UB-04 claims.
2. Says the ASC QC sees, “no indication that CMS plans any kind of field-testing at all; rather, the agency is proposing to move directly to implementation.”
3. Argues that given differences in claims CMS should not compare HOPDs and ASCs.

Response:

We believe the claims data the measure uses is valid for both ASCs and HOPDs in spite of the differences in the claims. We understand that ASCs only need to code diagnoses relevant to the colonoscopy on ASC claims. However, for both types of measures, we gather patient comorbidities from multiple care settings, linking inpatient and outpatient claims preceding the index event (i.e., the admission or colonoscopy visit). The colonoscopy measure also adjusts for procedural factors, which are present on ASC and HOPD claims. Thus, we do not expect differences in the claims to lead to differences in the comorbidities assessed for the patients in the two different settings. As noted above, CMS will conduct a dry run well in advance of the measure’s use.

The measure NQF application does cite as evidence of data validity a chart validation study showing that models developed using claims data profiled hospitals similarly to models developed using chart data. We cited this study even though hospital inpatient, hospital outpatient, and ASC claims vary because for both the hospital inpatient measures and the colonoscopy measure we gather diagnoses from a year prior to the index event across inpatient and outpatient settings as well as from the hospital/ASC claims. We therefore believe the findings contribute to the evidence for data validity for the colonoscopy measure.

B. Not valid in HOPDs given 3-day payment window

The ASC QC letter:

1. Asserts that the measure will undercount HOPD colonoscopies/outcomes.
2. States that prior Office of Inspector General (OIG) audit reports show physician point of service claims have a history of inaccuracy.
3. States, therefore, that HOPDs and ASCs should not be compared.

Response:

Our testing with 2010 data suggested the use of physician claims will accurately identify outpatient colonoscopy claims affected by the 3-day window payment policy. We are aware of the findings of the Office of Inspector General (OIG) reports. As stated in the final rule (79 FR 66976), CMS has “taken steps to educate physicians about the appropriate POS coding and actively audit physicians to improve the accuracy of POS coding <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7502.pdf>. In addition, from 2012 onwards, Medicare billing introduced the “PD” modifier to indicate physician claims affected by the 3-day window payment policy.” The PD modifier should further ensure our ability to identify outpatient claims for subsequently admitted patients.

Although CMS has confidence in its current approach, CMS will further evaluate the adequacy of the approach to identifying HOPD claims during the dry run, including evaluating whether the PD modifier enhances the identification of HOPD claims. CMS will share the results with stakeholders and NQF.

C. Measure rationale (performance gap) is not valid given 3-day payment policy changed mid-2010

The ASC QC letter:

1. Argues that the variation in measure scores that we demonstrated in the NQF application using 2010 data is due to this change in policy mid-2010.

Response:

We disagree that the policy transition would have created a spurious appearance of variation since all providers were undergoing the same transition. We believe the data we submitted to NQF clearly demonstrates variation consistent with NQF criteria. The national dry run data, however, will allow us to assess variation in more contemporary and complete data. We will plan to share the variation seen nationally with NQF as part of the measure’s NQF Annual Update.

D. Measure reliability is not adequate

The ASC QC letter:

1. States that we include all providers (HOPDs, ASCs, physician offices) to increase volume to address reliability.
2. Argues the intraclass correlation coefficient (ICC) calculated using Spearman-Brown prophecy formula (0.43) is still too low and that the reliability of a measure used for accountability should be “substantial” (0.61-0.80).
3. Says “measure cannot be implemented without addressing either the need to exclude low volume facilities or need to include multiple years of data... [yet] CMS is planning to use a one-year period.”

Response:

The (ICC) calculated with our test data shows the measure has acceptable reliability. An ICC of 0.43 is within the range of other NQF-approved outcome measures and other measures used in CMS’s public reporting programs. Further, the score reliability is likely to be higher in the national dataset CMS will use for the dry run and subsequent public reporting. CMS will further evaluate reliability during the national dry run.

We would like to clarify that the measure combines provider types for reasons completely unrelated to reliability. We include colonoscopies conducted in physician offices in fitting the patient-level risk model so that the reference group for calculating the relationship between risk factors and the outcome is derived from all providers in all settings (not to enhance volume). This approach ensures ASCs are evaluated relative to all providers, not just relative to other ASCs or HOPDs. Further, there is adequate volume to calculate the measure score regardless of whether one combines HOPDs and ASCs or calculates the scores for these types of facilities separately.

E. The measure score suffers a “lack of actionability” in ASCs

The ASC QC letter:

1. States that “the measure developer has not built usability into the measure, but is relying on those who implement the measure to come up with some means to provide actionable data.”
2. States ASCs cannot follow up with patients to do root cause analysis, and since data will have one-year lag, ASCs will not likely get information from patients to support quality improvement.
3. Asserts that hospitals’ most effective strategy for reducing readmissions has been interviewing admitted patients while they are in the hospital to identify quality problems and points out ASCs cannot use this approach.
4. Implies ASCs have very limited responsibility for post-discharge events. States that an ASC is a “unique supplier type that serves *solely* as the site for outpatient surgery and is involved with the care of the patient only immediately before, during, and immediately after the surgical procedure.”

Response:

As discussed in the NQF application and the November rule, CORE and CMS see this issue differently than the ASC QC. Publicly reporting an ASC measure score and providing patient-level data to ASCs will greatly facilitate quality improvement for two reasons. First, providers who conduct colonoscopies at ASC QCs (e.g., gastroenterologists and surgeons) have ongoing responsibility for their patients. These providers performing the procedure can only improve their care if they are fully aware of patient outcomes. As discussed in our application and the rule, physicians are often unaware that their patients seek acute care post colonoscopy. That is why our expert panel and the public supported increasing their awareness and accountability through this measure. Second, each facility's care also affects patients' outcomes. For example, anesthesia and post-op care may affect the need for acute care due to nausea, pain, or urinary retention. Hence, ASC facilities share accountability for the outcomes notwithstanding that they do not provide the follow-up care. Finally, the measure focuses only on short-term, post-procedure, acute care visits (those within 7 days), and does not count planned admissions; as such, ASC accountability for patient outcomes is appropriately limited. We are therefore confident that reporting the facility-level measure score, accompanied by detailed patient-level confidential data, will provide incentives for, and information to support further quality improvement for colonoscopies conducted at ASCs and improve patient outcomes.

F. Very limited ability to make distinctions among facilities

The ASC QC letter:

1. Points out there are few outliers in the data we provided (0.4%, which would be 21 facilities/5300).
2. Suggests the measure is "topped out" with little room for improvement.

Response:

The facility-level variation analysis we presented in the application was limited, as noted in the application, because we could not conduct it with a full national data set that included all cases for all facilities. Nevertheless, the variation presented in the application is meaningful and adequate, and the patient-level data CMS will provide with the measure score will greatly facilitate quality improvement. CMS will provide further data on variation when it reports the results of the national dry run later this year.

H. Incomplete adaptation to the outpatient setting

The ASC QC letter:

1. Asserts we applied inpatient measurement strategies to the outpatient setting and says the measure should not rely on "post-endorsement fixes" given that "pre-endorsement fixes" were needed.
2. Asserts that since ASC QC identified flaws in the measure specifications during a measure comment period (i.e., ESRD was listed as a potential complication of the procedure), the measure should not be approved. ASC QC asserts there are other conditions like ESRD that "have not been addressed."

Response:

We would like to clarify that from the outset that CMS and CORE assumed that the methods and claims processing used to design risk-adjusted outcome measures for hospitals were not likely to apply directly to outpatient settings. Rather, we undertook each aspect of measure development – the definition of the cohort and cohort exclusions, the definition of the outcome, development of the risk model, selection of risk-model variables, and reliability and validity testing – specifically considering the unique circumstances of the outpatient context. We engaged an expert panel and held a public comment period to ensure we had a full understanding of the potential challenges with the measure that are unique to the outpatient setting. These undertakings provided helpful feedback and identified issues we needed to further address. We view the identification of improvements needed to the specifications during development and NQF review as beneficial and not at all as a sign of the failure of the measure development and testing process. As discussed in the rule, the documentation error the ASC QC identified during NQF review has been corrected (79 FR 66976). Stakeholder engagement in this case has worked to strengthen the measure and to improve the documentation. We can confirm that all issues raised by the ASC QC previously have been carefully addressed with full transparency. CMS and CORE deeply appreciate the constructive input of the ASC QC to date, but respectfully disagree with its conclusion that the measure is not worthy of NQF approval at this juncture.



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42 CFR Parts 411, 412, 416, et al.

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data; Final Rule

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are adding one claims-based quality measure for the CY 2018 payment determination and subsequent years instead of the CY 2017 payment determination and subsequent years as proposed. However, prior to publicly reporting this measure, we plan to conduct a dry run (a preliminary analysis) for hospitals to review their performance and provide feedback using the most recently available data. There will be no payment impact during this dry-run period, and the results of the dry run will not be publicly reported. We are refining the criteria for determining “topped-out” measures, and we are removing the OP-6 and OP-7 measures due to “topped-out” status. In addition, we are updating several previously adopted measures. We are clarifying data submission requirements for OP-27 and are noting a delayed data collection for OP-29 and OP-30. We are excluding one previously adopted measure (OP-31) from the measure set for the CY 2016 payment determination and changing this measure from required to voluntary for the CY 2017 payment determination and subsequent years. We will not subject hospitals to payment reductions with respect to the OP-31 measure for the CY 2016 payment determination or during the period of voluntary reporting. In addition, we are formalizing a review and corrections period for chart-abstracted measures. We also are updating validation procedures and changes to regulation text to correct typographical errors. We are changing the eligibility criteria for validation; a hospital will only be eligible for random selection for validation if it submits at least 12 cases to the Hospital OQR Program Clinical Data Warehouse during the quarter with the most recently available data. Hospitals also will have the option to submit validation data using electronic methods and must identify the medical record staff responsible for submission of records to the designated CMS contractor. Finally, we are clarifying how we refer to the extraordinary circumstances extensions or exemptions process.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are adopting one new quality measure (ASC-12) for the CY 2018 payment determination and subsequent years. This measure will be computed using paid Medicare fee-for-service (FFS) claims data and will not impose any additional burden on ASCs. We also are excluding one measure

(ASC-11) previously adopted for the CY 2016 payment determination and providing that this measure may be voluntarily rather than mandatorily reported for the CY 2017 payment determination and subsequent years. We will not subject ASCs to payment reductions with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting. In addition, we are establishing a measure removal process and criteria, defining data collection timeframes and submission deadlines, and clarifying how we refer to the extraordinary circumstances extensions or exemptions process.

3. Summary of Costs and Benefits

In sections XXI. and XXII. of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the OPPS Update

(1) Impacts of All OPPS Changes

Table 49 in section XXI. of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2015 compared to all estimated OPPS payments in CY 2014. We estimate that the policies in this final rule with comment period will result in a 2.3 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2015, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children’s hospitals, cancer hospitals, and CMHCs) will be approximately \$56.1 billion, an increase of approximately \$5.1 billion compared to CY 2014 payments, or \$900 million, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 1.3 percent increase in CY 2015 payments to CMHCs relative to their CY 2014 payments.

(2) Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes and application of the frontier State wage index, including

changes resulting from the adoption of the new OMB labor market area delineations and the transitional 1-year, 50/50 blended wage index, will mitigate any negative changes due to the new CBSA delineations.

(3) Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2015 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural and cancer hospital payment adjustments, and the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(4) Impacts of the OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the OPD fee schedule increase factor of 2.2 percent to the conversion factor for CY 2015 will mitigate the small negative impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban and rural hospitals will experience increases of approximately 2.3 percent for urban hospitals and 1.9 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2015 payment rates compared to estimated CY 2014 payment rates ranges between – 4.0 percent for ancillary items and services and 14 percent for hematologic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2015 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our CY 2015 proposed policies to significantly affect the number of ASCs that do not receive a full annual payment update.

where hospitals do not submit information to the Hospital OQR Program due to lack of cases or low case volume. Where quality information is submitted, we make this information publicly available as statutorily required, and we state when it is not available. Furthermore, reporting of measure data by some hospitals and not others under voluntary reporting would not affect the validity of data reported for this Web-based measure any more so than a required measure where not all hospitals had cases. We note that at this time, we do not validate aggregate data submitted to CMS using an online tool, so difficulty to validate this information is not a program issue. We refer readers to section XIII.H.3 of this final rule with comment period where we discuss our validation procedures.

We understand some facilities are capable of reporting data for this measure at this time, and we believe those facilities should report if they are operationally able to do so. We believe voluntary reporting is beneficial for HOPDs because all HOPDs, both participating and not participating in voluntary reporting, can use the reported data to gauge their own performance and identify improvement efforts. By retaining the measure but allowing voluntary reporting, we can continue to monitor the data submitted to assess further enhancement of the measure as necessary.

Comment: Commenters expressed support for patient-reported outcome measures like OP-31 and recommended additional outcome measures for cataract procedures, such as Complications within 30 Days Following Cataract Surgery Requiring Additional Procedures (NQF #0564) and Better Visual Acuity Within 90 Days Following Cataract Surgery (NQF #0565).

Response: We thank the commenters for the support and their input regarding patient-reported outcome measures. We may consider these suggestions for future measure selection.

Comment: One commenter suggested that CMS allow voluntary reporting for all newly adopted measures, given the inconvenience and burden associated with preparing to report a measure that later may become suspended or for which we delay implementation.

Response: We thank the commenter for the suggestion. We understand that hospitals may have been inconvenienced by this measure, but disagree that all newly adopted measures should be voluntarily reported. We have retained the vast majority of measures adopted for the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing our proposal that hospitals have the option to voluntarily collect and submit OP-31 data for the CY 2015 encounter period/CY 2017 payment determination and subsequent years as proposed. For hospitals that choose to submit data, we request that they submit such data using the means and timelines finalized in the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75113 through 75115). We will not subject hospitals to a payment reduction with respect to this measure during the period of voluntary reporting. However, data submitted voluntarily will be publicly reported.

E. New Quality Measure for the CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPTS/ASC proposed rule (79 FR 41036 through 41039), we proposed to adopt one new claims-based measure into the Hospital OQR Program for the CY 2017 payment determination and subsequent years: OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Colonoscopy is one of the most frequently performed procedures in the outpatient setting in the United States.² The most recent data available indicate that, in 2002 alone, physicians performed an estimated 14 million colonoscopies in the United States.³ Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and cardiopulmonary events such as hypoxia, aspiration pneumonia, and cardiac arrhythmias. While hospital visits are generally unexpected after outpatient colonoscopy, the literature suggests that the majority of these visits occur within the first 7 days.^{4,5,6}

² Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*. Rockville (MD) 2006.

³ Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology*. Dec 2004; 127(6):1670–1677.

⁴ Rathgeber SW., Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. *Gastrointest Endosc*. 2006; 64:556–62.

⁵ Rabeneck L, Saskin R, Paszat LF. Onset and clinical course of bleeding and perforation after outpatient colonoscopy: A population-based study. *Gastrointest Endosc*. 2011; 73:520–3.

⁶ Ko CW, Riffle S, Michael L, et al. Serious complications within 30 days of screening and

Reported hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent at 7 to 14 days post procedure, and from 2.4 to 3.8 percent at 30 days post procedure.^{7,8,9} Some adverse events such as bleeding occur after the 7th day, but based on input from clinical experts, public comment, and empirical analyses, we concluded that unplanned hospital visits within 7 days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure. This measure provides the opportunity for providers to improve quality of care and to lower the rates of adverse events leading to hospital visits after outpatient colonoscopy; this measure will encourage providers to achieve the outcome rates of the best performers.

We believe it is important to reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care. Therefore, we proposed to include OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, which is based on paid Medicare FFS claims, in the Hospital OQR Program for the CY 2017 payment determination and subsequent years. We expect that the measure would promote improvement in patient care over time because transparency in publicly reporting measure scores will make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to providers and patients and encourage providers to incorporate quality improvement activities in order to reduce these visits. Providers are often unaware of complications following colonoscopy for which patients visit the hospital.¹⁰ This risk-standardized quality measure will address this information gap and

surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol*. 2010; 8:166–73.

⁷ Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc*. Apr 2007; 65(4):648–656.

⁸ Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med*. Oct 25 2010; 170(19):1752–1757.

⁹ Chukmaitov AS, Menachemi N, Brown SL, Saunders C, Tang A, Brooks R. Is there a relationship between physician and facility volumes of ambulatory procedures and patient outcomes? *J Ambul Care Manage*. Oct–Dec 2008; 31(4):354–369.

¹⁰ Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med*. Oct 25 2010; 170(19):1752–1757.

promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy.

The outcome measured in the OP-32 measure is all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility-level risk-standardized hospital visit rate, is derived from the calculation of the ratio of the numerator to the denominator multiplied by the crude rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits within 7 days of colonoscopy that the facility is predicted to have based on its case-mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with the facility's case-mix. The crude rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.

Based on discussions with clinical and technical panel experts, the measure excludes colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy because these patients are at a higher risk for hospital visits than patients undergoing a typical colonoscopy, and patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 1 month after the procedure to ensure all patients have complete data available for outcome assessment. The statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following colonoscopy. Additional methodology details and information obtained from public comments for measure development are available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html> under "Hospital Outpatient Colonoscopy."

Section 1890A(a)(2) of the Act outlines the pre-rulemaking process

established under section 1890A of the Act, which requires the Secretary to make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering. This measure was included on a publicly available document titled "MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs" on the NQF Web site at: http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx (formerly referred to as the "List of Measures Under Consideration") in compliance with section 1890A(a)(2) of the Act. (We note that at the time the measure was listed on the "MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs," it was named "High-Acuity Care Visits after Outpatient Colonoscopy Procedure.")

The MAP, which represents stakeholder groups, conditionally supported the measure, "noting the need to provide outcome information to inform consumer decisions and drive quality improvement." The MAP further stated that "[t]his measure addresses an important quality and safety issue with incidence of these events ranging from 10 to 22 per 1,000 after risk adjustment." However, the MAP also "recognized the need for the measure to be further developed and gain NQF endorsement. The MAP expects the endorsement process to resolve questions of the reliability and validity of the measure as well as with the accuracy of the algorithm for attributing claims data in light of possible effects of the Medicare 3-day payment window policy." As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program.

We believe we have addressed the concerns raised by the MAP to the extent possible. The measure is well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability. Reliability testing demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify

differences in quality. In order to ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of HOPD colonoscopies potentially affected by the policy, we identified physician claims for colonoscopy in the HOPD setting from the Medicare Part B Standard Analytical Files (SAF) with an inpatient admission within 3 days and lacking a corresponding HOPD facility claim. We then attribute the colonoscopies identified as affected by this policy to the appropriate HOPD facility using the facility provider ID from the inpatient claim.

Section 1833(t)(17)(C)(i) of the Act states that, "The Secretary shall develop measures . . . that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities." We believe that this proposed measure reflects consensus among the affected parties, because the MAP, which represents stakeholder groups, reviewed, conditionally supported the measure, and stated that it "would provide valuable outcome information to inform consumer decision and drive quality improvement." Further, the measure was subject to public comment during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (MAP Report, January 2014, p. 184 http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx). We also note that the measure was submitted to NQF for endorsement on February 21, 2014.

Currently, there are no publicly available quality of care reports for providers or facilities that conduct outpatient colonoscopies. Thus, adoption of this measure provides an opportunity to enhance the information available to patients choosing among providers who offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to providers and patients all unplanned hospital visits following the procedure. Further, providing outcome rates to providers will make visible to clinicians meaningful quality differences and encourage improvement. Although this measure is not NQF-endorsed, it is currently undergoing the endorsement process, as noted above. Therefore, we believe the

statutory requirement for included measures to have, to the extent feasible and practicable, been set forth by a national consensus-building entity has been met.

We invited public comment on the proposal to include OP-32 in the Hospital OQR Program for the CY 2017 payment determination and subsequent years.

Comment: Several commenters supported the adoption of OP-32, stating that it will provide patients with important information about the quality of colonoscopy care furnished in outpatient settings. Some commenters noted that CMS has appropriately considered the MAP's input in adopting this measure and that the measure's adoption is a good first step in the continued evolution of the Hospital OQR Program.

Response: We thank commenters for their support and acknowledgement that the measure is appropriate for the Hospital OQR Program. We agree that measuring quality of care associated with colonoscopy procedures is an important clinical care area to assess for HOPDs.

Comment: Many commenters urged CMS not to adopt OP-32 until it is NQF-endorsed. Several of these commenters also noted that the MAP supported this measure on condition of NQF-endorsement, and stated that the NQF process would resolve a number of questions about the reliability, validity and feasibility of this measure. The commenters requested that, in general, CMS only include measures in the Hospital OQR Program that have been NQF-endorsed in order to avoid subsequent suspension or removal of these measures.

Response: We note that not all of the measures adopted by the Hospital OQR Program are NQF-endorsed, and as we stated in our earlier discussion in this final rule with comment period, NQF endorsement is not a program requirement, as consensus among affected parties can be reached through means other than NQF endorsement. Under section 1833(t)(17)(C)(i) of the Act, the Secretary must develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by one or more national consensus building entities.

Whenever possible, we strive to adopt NQF-endorsed measures because these measures will meet these requirements. However, we believe the requirements that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad

acceptance and use of the measure, and through public comments. Further, it may not be feasible or practicable to adopt an NQF-endorsed measure, such as when an NQF-endorsed measure does not exist. Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the OQR Program be endorsed by a national consensus building entity, or by the NQF specifically. As discussed below, we believe the measure as developed exhibits sufficient levels of reliability, validity, and feasibility to be adopted for the Hospital OQR Program. We have also submitted this measure to the NQF for endorsement.

Comment: A few commenters noted that the measure is currently being reviewed by the NQF All-Cause Admissions and Readmissions Standing Committee. Commenters were disappointed that the Committee's minutes indicated there were no discussions of consideration of key elements of the measure's construction and testing.

Response: We thank the commenters for sharing their concerns. We believe the NQF process is rigorous and transparent. We understand the NQF All-Cause Admissions and Readmissions Standing Committee applies the four NQF criteria for measure endorsement¹¹ and votes on each criterion. In addition, our understanding is that the measure was discussed in detail by NQF working groups prior to the measure discussion at the All-Cause Admissions and Readmissions Standing Committee (<http://www.qualityforum.org/ProjectMaterials.aspx?projectID=73619>).

NQF also seeks public comments on measures before endorsement. http://www.qualityforum.org/comments_ByProject.aspx?projectID=110&ActivityID=762#p=3. (This link requires users to log in to the NQF Web site.) For questions related to NQF internal procedures, we suggest contacting the NQF directly at http://www.qualityforum.org/About_NQF/Contact_NQF.aspx.

Comment: Many commenters did not support CMS' proposal to finalize OP-32, stating that complications from colonoscopies are rare and hospitals already take steps to ensure colonoscopies are conducted in such a way so as to eliminate preventable complications. Some commenters specifically noted that the literature indicates the measured incidence rate is less than 2 percent, and does not rise to the level of importance needed for a national quality measurement program.

¹¹ Available at: http://www.qualityforum.org/docs/measurement_evaluation_criteria.aspx.

Response: Given the widespread use of colonoscopy for colorectal cancer screening in the outpatient setting, we consider measuring the quality of this high volume procedure to be a priority. We agree that the incidence of colonoscopy complications is relatively low. However, serious adverse events, such as perforation of the bowel and bleeding, may occur following colonoscopies. We view OP-32 as a critical outcome measure for which the goal is to drive toward and sustain zero harm. In addition, some literature suggests that many facilities performing colonoscopies are unaware of patients accessing hospital-based care with adverse events because patients return to different facilities, including other hospitals and emergency departments, and would not return to the same outpatient facility. For example, one study showed that physicians were unaware of nearly 75 percent of hospital admissions for adverse events following colonoscopy.¹² While most colonoscopies are performed without subsequent complication, we note that, among Medicare patients aged 65 and older, 1.6 percent of outpatient colonoscopies resulted in an unplanned hospital visit within 7 days.¹³ This is based on a 20-percent sample of nationwide Medicare FFS patients. If we were to use full national data (that is, a 100 percent sample), we estimate 1.7 million colonoscopies would have been performed among Medicare FFS patients and nearly 27,000 unplanned hospital visits would have occurred within 7 days of colonoscopy. These findings suggest that adverse events are not as rare or inconsequential as many believed and that quality measurement for colonoscopy procedures in the hospital outpatient setting is important.

Comment: Many commenters expressed concern that OP-32 includes hospital visits unrelated to colonoscopy (counted in the numerator). Some commenters questioned why the measure uses an all-cause categorization versus only admissions attributable to colonoscopies. One commenter suggested that all high-risk colonoscopies (such as patients with multiple biopsies, patients with

¹² Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010; 170(19): 1752–1757.

¹³ 2010 Medicare 20 percent fee-for-service sample. Based on an analysis of 20 percent sample of Medicare FFS data from 2010 during measure development. The 20 percent sample included 332,391 outpatient colonoscopies meeting the measure inclusion and exclusion criteria, and 1.6 percent of these colonoscopies were followed by an unplanned hospital visit. This equates to 5,331 unplanned hospital visits in the 20 percent sample.

inflammatory bowel disease, and diverticulitis) should be excluded from the measure. Commenters recommended that OP-32 should be limited to low-risk surveillance and screening colonoscopies as well as nontherapeutic colonoscopies for Medicare patients. One commenter appreciated that OP-32 includes a mechanism for excluding hospital visits for certain “planned” procedures, but encouraged CMS to expand that list to also include bone fractures and behavioral health disorders.

Response: We clarify that this measure is purposely designed to use a broad outcome of hospital visits following surgery rather than a narrow set of easily identifiable complications. From a patient and health care system perspective, the goal of this measure is to encourage and inform provider efforts to minimize all potential acute complications, not just those narrowly related to procedural technique. This is important as the literature^{14 15 16 17 18} suggests that hospital visits following colonoscopy occur due to a range of adverse events relating to the bowel preparation, anesthesia, the colonoscopy procedure itself, and follow-up care. These adverse events include a range of symptoms and signs such as abdominal pain, bloating, dizziness and collapse, electrolyte disturbances, and cardiorespiratory symptoms (from sedation use) in addition to other complications, such as bleeding and bowel perforation, that are directly related to procedural techniques. The broad outcome of unplanned hospital visits captures all of these potential acute complications of colonoscopy.

As to the suggestion of expanding the list to include bone fractures and behavioral health disorders, we note that inpatient admissions for bone fracture and behavioral health disorders (such as depression and anxiety) are typically acute and are not generally considered as “planned” admissions. We do not expect planned admissions

for these conditions within the first 7-days following colonoscopy. Furthermore, we have adapted the planned readmission algorithms developed by CMS independent of OP-32. This algorithm has been validated against medical record (chart-extracted) data to ensure it only removes planned admissions.

Our goal for including the measure is to encourage providers to be mindful of reducing post-colonoscopy admission caused by prior colonoscopy procedures performed at a HOPD. For example, patients may be at higher risk of falls post-colonoscopy secondary to dehydration following the bowel preparation for the procedure, and there may be opportunities for providers to minimize this risk. Furthermore, we removed planned admissions from the measure outcome by adapting CMS’ Planned Readmission Algorithm version 3.0.^{19 20} This algorithm removes nonacute admissions for scheduled procedures (for example, total hip replacement) and other types of care always considered planned (for example, rehabilitation or maintenance chemotherapy) from the outcome because these admissions do not reflect differences in colonoscopy quality of care.

Comment: One commenter noted that CMS stated that the statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables (such as number of polyps removed) that are strongly associated with risk of hospital visits within seven days following colonoscopy and certain patients receiving colonoscopies that would be more likely to have a subsequent visit were excluded. The commenter stated that CMS did not report the variation between hospitals in the application for NQF-endorsement. The commenter raised the possibility of no statistically significant difference between a hospital’s risk-adjusted visit rate and the national average. The commenter believed this scenario would make it impossible to identify poor performers and good performers for this measure. Without this type of differentiation, the commenter did not understand how this measure will be actionable for care improvement. The commenter suggested that CMS conduct a root cause analysis

for specific related readmission after colonoscopy or test of the variation of the measure between hospital providers. The commenter also suggested that The Joint Commission’s guidelines and relevant Conditions of Participation standards would enhance care improvement efforts.

Response: We thank the commenter for their suggestions to enhance improvement efforts for colonoscopy. We clarify that, in the application for NQF endorsement, we noted that the measure, following risk-adjustment, is able to detect statistically significant variation (good and poor performers) between outpatient facilities by demonstrating measure score variation using the 2010 Healthcare Cost and Utilization Project (HCUP) data from four States (California, New York, Nebraska, and Florida). Using a very conservative bootstrapping (sampling with replacement) statistical technique, we constructed 95 percent interval estimates (similar to confidence intervals) around the facility measure score and used the estimates to place facilities into three performance categories: worse than expected; no different than expected; and better than expected. Based on this analysis, we identified 5 outlier facilities among a total of 992 ASCs and HOPDs. This analysis included only about one-tenth of all outpatient facilities in the United States, and typically we see greater variation between facilities when 100 percent of nationwide facilities are included for actual measure implementation and reporting due to increased precision related to greater sample size.

We disagree with the notion that there is a possibility of no statistically significant difference between a hospital’s risk-adjusted visit rate and the national average. Our analysis shows statistically significant facility variation. Some facilities have a hospital visit rate that is higher than the expected national average rate and this is statistically significant. Also, we only tested provider variation using data from 4 States. We expect greater variation and more outliers using nationwide data.

We are committed to filling the performance gaps in colonoscopy performed in the outpatient setting. Therefore, we believe this measure is appropriate for the outpatient setting. However, in response to comments, to allow sufficient time to conduct further analysis of this measure, we are finalizing this measure beginning with the CY 2018 payment determination, rather than the CY 2017 payment determination as proposed. We plan to perform a dry run of the measure in

¹⁴ Day LW, Kwon A, Inadomi JM, et al. Adverse events in older patients undergoing colonoscopy: a systematic review and meta-analysis. 2011; 74:885–96.

¹⁵ Ko CW, Dominitz JA. Complications of colonoscopy: Magnitude and management. *Gastrointest Endosc Clin N Am* 2010;20:659–71.

¹⁶ ASGE Standards of Practice Committee, Fisher DA, Maple JT, et al. Complications of colonoscopy. *Gastrointest Endosc* 2011;74:745–52.

¹⁷ Baudet JS, Diaz-Bethencourt D, Aviles J, et al. Minor adverse events of colonoscopy on ambulatory patients: The impact of moderate sedation. *Eur J Gastroenterol Hepatol* 2009; 21:656–61.

¹⁸ Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. 2007; 65:648–56.

¹⁹ Horwitz L, Grady J, Dorsey K, Zhang W, Keenan M, Keshawar A, Cohen D, Ngo C, Okai M, Nwosu C, Lin Z, Bhat K, Krumholz H, Bernheim S. 2014 Measures Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission—Version 3.0. 2014: Centers for Medicare & Medicaid Services, 2014.

²⁰ Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

2015. From our perspective, a dry run is a preliminary analysis of data in which HOPDs may review their measure results, and ask questions about and become familiar with the measure methodology. Dry runs will include 3 to 4 years of paid Medicare FFS claims. We will use the most recent complete claims samples (usually 6 to 9 months prior to the start date) for dry runs. For example, if the dry run begins in March 2015, the most recent data available may be July 2011 to June 2014 (assuming we use 3 years of data). Because we use paid Medicare FFS claims, HOPDs will not need to submit any additional data for the dry run. General information about dry run as well as confidential reports will be made available for hospitals to review on their accounts at <https://www.qualitynet.org>. The dry run will generate confidential reports at the patient level, indicating whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. Further, the dry run will enable HOPDs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. In addition, we will continue to generate these reports for HOPDs after we implement the measure beginning with the CY 2018 payment determination. HOPDs can use the information to identify performance gaps and develop quality improvement strategies.

Dry run results are not linked to public reporting, payment determinations, or reliability testing. We expect the dry run to take approximately one month to conduct, during which facilities will be provided the confidential report and the opportunity to review their performance and provide feedback to us. The measure will have no payment impact until the CY 2018 payment determination and subsequent years. Public display of data will occur on or after December 1, 2017, but there will be no public display of the dry run data.

We agree that adhering to The Joint Commission's guidelines and relevant Conditions of Participation standards could enhance care improvement efforts and hospitals' rates on this measure, and we encourage hospitals to follow these guidelines and standards. We also believe that issuing reports to hospitals, such as those that we will provide during the dry-run, would help hospitals to identify the root cause (practices and conditions) that could cause hospital visits after colonoscopy.

Comment: Many commenters expressed concern that OP-32 is not sufficiently reliable to be included in the Hospital OQR Program; specifically, the measure developer has indicated that the measure is only "fairly" reliable, with an interclass correlation coefficient (ICC) of 0.335. These commenters contended that "fair" reliability is not sufficient for publicly reported quality metrics since such information could misinform the public, and urged CMS to conduct an analysis on the measure's reliability to understand the amount of data required to achieve "good" reliability. Several commenters argued that "good" reliability should result in an ICC of at least 0.60. Other commenters believed that reliability will improve with several years' worth of data. Another commenter requested that data from this measure be withheld from public reporting until concerns about its reliability and validity can be thoroughly assessed.

Response: We disagree with commenters and believe that OP-32 is sufficiently reliable to be included in the Hospital OQR Program. The ICC value submitted in the initial NQF application (0.335) was calculated using a split sample of data from 2 years. We randomly split the patient cohort at each hospital into two equal halves, calculated the measure using each half, and then calculated the agreement between these two (the 'test' and the 'retest'). After submitting the measure to NQF for endorsement review, we conducted additional calculations of the reliability testing score, this time using the Spearman-Brown prophecy formula. The Spearman-Brown prophecy formula is an accepted statistical method which estimates the ICC if the sample were increased. Therefore, it allows us to estimate what the reliability score would be if all observations were used for public reporting rather than using a split sample. Our Spearman-Brown prophecy formula calculations resulted in a higher ICC of 0.43.

The NQF considers the ICC values ranging from 0.21 to 0.40 as "fair" reliability and values ranging from 0.41 to 0.60 as "moderate" reliability. Therefore, the ICC values of 0.335 and 0.43 are interpreted as "fair" and "moderate" reliability, respectively. These ICC values are also in line with other NQF-endorsed outcome measures used in other CMS programs. For example, in the Hospital Readmissions Reduction Program, the Inpatient Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission measure (NQF #0505) (76 FR 51667) has an ICC of 0.369, and the Pneumonia (PN) 30-

day Risk Standardized Readmission measure (NQF #0506), also in the Hospital Readmissions Reduction Program (76 FR 51667), has an ICC of 0.406. Both measures are NQF-endorsed.

Regarding the concerns that the public may be misinformed and that we should withhold public reporting until the measure's reliability and validity is addressed, as stated above, we believe the reliability of the measure is sufficiently reliable for inclusion in the Hospital OQR Program and do not agree that the public may be misinformed or that we should withhold public reporting. In addition to our calculations above, reliability testing previously conducted by the measure steward demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Also, validity testing by the measure steward demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

As the commenters suggested, the measure reliability may be further improved by using several years' worth of data; however, we must balance the reliability of the measure with the timeliness of the measure. As discussed, at this time, we believe that 1 year of data appropriately balances these competing interests for payment determination purposes, but we will continue to assess this belief during the dry run. Also, we will consider conducting additional reliability assessments of the measure using an extended data period.

Moreover, we believe it is important to include this measure in the program because colonoscopy is a high volume, common procedure performed at outpatient facilities and is frequently performed on relatively healthy patients to screen for colorectal cancer (CRC). Given the widespread use of colonoscopy, understanding and minimizing procedure-related adverse events is a high priority. These adverse events, such as abdominal pain, bleeding, and intestinal perforation, can result in unanticipated hospital visits post procedure. Physicians performing colonoscopies are often unaware that patients seek acute care at hospitals following the procedure and the associated adverse events are potentially preventable. We strongly believe that the measure would promote improvement in patient care over time because transparency in publicly

reporting measure scores would make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to HOPDs and patients and incentivize HOPDs to incorporate quality improvement activities in order to reduce these visits.

Finally, we believe this measure should be included in the program because currently, this risk-standardized colonoscopy quality measure is the only measure available that would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy. There are no publicly available quality of care reports for HOPDs that conduct outpatient colonoscopies. Therefore, adoption of this measure provides an opportunity to enhance the information available to patients choosing among HOPDs that offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to HOPDs and patients all unplanned hospital visits following the procedure. In addition, providing outcome rates to HOPDs would make visible to clinicians meaningful quality differences and incentivize improvement.

In response to comments, however, to allow sufficient time to conduct further analysis of this measure, we are finalizing this measure beginning with the CY 2018 payment determination, rather than the CY 2017 payment determination as proposed. We plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to our discussion of the dry run above, in response to a previous comment.

With national implementation of a dry run of this measure, we will also review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We require a minimum volume (cutoff volume) of colonoscopies per facility to be able to calculate a reliable measure score for the facility. We have yet to determine the minimum volume per facility (that is, the cutoff colonoscopy volume). Because we used a Medicare 20 percent sample to develop the measure, we could not estimate this cutoff during measure development. However, testing during the measure dry-run with 100 percent of the sample per facility will help us to determine the appropriate

cutoff volume of colonoscopies per facility. HOPDs will be notified via the QualityNet Web site of the cutoff volume of colonoscopies per facility.

While some HOPDs perform too few colonoscopies for us to calculate a measure score, and we would not publicly report their data, these facilities would remain in the measure cohort. Typically, for public reporting of hospital measures on the *Hospital Compare* Web site, the measure score is reported as “Number of cases too small” for hospitals with fewer cases than the cutoff. We will use the same protocol when the measure is publicly reported for the Hospital OQR Program, and will report a measure score as “Number of cases too small” for HOPDs with fewer cases than the cutoff on the QualityNet Web site.

Comment: Many commenters were concerned that HOPDs may not have actionable information generated from OP-32. Specifically, commenters were concerned that claims would not accurately capture the data of patients who had initial colonoscopy at a facility but had a subsequent hospital visit at a different facility. Several of these commenters questioned whether this measure will benefit facilities or patients if each facility only receives a report with an aggregate number of claims based on historical data. Commenters requested that CMS clarify its plan to report detailed patient-level data confidentially to facilities that indicate whether the patient had a hospital visit, the type of visit (admission, emergency department visit, and observational stay), the admitting facility, and the principal discharge diagnosis. These reports would enable facilities to understand their performance and take steps where remediation is needed. One commenter also recommended that CMS allow at least a two-quarter black-out period so that hospitals have ample time to review and request corrections to their data.

Response: We do not believe that claims data will be difficult to capture at a facility different from where the colonoscopy was performed. Hospitals are responsible for accurately populating claims, regardless of where the patient had the procedure done.

In addition, due to commenters' concerns, we intend to conduct a dry run (discussed in detail above) and provide detailed facility specific information containing confidential patient-level data to all HOPDs. The dry run will generate confidential reports at the patient level, indicating whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the

admitting facility, and the principal discharge diagnosis. Further, it will enable HOPDs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. In addition, we will continue to generate these reports for HOPDs after we implement the measure beginning with the CY 2018 payment determination. HOPDs can use the information to identify performance gaps and develop quality improvement strategies. As we previously stated, dry runs have no payment impact and are not linked to public reporting. The main purpose of the dry run is to provide opportunities for hospitals to review their measure results and ask questions about measure methodology.

Comment: A few commenters stated that the measure methodology should include risk adjustment for socioeconomic factors so the results are accurate and reflect differences in socioeconomic burden and racial composition of patients across hospitals. Commenters were concerned that without proper risk adjustment, a hospital that serves a disproportionate share of low-income patients with confounding socioeconomic factors may have more unplanned visits following outpatient procedures. Commenters stated that the measure score can be skewed by factors such as race, homelessness, cultural and linguistic barriers, and low literacy. Commenters also stated that the readmissions of low-income patients with confounding socioeconomic factors are caused by factors beyond the control of the hospital and, therefore, do not reflect the quality of care being provided. Several commenters recommended that, after the NQF has reviewed OP-32, CMS consider submitting this measure as part of the socioeconomic status (SES) trial period created by the NQF Board of Directors.

Response: We do not believe that the measure is biased for low-income patients with confounding socioeconomic factors. When developing the measure, we tested how the measure score varied among outpatient facilities with varying proportion of low SES patients. Using patient dual eligibility status as an indicator of low SES, we noted that the median measure score, and the measure score distribution, was similar among facilities with many low SES patients compared to facilities with a few low SES patients. Based on our testing as well as input from the measure developer and the national technical expert panel, we concluded that facilities with a high proportion of low

SES patients were not biased by this measure and that the measure score was unaffected by SES status. These findings were presented to the NQF All-Cause Admissions and Readmissions Measures Standing Committee on May 6, 2014.²¹

Also, we thank the commenters for the suggestions to submit the measure as part of the SES trial period, which is a trial for a defined period that would assess the impact and implications of risk adjusting relevant quality measures for sociodemographic factors and was a recommendation of the Consensus Standards Approval Committee following its review of the NQF Expert Panel's report Risk Adjustment for Socioeconomic Status and Other Sociodemographic Factors. (http://www.qualityforum.org/Press_Releases/2014/NQF_Board_Approves_Trial_Risk_Adjustment.aspx). We will take this suggestion into consideration in future years.

Comment: One commenter requested clarification of how the measure numerator and denominator for OP-32 are calculated.

Response: The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the crude national rate. The measure score numerator is the predicted rate, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. This is sometimes referred to as the "adjusted actual rate."

The measure score denominator is the expected rate, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with that facility's case and mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average facility. The contribution of each risk factor (for example, age) to the patient's risk of a hospital admission is calculated based on all of the patients in the measure cohort. The crude national rate is the average rate of hospital visits following colonoscopy observed in the entire measure cohort. We also refer readers to the measure discussion above and measure specifications (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=75057>) for a more detailed

discussion of how the numerator and denominator are calculated.

Comment: Commenters believed that the Medicare 3-day window payment policy for hospitals does not allow HOPDs to generate a claim when there is an inpatient admission during the 3-day window payment policy, that is, during the 3 days subsequent to the colonoscopy. Commenters stated that HOPDs may be advantaged with systematic undercounting of hospital visits while ASCs get a full count of all hospital visits within 7 days subsequent to outpatient colonoscopy. Commenters did not believe the methodological solution proposed by the measure developer, using physician claims with an HOPD Place of Service (POS) code, is adequate due to the high error rates in POS coding on physician claims. Commenters were concerned that these challenges would make comparisons of HOPD and ASC data impossible, and significantly reduce the validity of the measure in the HOPD setting.

Response: We agree that the ability to detect meaningful variation is an important indication of the value of a measure. We have shown facility variation in unplanned hospital visits following colonoscopy in both nationwide Medicare data from HOPDs and also in the 2010 Healthcare Cost and Utilization Project (HCUP) data. We have also shown facility variation in unplanned hospital visits among ASCs alone using HCUP data from California. ASCs are unaffected by the 3-day payment window policy.²² We are confident that the variation shown is a reflection of facility variation in quality and not as a result of any issues to do with the 3-day window payment policy. We are aware of the impact of the 3-day window payment policy and will ensure HOPD colonoscopies affected by the 3-day window payment policy are included in the measure cohort and outcome to the fullest extent possible. Based on our internal testing with claims data, we believe our current algorithm is appropriate and accurate. However, since we always strive for improvement, we will evaluate the colonoscopy measure dry run data and work with HOPDs and ASCs to further review and refine the algorithm if necessary.

We clarify that HOPD colonoscopy claims for calculation of the measure are identified using both the physician and the facility claims. We did not intend to imply that colonoscopies performed in

HOPDs are solely identified from physician claims. For both ASCs and HOPDs, the measure first identifies colonoscopy claims using both the physician claim and the corresponding facility claim to ensure that each colonoscopy claim is attributed to the appropriate facility. As a second step, the measure matches (1) physician claims that contain HOPD as the POS that do not have a matching facility claim with (2) inpatient claims to identify potential HOPD colonoscopies that have a subsequent inpatient admission within the measure's timeframe of interest. This second step identifies HOPD colonoscopy claims affected by the 3-day window payment policy.

An OIG review (<http://oig.hhs.gov/oas/reports/region10/11000516.pdf>), concluded that, based on a sample of 2009 claims, inaccuracies in physician POS coding often occur where a procedure occurs at a HOPD or ASC and a facility claim exists, yet the physician claimed a nonfacility POS. By matching both facility and physician colonoscopy claims for any given patient, we ensure that we accurately identify colonoscopy claims to the fullest extent possible and attribute the colonoscopy to the appropriate provider including HOPD colonoscopies affected by the 3-day window payment policy.

We also have taken steps to educate providers about the appropriate POS coding and actively audit providers to improve the accuracy of POS coding. Beginning in 2012, we also introduced the "PD" modifier to indicate physician claims affected by the 3-day window payment policy.

Regarding the comment concerning challenges in comparing HOPD and ASC data, the measure includes colonoscopies from all outpatient settings to ensure that the expected hospital visit rate for any facility is estimated using the full national experience of colonoscopy patients. We appreciate the concern that there are structural differences in claims across HOPD and ASC settings. However, the measure links claims across multiple settings to identify outpatient colonoscopy claims, comorbidities for risk-adjustment, and patient outcomes. Linking patient claims across multiple settings largely mitigates the impact of potential difference in coding practice among settings and allows comparisons of colonoscopy quality across settings.

Comment: One commenter was concerned that the low occurrence rate may make the measure unreportable.

Response: On *Hospital Compare*, we report measure rates, but may refrain from publishing numerator and/or

²¹ Available at: http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx.

²² Center for Medicare and Medicaid Services, "Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy," National Quality Form Measure Submission Form, 20.

denominator data if either are less than 11. Consistent with the CMS Policy for Privacy Act Implementation & Breach Notification, 2007, CMS statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/SystemLifecycleFramework/downloads/privacypolicy.pdf>.

Comment: Many commenters expressed concern that, if finalized, the OP-32 measure's data collection period would begin July 1, 2014, several months before adoption of the measure is finalized. These commenters requested that CMS delay the beginning of the data submission period until at least 30 days after the rule is finalized.

Response: After consideration of the public comments we received, we are not finalizing our proposal to use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. We will

not use administrative claims data for services that occur prior to January 1, 2015. Instead, after the dry run, we will use paid Medicare FFS claims from a 12-month period from January 1 to December 31 of the year 2 years before a payment determination year. Specifically, since we are finalizing this measure beginning with the CY 2018 payment determination, and we will start with paid Medicare FFS claims from January 1, 2016 to December 31, 2016.

Comment: Some commenters suggested that CMS consider developing additional outcomes measures specific to colonoscopies, such as a measure of whether colonoscopy patients remain cancer free.

Response: We appreciate the commenters' suggestions and will take them into consideration for future measure selection.

We continue to believe that quality of care measurement in the clinical area of outpatient colonoscopy is an important gap area with ample room for improvement and that this measure has sufficient reliability and validity for use in the Hospital OQR Program. Therefore, after consideration of the public comments we received, we are

finalizing our proposal to adopt the OP-32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure for the Hospital OQR Program. However, to allow HOPDs sufficient time to review their measure data from the dry run and utilize the confidential facility reports with patient-level associated hospital event information, we are finalizing to make this measure required beginning with the CY 2018 payment determination and subsequent years, instead of the CY 2017 payment determination and subsequent years as proposed.

We plan to perform a dry run of the measure in 2015. Also, with national implementation of a dry run of this measure, we will also review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We refer readers to our discussion of the dry run and the cutoff volume above, in responses to previous comments.

The finalized measure set for the Hospital OQR Program CY 2017 payment determination and subsequent years, which includes previously finalized measures, is listed below.

FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
N/A	OP-1: Median Time to Fibrinolysis.
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. ****
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP-4: Aspirin at Arrival.
0289	OP-5: Median Time to ECG.
0514	OP-8: MRI Lumbar Spine for Low Back Pain.
N/A	OP-9: Mammography Follow-up Rates.
N/A	OP-10: Abdomen CT—Use of Contrast Material.
0513	OP-11: Thorax CT—Use of Contrast Material.
N/A	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
N/A	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.
N/A	OP-17: Tracking Clinical Results between Visits.
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP-21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP-22: ED—Left Without Being Seen. ***
0661	OP-23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP-25: Safe Surgery Checklist Use.
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures. *
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP-31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. **

* OP-26: Procedure categories and corresponding HCPCS codes are located at: http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadname1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of this final rule with comment period.

*** Name has been updated to correspond with NQF-endorsed name.

The finalized measure set for the Hospital OQR Program CY 2018 payment determination and subsequent

years, which includes previously finalized measures, and which includes

the newly adopted measure, OP-32, is listed below.

FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
N/A	OP-1: Median Time to Fibrinolysis.
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. ****
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP-4: Aspirin at Arrival.
0289	OP-5: Median Time to ECG.
0514	OP-8: MRI Lumbar Spine for Low Back Pain.
N/A	OP-9: Mammography Follow-up Rates.
N/A	OP-10: Abdomen CT—Use of Contrast Material.
0513	OP-11: Thorax CT—Use of Contrast Material.
N/A	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
N/A	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.
N/A	OP-17: Tracking Clinical Results between Visits.
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP-21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP-22: ED—Left Without Being Seen. ***
0661	OP-23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP-25: Safe Surgery Checklist Use.
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures. *
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP-31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. **
N/A	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. ****

*OP-26: Procedure categories and corresponding HCPCS codes are located at: http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadname1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v-6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of this final rule with comment period.

*** Name has been updated to correspond with NQF-endorsed name.

**** New measure finalized for the CY 2018 payment determination and subsequent years.

F. Possible Hospital OQR Program Measures and Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess processes of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of health information technology (health IT), care coordination, patient safety, and volume. For future payment determinations, we are considering expanding these measure areas and creating measures in new areas. Specifically, we are exploring (1) electronic clinical quality measures; (2) partial hospitalization measures; (3) behavioral health measures; and (4) other measures that align with the National Quality Strategy and the CMS Quality Strategy domains.

1. Electronic Clinical Quality Measures

HHS believes all patients, their families, and their health care providers should have consistent and timely

access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, "Principles and Strategy for Accelerating Health Information Exchange" (http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf). The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable health IT; (3) support for privacy and security

of patient information across all HIE-focused initiatives; and (4) governance of health information networks.

More information on the governance of health information networks and its role in facilitating interoperability of health information systems can be found at: <http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf>.

These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs as well as those who are not eligible for those programs, and are designed to improve care delivery and coordination across the entire care continuum. For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs (77 FR 54017 through 54020) requires HIE to share summary records for more than 10 percent of care transitions.

Polyps—Avoidance of Inappropriate Use (NQF # 1536).

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form and manner for data submission of these measures.

As we noted in the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we neither proposed new chart-abstracted measures where patient-level data is submitted directly to CMS nor proposed new requirements for data submission for chart-abstracted measures.

c. Claims-Based Measure Data Requirements for the CY 2017 and CY 2018 Payment Determination and Subsequent Years

We proposed one additional claims-based measure for the CY 2017 payment determination and subsequent years, OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 41036 through 41039). However, as discussed in section XIII.E. of this final rule with comment period, we are finalizing this measure for the CY 2018 payment determination and subsequent years instead of the CY 2017 payment determination and subsequent years as proposed. As discussed in section XIII.E. of this final rule with comment period, we will use claims data from January 1, 2016–December 31, 2016 to calculate OP-32 for the CY 2018 payment determination in order to use the most recently available data. Therefore, we are finalizing that to calculate OP-32, we will use claims data from January 1–December 31 of the calendar year 2 years prior to the payment determination year (for example, for the CY 2018 payment determination, we will use data from January 1, 2016–December 31, 2016).

Therefore, there will be a total of seven claims-based measures for the CY 2017 payment determination and subsequent years:

- OP-8: MRI Lumbar Spine for Low Back Pain (NQF # 0514);
- OP-9: Mammography Follow-Up Rates;
- OP-10: Abdomen CT—Use of Contrast Material;
- OP-11: Thorax CT—Use of Contrast Material;
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (NQF # 0669);
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT); and
- OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

For the CY 2018 payment determination and subsequent years, there will be a total of eight claims-based measures:

- OP-8: MRI Lumbar Spine for Low Back Pain (NQF # 0514);
- OP-9: Mammography Follow-Up Rates;
- OP-10: Abdomen CT—Use of Contrast Material;
- OP-11: Thorax CT—Use of Contrast Material;
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (NQF # 0669);
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT);
- OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache; and
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years.

In the CY 2012 OPPS/ASC final rule with comment period, we deferred the public reporting of OP-15 (76 FR 74456). We extended the postponement of public reporting for this measure in the CY 2013 and CY 2014 OPPS/ASC final rules with comment period (77 FR 68481, 78 FR 75111). As we noted in the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we did not propose any changes to this policy. Public reporting for OP-15 continues to be deferred, and this deferral has no effect on any payment determinations; however, hospitals are still required to submit data as previously finalized (76 FR 74456).

Comment: One commenter supported the proposed deferral of the public reporting of OP-15. The commenter appreciated CMS' concerns regarding inappropriate use of brain CT imaging and the need for an established clinical guideline to address this issue. However, the commenter did not believe older adults or adults on anticoagulant medications should be included in OP-15, and noted that current research suggests headaches are a potential contraindication. The commenter also expressed concern that claims are not detailed enough to capture the clinical indications needed for appropriate exclusions. As a result, the commenter was concerned that this measure may discourage clinically appropriate brain CTs for higher-risk

older populations. The commenter believed that CMS should focus its efforts on other CT measures, particularly after trauma or suspected pulmonary embolism. Another commenter asked CMS to remove OP-15 from the measure set.

Response: Given stakeholder concerns, including those of this commenter, we continue to evaluate whether OP-15 needs to be refined before being publicly reported. We continue to believe, for the reasons stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74456), that the measure has value, and we will continue to collect data with regard to this measure. However, we will also continue to defer public reporting until we have resolved these concerns. Because the measure is claims-based, this deferral does not affect data submission requirements for the Hospital OQR Program (that is, HOPDs do not submit data for claims-based measures other than the actual FFS claims), and an HOPD's payment determination will not be affected based on OP-15 while public reporting is deferred.

d. Data Submission Requirements for Measure Data Submitted via the CMS Web-Based Tool for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) for a discussion of the requirements for measure data submitted via the Web-based tool on a CMS Web site (the QualityNet Web site) for the CY 2016 payment determination and subsequent years.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we did not propose any changes to the data submission requirements for data submitted via the CMS Web-based tool.

e. Population and Sampling Data Requirements for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted. In the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we did not propose any changes to this policy.

ASC PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	Measure name
ASC-1	0263	Patient Burn.
ASC-2	0266	Patient Fall.
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC-4	0265	Hospital Transfer/Admission.
ASC-5	0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC-6	N/A	Safe Surgery Checklist Use.
ASC-7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier2&cid=1228772475754 .
ASC-8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*

* Measure voluntarily collected as set forth in section XIV.E.3.c. of this final rule with comment period.

The comments we received on these previously adopted measures and our responses are set forth below.

Comment: Some commenters asked CMS to remove some previously adopted measures for ASCs, because they believed these measures were either inappropriate or too burdensome for ASCs.

Response: We thank the commenters for their suggestions. At this time, we are not removing any of the measures suggested by commenters. We did not propose to remove any measures from the ASCQR Program in the CY 2015 OPPS/ASC proposed rule. Further, there is no evidence that continued use of the measures as specified raises patient safety concerns that would require immediate removal of the measures based on the process we are finalizing in this final rule with comment period. However, we will take these suggestions into consideration in future years using the measure removal criteria we are adopting in this final rule with comment period.

5. New ASCQR Program Quality Measure for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to ASCQR measure selection. In the CY 2015 OPPS/ASC proposed rule (79 FR 41046 through 41048), we proposed to adopt one new claims-based measure into the ASCQR Program for the CY 2017 payment determination and subsequent years: ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

Colonoscopy is the most commonly performed ambulatory surgery in the United States.²⁸ The most recent data available indicate that, in 2002 alone, physicians performed an estimated 14 million colonoscopies in the United States.²⁹ Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and cardiopulmonary events such as hypoxia, aspiration pneumonia, and cardiac arrhythmias. While hospital visits are generally unexpected after outpatient colonoscopy, the literature suggests that the majority of these visits occur within the first 7 days.^{30 31 32} Reported hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent at 7 to 14 days post procedure, and from 2.4 to 3.8 percent

²⁸ Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*. Rockville (MD) 2006.

²⁹ Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology*. Dec 2004; 127(6):1670–1677.

³⁰ Rathgaber SW., Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. *Gastrointest Endosc*. 2006; 64:556–62.

³¹ Rabeneck L, Saskin R, Paszat LF. Onset and clinical course of bleeding and perforation after outpatient colonoscopy: a population-based study. *Gastrointest Endosc*. 2011; 73:520–3.

³² Ko CW, Riffle S, Michael L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol*. 2010; 8:166–73.

at 30 days post procedure.^{33 34 35} Some adverse events such as bleeding occur after day 7, but based on input from clinical experts, public comment, and empirical analyses, we concluded that unplanned hospital visits within 7 days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure. This measure provides the opportunity for ASCs to improve quality of care and to lower the rates of adverse events leading to hospital visits after outpatient colonoscopy; this would encourage ASCs to achieve the outcome rates of the best performers.

We believe it is important to reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care. Therefore, we proposed to include the ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is calculated from paid Medicare FFS claims, in the ASCQR Program for the CY 2017 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time because transparency in publicly reporting

³³ Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc*. Apr 2007;65(4):648–656.

³⁴ Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med*. Oct 25 2010; 170(19):1752–1757.

³⁵ Chukmaitov AS, Menachemi N, Brown SL, Saunders C, Tang A, Brooks R. Is there a relationship between physician and facility volumes of ambulatory procedures and patient outcomes? *J Ambul Care Manage*. Oct–Dec 2008; 31(4):354–369.

measure scores would make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities in order to reduce these visits. ASCs are often unaware of complications following colonoscopy for which patients visit the hospital.³⁶ This risk-standardized quality measure would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy.

The outcome measured in the ASC-12 measure is all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility-level risk-standardized hospital visit rate, is derived from the calculation of the ratio of the numerator to the denominator multiplied by the crude rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits within 7 days of colonoscopy that the facility is predicted to have based on its case-mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with the facility's case-mix. The crude rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.

Based on discussions with clinical and technical panel experts, the measure excludes colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy because these patients are at a higher risk for hospital visits than patients undergoing a typical colonoscopy, and patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the first month

after the procedure to ensure all patients included in the analysis have complete data available for outcome assessment. The statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following a colonoscopy. Additional methodology details and information obtained from public comment for measure development are available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Section 1890A of the Act requires the Secretary to establish a pre-rulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The measure that we proposed was reviewed by the MAP and was included on a publicly available document entitled "MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs" (formerly referred to as the "List of Measures Under Consideration") on the NQF Web site at: http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx ("MAP Report"). We note that, at the time the measure was listed on the "MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs," it was named "High-Acuity Care Visits after Outpatient Colonoscopy Procedure." The MAP conditionally supported this measure for the ASCQR Program.

The MAP Report stated that the measure "[s]hould be submitted for and receive NQF endorsement; Measure is promising but needs further development" (p. 187). Further, the MAP Report stated that the measure "would provide valuable outcome information to inform consumer decision and drive quality improvement" and that the "NQF endorsement process would resolve questions about the reliability and validity of the measure." The MAP also stated that NQF endorsement would resolve questions about "the feasibility of the algorithm for attributing claims data in light of possible effects of the Medicare three-day payment window" (p. 187, MAP Report). However, this concern with Medicare Part A hospital

payments relates to the Hospital OQR Program and not the ASCQR Program. As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the ASCQR Program.

We believe we have addressed the concerns raised by the MAP to the greatest extent possible. The measure was submitted to NQF for endorsement on February 21, 2014. The measure is well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability. Reliability testing demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

Currently, there are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies. Therefore, adoption of this measure provides an opportunity to enhance the information available to patients choosing among ASCs that offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to ASCs and patients all unplanned hospital visits following the procedure. In addition, providing outcome rates to ASCs would make visible to clinicians meaningful quality differences and incentivize improvement.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. As stated in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory

³⁶ Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010; 170(19):1752-1757.

requirements. We believe that this measure is appropriate for the measurement of quality of care furnished by ASCs because this procedure is commonly performed in ASCs and, as discussed above, can signify important issues in the care being provided in ASCs. We also believe this measure reflects consensus among affected parties because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure, and stated that it “would provide valuable outcome information to inform consumer decision and drive quality improvement.” Further, the measure was subject to public comment during the MAP and measure

development processes, with some public commenters agreeing with the MAP’s conclusions on the measure (p. 187, MAP Report, January 2014; http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx). As discussed above, the statute also requires the Secretary, except as the Secretary may otherwise provide, to include measures set forth by one or more national consensus building entities to the extent feasible and practicable. This measure is not NQF-endorsed; however, as noted above, this measure is currently undergoing the NQF endorsement process. We note that

sections 1833(i)(7)(B) and (t)(17) of the Act do not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act, which contains this requirement, applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt nonendorsed measures. In summary, we proposed to adopt one new measure for the ASCQR Program for the CY 2017 payment determination and subsequent years.

ASC #	NQF #	Proposed ASCQR measure for the CY 2017 payment determination and subsequent years.
ASC–12	Pending	Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

We invited public comment on our proposal to include ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy in the ASCQR Program beginning with the CY 2017 payment determination. *Comment:* Several commenters agreed that the ASC–12 measure addresses an important area to monitor for quality improvement, given the number of colonoscopy procedures performed annually in ASCs. *Response:* We thank the commenters for their support. We agree that the quality of care associated with colonoscopy procedures is an important clinical care area to assess quality of care for ASCs. *Comment:* Many commenters urged CMS not to adopt ASC–12 until it is NQF-endorsed. Several of these commenters also noted that the MAP supported this measure on condition of NQF-endorsement, noting that the NQF process would resolve a number of questions about the reliability, validity and feasibility of this measure. These commenters requested that, in general, CMS only include measures in the ASCQR Program that have been NQF-endorsed in order to avoid later suspending or removing these measures. *Response:* We appreciate the commenters’ concerns. Under sections 1833(i)(7)(B) and (t)(17)(C)(i) of the Act, except as the Secretary may otherwise provide, the Secretary must develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by a national consensus building entity. Whenever

possible, we strive to adopt NQF-endorsed measures because these measures will meet these requirements. However, we believe the requirements that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. Further, it may not be feasible or practicable to adopt an NQF-endorsed measure, such as when an NQF-endorsed measure does not exist. Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Moreover, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that do not reflect consensus among affected parties and that are not endorsed by a national consensus building entity. Therefore, not all of the measures adopted for the ASCQR Program are required to be NQF-endorsed. As discussed below, we believe the measure as developed exhibits sufficient levels of reliability, validity, and feasibility to be adopted for the ASCQR Program. As noted above, we also have submitted this measure to NQF for endorsement. *Comment:* Many commenters did not support CMS’ proposal to finalize ASC–12 because complications from

colonoscopies are very rare and ASCs already take steps to ensure colonoscopies are conducted to eliminate preventable complications. Many commenters noted that the literature on the measure indicates the incidence of complications following colonoscopy is less than 2 percent. These commenters suggested that this low incidence meant that the measure should not be included in the ASCQR Program as it may be topped out or that the quality concern addressed by the measure does not rise to the level of importance needed for a national quality measurement program. *Response:* Given the widespread use of colonoscopy for colorectal cancer screening in the outpatient setting, we consider colonoscopy a high volume procedure and measuring the quality of care associated with colonoscopies a high priority for us. We commend ASCs that are already taking steps to ensure colonoscopies are conducted to eliminate preventable complications. While we agree that the incidence of colonoscopy complications is relatively low, serious adverse events, such as perforation of the bowel and bleeding, may occur following colonoscopies. We view this measure as a critical outcome measure where the goal is to drive toward and sustain zero harm. In addition, some literature suggests that many facilities performing colonoscopies are unaware of patients accessing hospital-based care with adverse events because patients return to different facilities, including hospitals and emergency departments, and would not return to the ASC

facility. For example, one study showed that physicians were unaware of nearly 75 percent of hospital admissions for adverse events following colonoscopy.³⁷ While most colonoscopies are performed without subsequent complication, we note that, in our analysis of Medicare FFS data, this measure showed that among Medicare patients aged ≥ 65 , 1.6 percent of outpatient colonoscopies resulted in an unplanned hospital visit within 7 days.³⁸ This estimate is based on a 20 percent sample of nationwide Medicare fee-for-service patients. If we were to use full national data (that is, a 100 percent sample), we estimate 1.7 million colonoscopies would have been performed among Medicare FFS patients and nearly 27,000 unplanned hospital visits would have occurred within 7-days of the procedure. These findings suggest adverse events are not as rare or inconsequential as many believed and that quality measurement for colonoscopy procedures in the outpatient setting is important.

We agree with the commenters' statement that the low incidence rate may suggest that the measure is topped-out, but in addition to the reasons for adopting this measure discussed above, we believe that a low incidence rate does not conclusively determine whether a measure has reached topped-out status. After the measure has been implemented, over time, we will assess it again for topped-out status using the two topped-out criteria we are finalizing in section XIV.B.3. of this final rule with comment period.

Comment: Many commenters expressed concern that ASC-12 is not sufficiently reliable to be included in the ASCQR Program, specifically, that the measure developer has indicated that the measure is only "fairly" reliable, with an interclass correlation coefficient (ICC) of 0.335. These commenters contended that "fair" reliability is not sufficient for publicly reported quality metrics because such information could misinform the public, and urged CMS to conduct an analysis on the measure's reliability to understand the amount of data required to achieve "good" reliability. Several

commenters argued that "good" reliability should result in an ICC of at least 0.60. Other commenters believed that reliability will improve with several years' worth of data. Another commenter requested that data from this measure be withheld from public reporting until concerns about its reliability and validity can be thoroughly assessed.

Response: We disagree with commenters and believe that ASC-12 is sufficiently reliable to be included in the ASCQR Program. The ICC value submitted in the initial NQF application (0.335) was calculated using a split sample of data from 2 years. We randomly split the patient cohort at each hospital into two equal halves, calculated the measure using each half, and then calculated the agreement between these two (the 'test' and the 'retest'). After submitting the measure to NQF for endorsement review, we conducted additional calculations of the reliability testing score, this time using the Spearman-Brown prophecy formula. The Spearman-Brown prophecy formula is an accepted statistical method which estimates the ICC if the sample were increased. Therefore, it allows us to estimate what the reliability score would be if all observations were used for public reporting rather than using a split sample. Our Spearman-Brown prophecy formula calculations resulted in a higher ICC of 0.43.

The NQF considers the ICC values ranging from 0.21 to 0.40 as "fair" reliability and values ranging from 0.41 to 0.60 as "moderate" reliability. Therefore, the ICC values of 0.335 and 0.43 are interpreted as "fair" and "moderate" reliability, respectively. These ICC values are also in line with other NQF-endorsed outcome measures used in other CMS programs. For example, in the Hospital Readmissions Reduction Program (76 FR 51667), the Inpatient Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission measure (NQF #0505) has an ICC of 0.369 and the Pneumonia (PN) 30-day Risk Standardized Readmission measure (NQF #0506) has an ICC of 0.406. Both measures are NQF-endorsed. We consider the reliability of 0.335, as noted in the proposed rule, acceptable for the ASCQR Program.

Regarding the concerns that we should withhold public reporting until the measure's reliability and validity is addressed, as stated above, we believe the reliability of the measure is sufficiently reliable for inclusion in the ASCQR Program and do not agree that the public may be misinformed or that we should withhold public reporting. In addition to our calculations above,

reliability testing previously conducted by the measure steward demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Also, validity testing by the measure steward demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

As the commenters suggested, the measure reliability may be further improved by using several years' worth of data; however, we must balance the reliability of the measure with the timeliness of the measure. As discussed, at this time, we believe that 1 year of data appropriately balances these competing interests for payment determination purposes, but we will continue to assess this belief during the dry run we discuss below. Also, we will consider conducting additional reliability assessments of the measure using an extended data period.

Moreover, we believe it is important to include this measure in the program because colonoscopy is a high volume, common procedure performed at outpatient facilities and is frequently performed on relatively healthy patients to screen for colorectal cancer. Given the widespread use of colonoscopy, understanding and minimizing procedure-related adverse events is a high priority. These adverse events, such as abdominal pain, bleeding, and intestinal perforation, can result in unanticipated hospital visits post procedure. Physicians performing colonoscopies are often unaware that patients seek acute care at hospitals following the procedure and the associated adverse events are potentially preventable. We strongly believe that the measure would promote improvement in patient care over time because transparency in publicly reporting measure scores would make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities in order to reduce these visits.

Finally, we believe this measure should be included in the program because currently this risk-standardized quality measure is the only measure available that would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates

³⁷ Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med*. Oct 25 2010;170(19):1752-1757.

³⁸ 2010 Medicare 20 percent fee-for-service sample. Based on an analysis of 20 percent sample of Medicare FFS data from 2010 during measure development. The 20 percent sample included 332,391 outpatient colonoscopies meeting the measure inclusion and exclusion criteria, and 1.6 percent of these colonoscopies were followed by an unplanned hospital visit. This equates to 5,331 unplanned hospital visits in the 20 percent sample.

and variation across facilities in unplanned hospital visits after colonoscopy. There are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies. Therefore, adoption of this measure provides an opportunity to enhance the information available to patients choosing among ASCs that offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to ASCs and patients all unplanned hospital visits following the procedure. In addition, providing outcome rates to ASCs would make visible to clinicians meaningful quality differences and incentivize improvement.

In response to comments, however, to allow sufficient time to conduct further analysis of this measure, we are finalizing the adoption of this measure beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed. We plan to perform a dry run of the measure in 2015. From our perspective, a dry run is a preliminary analysis of data in which ASCs may review their measure results, and ask questions about and become familiar with the measure methodology. Dry runs will include three to four years of paid Medicare FFS claims. We will use the most recent complete claims samples (usually 6 to 9 months prior to the start date) for dry runs. For example, if the dry run begins in March 2015, the most recent data available may be July 2011 to June 2014 (assuming 3 years of data). Because we use paid Medicare FFS claims, ASCs will not need to submit any data for the dry run. The general information on the dry run as well as the confidential dry run reports will be available for ASCs to review on their accounts at <https://www.qualitynet.org>. The dry run will generate confidential reports at the patient level, indicating whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. Further, the dry run will enable ASCs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. ASCs can use the information to identify performance gaps and develop quality improvement strategies. Dry run results are not linked to public reporting or payment determinations. We expect the

dry run to take approximately 1 month to conduct once data are obtained, after which facilities will be provided the confidential report and the opportunity to review their performance and provide feedback to us.

In addition, we will continue to generate these reports for ASCs after we implement the measure beginning with the CY 2018 payment determination. The measure will have no payment impact until the CY 2018 payment determination and subsequent years. Public display of measure data will occur on or after December 1, 2017, but there will be no public display of the dry run data.

With national implementation of a dry run of this measure, we also will review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We require a minimum volume (cutoff volume) of colonoscopies per facility to be able to calculate a reliable measure score. We have yet to determine the minimum volume per facility (that is, the cutoff colonoscopy volume). Because we used a Medicare 20-percent sample to develop the measure, we could not estimate this cutoff during measure development. However, testing during the measure dry-run with 100 percent of the sample per facility will help us to determine the appropriate cutoff volume of colonoscopies per facility. ASCs will be notified via the QualityNet Web site of the cutoff volume of colonoscopies per facility, if any.

While some ASCs perform too few colonoscopies for us to calculate a measure score and we would not publicly report their data, these facilities would remain in the measure cohort. Typically, for public reporting of hospital measures on the CMS Web site *Hospital Compare*, the measure score is reported as “Number of cases too small” for hospitals with fewer cases than the cutoff. We will use the same protocol when the measure is publicly reported for the ASCQR Program, and will report a measure score as “Number of cases too small” for ASCs with fewer cases than the cutoff on the QualityNet Web site.

Comment: Several commenters pointed out that, from the perspective of using claims as a data source for this measure, the codes for ASCs are services rendered-driven, while the codes for HOPDs are diagnosis-driven. Commenters were concerned that the coded information and the associated risk-adjustment for this measure may not be able to capture the sensitivity and specificity of the clinical care following an outpatient colonoscopy. Given the difference in coding practices and claims architecture between HOPDs and

ASCs, commenters recommended further testing for a fair performance comparison between HOPDs and ASCs. One commenter inquired if CMS plans to field test this measure prior to implementation. Commenters contended that the measure must be systematically assessed to assure the measure results are attributable to differences in quality alone. The commenters suggested that the measure score should be directly validated against outpatient medical records and measure results across settings must be assessed to ensure that any comparisons are valid.

Response: We thank the commenters for expressing their concerns regarding possible effects of coding practices and claims architecture on the data available through administrative claims in capturing the sensitivity and specificity of the clinical care following an outpatient colonoscopy. The measure is designed, however, to mitigate any differences in coding practices across HOPDs and ASCs. For example, to capture comorbidities for risk adjustment, the measure uses claims across care settings, including physician outpatient claims, so differences in claims submitted during the procedure are not likely to affect the comorbidities assigned to the patient. In addition, the outcome counts hospital visits regardless of whether they are billed as admissions, emergency room visits, or observations stays; therefore, if there are differences between colonoscopies done at ASCs and HOPDs in the type of hospital visit a patient with complications incurs (for example, whether observation stays or ED visits are used), the measure will be insensitive to these differences.

We recognize that the claims architecture differs for HOPDs and ASCs because the two facility types utilize different bill forms and have different payment systems. However, we do not agree that our measure specifications do not account for differences in claims architecture and necessary billing codes in discerning hospital events following colonoscopy. The measure includes colonoscopies from all outpatient settings to ensure that the expected hospital visit rate for any facility is estimated using the full national experience of colonoscopy patients. Specifically, we include all outpatient colonoscopies to make sure that: (1) The effects that risk factors exert on the outcome are estimated based on colonoscopies performed among all outpatient settings; and (2) the national average rate of hospital visits following colonoscopy is calculated based on all outpatient colonoscopies. Our approach

includes all outpatient claims, including HOPD, ASC, and physician claims. To identify all outpatient colonoscopy claims, including claims affected by the Medicare 3-day payment window policy, the measure specifications link claims across multiple care settings (outpatient and inpatient). Furthermore, the measure specifications link claims across multiple care settings to derive comorbidity data to ensure the patient comorbidities are captured to the fullest extent possible for risk-adjustment and to identify patient outcomes.

Linking patient claims across multiple settings largely mitigates the impact of potential difference in coding practice among settings and allows comparisons of colonoscopy quality across settings. For example, potential variation in the coding of comorbidities in the index colonoscopy claim may occur based on the setting. However, we derive comorbidities for risk adjustment from all inpatient and outpatient claims in the preceding 12 months. By using all claims in the preceding year, we capture patient comorbidities to the fullest extent possible and mitigate the impact of potential coding differences between settings that would occur if we used the index colonoscopy claim alone.

Further, similar approaches to deriving comorbidities from claims data are used for other risk-adjusted outcome measures. The measure developer has validated the accuracy of this approach on multiple occasions for prior measures developed for the inpatient setting. For example, in the Hospital Readmissions Reduction Program (76 FR 51667), the Inpatient Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission measure (NQF #0505) has an ICC of 0.369, and the Pneumonia (PN) 30-day Risk Standardized Readmission measure (NQF #0506) has an ICC of 0.406. Both measures are NQF-endorsed.

Regarding the suggestion that the measure score should be directly validated against outpatient medical records, at this time, we believe that it would be overly burdensome to validate the reported data, because of the limited experience that ASCs have with reporting quality data to CMS coupled with the low incidence of cases for this measure. In addition, as stated in section XIV.D.6. of this final rule with comment period, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642) for a complete discussion of our policy not to require validation of claims-based measures (beyond the usual claims validation activities conducted by our Medicare Administrative Contractors).

We appreciate commenters' concerns regarding factors that may impact HOPDs and ASCs. In response to comments, to allow sufficient time to conduct further analysis of this measure, we are finalizing the adoption of this measure beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed.

In addition, we plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to our discussion of the dry run above, in response to a previous comment.

Comment: Several commenters disagreed with the statement in the proposed rule (79 FR 41047) that the ASC-12 measure is "well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability." These commenters raised the issue that the Medicare payment window policy that applies to hospitals will result in under-detection of hospital events for colonoscopies performed by HOPDs; the 3-day (or 1-day) payment window applies to outpatient services furnished by hospitals and hospitals that are wholly owned or wholly operated Part B entities. Hospitals are required to bundle the technical component of all outpatient diagnostic services and related nondiagnostic services (for example, therapeutic) with the claim for an inpatient stay when services are furnished to a Medicare beneficiary in the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1-day) preceding an inpatient admission in compliance with section 1886 of the Act. Commenters expressed their concern that as a result of this payment policy, HOPDs may have systematic undercounting of hospital visits while ASCs get a full count of all hospital visits within 7 days subsequent to outpatient colonoscopy. Commenters did not believe the methodological solution proposed by the measure developer, using physician claims with an HOPD Place of Service (POS) code indicating the colonoscopy was performed at an HOPD, is adequate due to the high error rates in POS coding on physician claims. Commenters were concerned that these challenges would make comparison of HOPD and ASC data impossible, and significantly reduce the validity of the measure in the HOPD setting.

Response: We disagree with the commenters, and we continue to believe this measure is "well-defined and precisely specified for consistent implementation within and between organizations that will allow for

comparability," as we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 41047).

We agree that the ability to detect meaningful variation is an important indication of the value of a measure. As the commenter has correctly noted, we have shown facility variation in unplanned hospital visits following colonoscopy in both nationwide Medicare data from HOPDs and also in the 2010 Healthcare Cost and Utilization Project (HCUP) data. We have also shown facility variation in unplanned hospital visits among ASCs alone using HCUP data from California.³⁹ The observed average hospital visit rate and the variation in unplanned hospital visit rates among ASCs, which are unaffected by the 3-day payment window policy, were very similar to HOPDs suggesting that the measure performs equally well in both settings. Accordingly, we are confident that the variation shown is a reflection of facility variation in quality and not as a result of any issues to do with the 3-day payment window policy.

Based on our internal testing with claims data, we believe our current algorithm is appropriate and accurate. However, since we always strive for improvement, we will evaluate the colonoscopy measure dry run data and work with HOPDs and ASCs to further review and refine the algorithm if necessary.

Regarding POS billing, the OIG has found billing errors incorrectly assigning the service site for both HOPDs and ASC-related claims on physician claims where there were matching HOPD or ASC claims and that the percentage of incorrectly billed claims was significantly higher for ASC-related claims.⁴⁰ Many physicians' services can be furnished either in a facility setting such as an HOPD or ASC, or in a non-facility setting such as a physician's office, urgent care center or independent clinic. For these services, Medicare has two different payment rates under the physician fee schedule (PFS). The PFS facility rate is generally lower to reflect the fact that certain resources are supplied by the facility, and Medicare makes a separate payment to the facility under another payment system. By matching both facility and physician colonoscopy claims for any given patient, the current measure methodology ensures that colonoscopy claims are identified to the fullest extent

³⁹ Center for Medicare and Medicaid Services, "Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy," National Quality Form Measure Submission Form, 20.

⁴⁰ OIG, Physician services processed by Medicare Part B Contractors during Calendar Year 2009, September 2011, A-01-10-00516.

possible and attribute the colonoscopy to the appropriate provider when billing is affected by the 3-day window payment policy.

We clarify that HOPD claims for colonoscopy procedures for calculation of the measure are identified using both physician and facility claims. We did not intend to imply that HOPD colonoscopy claims are identified solely from physician claims. For both ASCs and HOPDs, the measure first identifies colonoscopy claims using both the physician claim and the corresponding facility claim to ensure the site of the colonoscopy service is attributed to the appropriate provider. As a second step, the measure matches: (1) Physician claims that contain HOPD as the POS that do not have a matching facility claim with (2) inpatient claims to identify potential HOPD colonoscopies resulting in an inpatient admission. This second additional step identifies HOPD colonoscopy claims affected by the 3-day window payment policy.

Therefore, we do not agree that ASCs will be adversely affected by use of POS billing to locate colonoscopies performed by physicians due to high levels of coding errors in POS coding on Part B for physician services because our measure calculation methodology addresses this concern.

We also have taken steps to educate physicians about the appropriate POS coding and actively audit physicians to improve the accuracy of POS coding <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7502.pdf>. In addition, from 2012 onwards, Medicare billing introduced the “PD” modifier to indicate physician claims affected by the 3-day window payment policy.

Comment: In reference to the statement in the CY 2015 OPPS/ASC proposed rule (79 FR 41047) that “there are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies,” one commenter stated that, on the *Physician Compare* Web site, CMS includes data on colonoscopy measures that provide a detailed look at the quality of colonoscopy services provided. This commenter suggested that CMS further enhance publicly available data by including measures captured by Qualified Clinical Data Registries to increase the robustness of publicly available data on colonoscopy provided across all sites of service.

Response: We thank the commenter for providing this input, but note that the cited information is available at the physician level. We believe that quality of care measure information also should be reported at the facility level, and that

facilities have a role in monitoring the surgical procedures performed at their facility and subsequent adverse outcomes. Patients and facilities should be able to review reported quality of care measure information at the ASC-facility level. We thank the commenter for the suggestion to include measures captured by Qualified Clinical Data Registries to further enhance publicly available data such as the colonoscopy data and we may take this into consideration in future rule making.

Comment: While some commenters believed that a long collection period, such as three years, is needed in order to generate measure scores that are moderately reliable, they also were concerned that the publicly reported measure score would not be a reflection of current, or even recent, performance. Commenters were concerned that consumers could be misled by the outdated data.

Response: As discussed previously, we agree with the commenter that a longer data collection period may increase measure reliability. However, we must balance the reliability of the measure with the timeliness of the measure and, as discussed later, at this time, we believe that 1 year of data appropriately balances these competing interests. We will continue to assess this belief during the dry run.

Comment: Several commenters expressed concern that the measure that was put forth to NQF review retained elements of the inpatient measure. Commenters stated that including these elements was inappropriate, and interpreted this action to mean that the measure has not been thoroughly reviewed and fully adapted for outpatient use. These commenters gave examples of the alleged inappropriate inpatient elements: (1) Certain condition categories (CCs) are not included in risk adjustment if they are only recorded at the time of the colonoscopy, and yet they are considered to be possible adverse outcomes; and (2) although end stage renal disease (ESRD) would not be a complication of colonoscopy diagnosed and recorded at the time of the procedure, it was included on the list of CCs. Commenters urged CMS to ensure that revised specifications are developed and then independently reviewed to ensure outpatient adaptation is complete prior to measure implementation.

Response: We appreciate the commenters’ concerns. In keeping with good practice, we have continued to review and seek comment on the measure specifications subsequent to measure development and implementation to ensure the measure

remains up-to-date in view of any potential new information. As the commenters noted, the measure technical specifications included a list of CCs that the measure does not consider for risk adjustment if the CC(s) occurred at the time of colonoscopy. In view of the comments, we have revised the list of CCs and updated the measure specifications to ensure only conditions relevant to colonoscopy are included. Of note, the inclusion of ESRD on the list was an error; we have revised the list and will use the revised list in implementing the measure. We corrected the list in subsequent measure descriptions during the NQF public comment period.

Comment: Many commenters expressed concern that the ASC–12 measure includes hospital visits unrelated to colonoscopy. Some commenters requested explanation for why the measure uses an all-cause categorization rather than only admissions related to colonoscopies.

Response: We clarify that this measure is purposely designed to use a broad outcome of hospital visits following surgery rather than a narrow set of easily identifiable complications. From a patient and health system perspective, the goal of this measure is to encourage and inform ASC efforts to minimize all potential acute complications, not just those narrowly related to procedural technique. This is important as the literature suggests,^{41, 42, 43, 44} that hospital visits following colonoscopy occur due to a range of adverse events relating to the bowel preparation, anesthesia, the colonoscopy procedure itself, and follow-up care. These include a range of symptoms and signs such as abdominal pain, bloating, dizziness and collapse, electrolyte disturbances, and cardiorespiratory symptoms (from sedation use), in addition to complications that are directly related to procedural technique such as bleeding and bowel perforation. The broad outcome of unplanned hospital visits captures all of these potential acute complications of colonoscopy.

⁴¹ Ko CW, Dominitz JA. Complications of colonoscopy: magnitude and management. *Gastrointest Endosc Clin N Am* 2010;20:659–71.

⁴² ASGE Standards of Practice Committee, Fisher DA, Maple JT, et al. Complications of colonoscopy. *Gastrointest Endosc* 2011;74:745–52.

⁴³ Baudet JS, Diaz-Bethencourt D, Aviles J, et al. Minor adverse events of colonoscopy on ambulatory patients: the impact of moderate sedation. *Eur J Gastroenterol Hepatol* 2009;21:656–61.

⁴⁴ Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. 2007;65:648–56.

Our goal for the measure is to encourage ASCs to be mindful of reducing post-colonoscopy admissions caused by the prior colonoscopy procedure performed at their facility. For example, patients may be at higher risk of falls post-colonoscopy secondary to dehydration following the bowel preparation for the procedure and there may be opportunities for ASCs to minimize this risk. We removed planned admissions from the measure outcome adapting CMS' Planned Readmission Algorithm version 3.0.^{45 46} This algorithm removes nonacute admissions for scheduled procedures (for example, total hip replacement) and other types of care always considered planned (for example, rehabilitation or maintenance chemotherapy) from the outcome. That is, we removed planned admissions from the outcome because planned admissions do not reflect differences in colonoscopy quality of care.

Comment: One commenter requested that CMS clarify how the numerator and denominator for ASC-12 are calculated.

Response: The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the crude national rate. The measure score numerator is the predicted rate, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. This is sometimes referred to as the "adjusted actual rate."

The measure score denominator is the expected rate, which is the number of unplanned hospital visits the facility is expected to have, based on the nation's performance with that facility's case-mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average hospital. The contribution of each risk factor (for example, age) to the patient's risk of a hospital admission is based on all of the patients in the measure cohort. The crude national rate is the average rate of hospital visits following colonoscopy observed in the entire measure cohort.

We also refer readers to the measure discussion above and measure specifications (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=75057>) for a more detailed discussion of how the numerator and denominator are calculated.

Comment: Many commenters were concerned that facilities would lack actionable information generated from ASC-12. Several of these commenters questioned whether this measure will benefit facilities and patients because each facility will only receive a report with an aggregate number of claims that will be based on historical data, which will make it difficult for the facility to set a course for improvement if needed. Commenters requested that CMS clarify its plan to report detailed patient-level data confidentially to ASCs that indicates whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis to assist facilities with quality improvement, to enable facilities to understand their performance and take steps where remediation is needed. Several commenters also noted that ASCs do not provide post-operative follow-up care after patient discharges and do not have direct access to the records of other health care facilities. Consequently, this constraint would limit their ability to identify improvements based on the data provided by this measure.

Response: The primary purpose of this measure is to illuminate the quality differences in colonoscopies that are presently not visible to patients and may not be visible to some facilities. In measure development, we found the facility variations in the measure score suggest some facilities provide worse than expected care. We believe the detailed patient-level data that we will provide confidentially to ASCs will help them identify areas for improvement efforts. The data would indicate whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. The dry run will enable ASCs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. We will continue to generate these reports for ASCs after we implement the measure beginning with the CY 2018 payment determination. ASCs can use the information to identify performance

gaps and develop quality improvement strategies.

We understand the challenges involved in following up with ASC patients. The colonoscopy measure addresses these challenges by providing feedback to facilities and clinicians about the outcomes experienced by their patients following colonoscopy. Many clinical experts noted that facilities were often unaware of patients' return visits to hospitals. They noted that many patients would often return to a different facility or an emergency department. One study noted that physicians were unaware of 75 percent of return hospital visits following colonoscopy at a major tertiary center.⁴⁷

Comment: Several commenters expressed concern that ASC-12 does not include risk-adjustment to account for patient differences, stating that CMS does not report the variation between ASCs once this risk adjustment has been applied and that there may be no statistically significant difference between an ASC's risk-adjusted visit rate and the national average making it impossible to identify low performers and high performers. One commenter specifically recommended that patients with conditions such as inflammatory bowel disease and diverticulitis should be included with appropriate risk adjustment. Commenters recommended CMS consider the drawbacks of the current methodology, conduct analysis to test the variation of the measure between ASCs, and reconsider this measure for inclusion in future proposals.

Response: We thank the commenters for all the suggestions to improve the measure. In the measure application for NQF endorsement, we note that the measure, following risk-adjustment, is able to detect statistically significant variation between outpatient facilities by demonstrating measure score variation using the 2010 HCUP data from four States (California, New York, Nebraska, and Florida). Using a very conservative sampling technique (sampling with replacement),⁴⁸ we constructed 95 percent interval estimates around the facility measure score (similar to confidence intervals) and used the estimates to place facilities into three performance categories: Worse than expected; no different than expected; and better than expected. Based on this analysis, we identified 5 outlier facilities among a total of 992

⁴⁵ Horwitz L, Grady J, Dorsey K, Zhang W, Keenan M, Keshawar A, Cohen D, Ngo C, Okai M, Nwosu C, Lin Z, Bhat K, Krumholz H, Bernheim S., 2014 Measures Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission—Version 3.0. 2014: Centers for Medicare & Medicaid Services, 2014.

⁴⁶ Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

⁴⁷ Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med* 2010;170:1752–7.

⁴⁸ Efron, B. (1979). Bootstrap methods: Another look at jackknife. *Ann. Stat.* 7, 1–26.

ASCs and HOPDs. This analysis included only about one-tenth of all outpatient facilities in the United States. Typically, we see greater variation between facilities when 100 percent of nationwide facilities are included for actual measure implementation and reporting.

As to the commenter's recommendation to risk-adjust patients with certain conditions, we excluded patients with inflammatory bowel disease (IBD) and diverticulitis because it is difficult to assess from claims data whether these patients have an active or inactive disease which may alter their risk of the outcome. We determined that we could not adequately risk-adjust for the risk of the outcome for these patients. Second, our analysis suggested that nearly half of the patients with IBD and diverticulitis have post-colonoscopy hospital visits with a primary diagnosis of IBD and diverticulitis respectively. We could not tell from the claims data whether these visits were planned or unplanned. We did test for variation among ASCs and HOPDs independently using HCUP data from California (see Measure Technical Report). As we previously discussed, the measure was able to adequately detect variation in the measure score among ASCs.

As for the inquiry about further testing the measure, we have more time to further test the measure because, in response to comments, we are finalizing the adoption of this measure beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed. We plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to our discussion of the dry run above, in response to a previous comment.

Comment: One commenter expressed concern that ASCs would have difficulty gathering and reporting the information for the proposed ASC-12 measure.

Response: We thank the commenter for providing this input and note that this measure will be calculated completely from data obtained from paid Medicare FFS claims submitted by ASCs, hospitals, and physicians. For this reason, it will not require any additional information-gathering on the part of ASCs.

We continue to believe that quality of care measurement in the clinical area of outpatient colonoscopy is an important gap area with ample room for improvement and that this measure has sufficient reliability and validity for use

in the ASCQR Program. Therefore, after consideration of the public comments we received, we are finalizing our proposal to adopt the ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure for the ASCQR Program. However, to allow ASCs sufficient time to review their measure data from the dry run and utilize the confidential facility reports with patient-level associated hospital event information, we are finalizing the adoption of this measure for the CY 2018 payment determination and subsequent years, instead of the CY 2017 payment determination and subsequent years as proposed.

We plan to perform a dry run (a preliminary analysis) of the measure in 2015. Also, with national implementation of a dry run of this measure, we also will review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We refer readers to our discussion of the dry run and the cutoff volume above, in our response to a previous comment.

The finalized measure set for the ASCQR Program CY 2017 payment determination and subsequent years, is listed below.

FINALIZED ASC PROGRAM MEASURE SET FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC-1	0263	Patient Burn.
ASC-2	0266	Patient Fall.
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC-4	0265	Hospital Transfer/Admission.
ASC-5	0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC-6	N/A	Safe Surgery Checklist Use.
ASC-7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754 .
ASC-8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*

* Measure voluntarily collected starting as set forth in section XIV.E.3.c. of this final rule with comment period.

The finalized measure set for the ASCQR Program CY 2018 payment

determination and subsequent years, which includes previously finalized

measures and the newly-adopted measure, ASC-12, is listed below.

FINALIZED ASC PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC-1	0263	Patient Burn.
ASC-2	0266	Patient Fall.
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC-4	0265	Hospital Transfer/Admission.
ASC-5	0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC-6	N/A	Safe Surgery Checklist Use.

FINALIZED ASC PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—
Continued

ASC No.	NQF No.	Measure name
ASC-7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754 .
ASC-8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*
ASC-12	Pending	Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.**

* Measure voluntarily collected starting as set forth in section XIV.E.3.c. of this final rule with comment period.

** New measure finalized for CY 2018 payment determination and subsequent years.

6. ASCQR Program Measures for Future Consideration

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), where we finalized our approach to future measure selection for the ASCQR Program. We seek to develop a comprehensive set of quality measures to be available for widespread use for informed “patient decision-making and quality improvement in the ASC setting” (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and value-based purchasing programs, as appropriate. Accordingly, as we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 41048 through 41049), in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer; strengthen person and family engagement; promote effective communication and coordination of care; promote effective prevention and treatment; work with communities to promote best practices of healthy living; and make care affordable.

Comment: Commenters supported CMS’ alignment efforts. One commenter supported the direction of the ASCQR Program to align future measures with the NQS priorities, noting that doing so will make the ASCQR Program more consistent with the Hospital IQR Program. Another commenter agreed with the goal of aligning measures in the ASCQR Program with the Hospital OQR Program and the Hospital IQR Program, and urged that the alignment should eliminate confusion and avoid disadvantaging ASCs.

Response: We thank the commenters for supporting our alignment efforts. To the extent practicable, we strive to align measures with national priorities,

including the NQS priorities as well as across our quality reporting and value-based purchasing programs.

Comment: Several commenters requested that CMS collaborate with stakeholder communities to develop and implement appropriate ophthalmic measures for the ASC setting, potentially including measures of incidence of toxic anterior segment syndrome in cataract surgery patients, incorrect intraocular lens implantation in cataract surgery patients, and unplanned anterior vitrectomy in cataract surgery patients. Another commenter suggested that CMS consider several new measures in the future, including adverse outcomes from high-volume procedures such as cataract removals, other eye procedures, endoscopies, musculoskeletal procedures, and colonoscopies. This commenter also encouraged CMS to develop composite measures of common surgical infections and to involve consumers and purchasers in refinement of the CAHPS survey for the outpatient setting. In addition, this commenter urged CMS to continue to analyze and address the role of the survey and discuss the comparative roles of PQRS CAHPS, ACO CAHPS, S-CAHPS, or the HOSD/ASC CAHPS surveys.

Response: We thank the commenters for these recommendations and will consider these types of measures in future years. We have included an unplanned anterior vitrectomy in cataract surgery patients and patient experience of care survey measures in our Measures under Consideration (MUC) list for the MAP for the ASC setting. We agree that the adoption and implementation of appropriate cataract surgery measures are important for the ASCQR Program, given the number of such procedures performed on Medicare beneficiaries in this setting.

We use patient experience of care surveys in a variety of health care settings. We agree that, to the extent feasible, survey instruments should be aligned and coordinated across settings. The developmental process of CAHPS and patient experience of care surveys involves several opportunities for input from patients, patient advocates, and stakeholders from the HOPD and ASC industry, including professional associations, clinicians, accreditation organizations, and the government.

Comment: One commenter requested that CMS provide additional guidance with respect to the process for suggesting and submitting future ASCQR Program measures. This commenter further requested that CMS distinguish, when establishing reporting requirements, between ASCs that are equipped for the performance of sterile surgical operations and ambulatory endoscopy centers that are equipped to perform nonsurgical endoscopy procedures.

Response: We generally request comments on future ASCQR Program measure topics through the rulemaking process and did so in the CY 2014 OPPS/ASC proposed rule (78 FR 43664). We also accepted measures for consideration from associations through ONC’s measure project tracking system (<http://oncprojecttracking.org/>); associations were invited via the CMS Listserv to attend a training session for how to submit measures into this system. Regarding distinguishing ASCs by the services provided, we are aware that ASCs vary in the types of services they provide. This variety presents challenges in devising a measure set that can glean applicable quality of care information across ASCs. With respect to current claims-based measures that include surgical procedures, at this time, we are not able to identify facilities that would never perform surgical procedures from the

information on claims. Therefore, we are not able to distinguish ineligibility for a measure from non-reporting.

Comment: One commenter recommended that CMS consider the following measure topics for the ASCQR Program: (1) Equipment Reprocessing (for patient safety, high-level disinfection and sterilization, with a particular emphasis on endoscope reprocessing); and (2) Sedation Safety—A possible anesthesia-related measure could include the use of reversal agents to patients given moderate sedation agents (medications used to rescue patients from deeper levels of sedation than intended).

Response: We thank the commenter for these recommendations and will consider these measure topics for the ASCQR Program in future years.

Comment: One commenter noted that the program currently includes a measure on hospital transfer or admission after a procedure, which tracks whether patients are transferred or admitted directly to a hospital (including a hospital emergency room) upon discharge from an ASC. This commenter believed that this measure could be expanded to include patients who return home after the ASC procedure, but are admitted to a hospital shortly thereafter because of a problem related to the procedure because doing so would enable us to more comprehensively track patients who experience serious complications or medical errors related to an ASC procedure.

Response: We thank the commenter for providing this information and note that the ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure includes all unplanned hospital visits (emergency department visits, observation stays and inpatient admissions) within 7 days following the procedure. We will continue to consider additional measures that track hospital visits following ASC procedures as appropriate in the future.

Comment: One commenter recommended that CMS develop a measure to track surgical site infection rates for ambulatory surgeries in ASCs. The commenter observed that CMS stated in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74503 through 74504) that we would consider proposing an SSI measure and requested an update.

Response: We agree that it is important to encourage the reduction of SSIs. In the CY 2012 OPPI/ASC rulemaking, we proposed but did not finalize the Surgical Site Infection Rate measure (NQF #0299), but stated that

we will consider proposing the measure once a suitable set of procedures and a protocol for ASCs and HOPDs has been developed (76 FR 74504). We are not aware of any updates to this measure, but will consider these types of measures in future years.

Comment: One commenter recommended that the ASCQR Program should move to a value-based purchasing model no later than 2016, rewarding high-performing ASCs and penalizing low-performing ASCs.

Response: We thank the commenter for this recommendation. As we noted in the CY 2014 OPPI/ASC final rule with comment period (78 FR 75122), we currently do not have express statutory authority to implement a value-based purchasing program for ASCs.

Comment: One commenter requested that CMS publish each year, as part of the proposed rule, a 2-year or 3-year timeline of anticipated changes to the ASCQR Program to facilitate ASC facility planning.

Response: We thank the commenter for the comment and note that we seek to provide information to ASC facilities in advance whenever possible to support future planning. For example, in the CY 2012 OPPI/ASC rulemaking, we finalized measures sets for the CY 2014, CY 2015, and CY 2016 payment determinations (76 FR 74496 to 74511). Similarly, in the CY 2013 OPPI/ASC final rule with comment period, we finalized a data collection and processing period policy for claims-based measures using QDCs for the CY 2015 payment determination and subsequent years (77 FR 68497 through 68498), and in the CY 2014 OPPI/ASC final rule with comment period, we finalized our policy regarding participation status for the CY 2016 payment determination and subsequent years (78 FR 75134 through 75135). In this year's rulemaking, we also are finalizing policies that span more than one year, such as including the ASC-12 measure in the ASCQR Program measure set for the CY 2018 payment determination and subsequent years, the process for removing measures, and topped-out criteria. While we cannot commit to providing a 2-year or 3-year timeline at this point due to the rapidly evolving quality measurement and program environment, we will continue to provide information to ASCs through the QualityNet Web site, the ASCQR Program ListServe, and the rulemaking process as appropriate.

Comment: Several commenters stated that they would welcome opportunities to work with CMS to explore alternative reporting options for measures that cut across CMS quality reporting programs,

particularly measures that are included in both the ASCQR Program and PQRS.

Response: We thank the commenters for their offer to collaborate with CMS on alternative reporting options. We will continue to look for opportunities to work with ASC community stakeholders to continuously improve the ASCQR Program.

Comment: Several commenters expressed concern about the MAP, specifically the public comment process and the practice of submitting measure concepts for consideration. These commenters believed that the MAP does not adequately consider public comments, and stated that the MAP session agendas scheduled voting activities prior to public comments, which limited the ability of comments to impact voting, and that the public could not address the Coordinating Committee until after deliberations were completed. These commenters also stated that the public could comment on the draft MAP Pre-Rulemaking Report, but that these comments were not considered by the Coordinating Committee and, therefore, did not result in revisions to the final report. These commenters recommended that public comments be solicited prior to, rather than, after voting on agenda items, and that the MAP Coordinating Committee be required to formally consider and respond to public comments on the draft report. Several other commenters expressed concern regarding the MAP's review of measure "concepts" that have not been fully developed, saying that recommendations are premature for measure concepts or measure drafts. These commenters recommended that when "concepts" are presented, the MAP should determine whether the measure concept/draft would fill a measure gap but reserve further judgment for the completed measure. These commenters are further concerned that the inclusion of measure "concepts" results in an unreasonably large number of items for the MAP to consider, which can limit the time allotted to consider each measure.

Response: We thank the commenters for their comments and concerns, but note that they do not directly address any proposals included in the CY 2015 OPPI/ASC proposed rule; rather, they are directed towards MAP-specific processes. We invite the commenters to submit their MAP-specific concerns directly to the NQF, which convenes the MAP.

In response to the comments concerning the MAP's review of measure "concepts" that have not been fully developed, resulting in recommendations that are premature for

measure concepts or measure drafts, we interpret the commenters' use of the terms "concept" and "draft" to refer to measures under development as defined in our legend on page 87 of the List of Measures under Consideration for December 1, 2013 (https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.qualityforum.org%2FSetting_Priorities%2FPartnership%2FMeasures_Under_Consideration_List.aspx&ei=aQUuVJrsM6nIsAT61IDQAg&usg=AFQjCNFPjzG9-t7flmf-RFf-7o_rSvpxxQ&sig2=V6HiGdCM2OUcP5xkoudcw&bvm=bv.76802529,d.cWc). We strive to ensure that the pre-rulemaking process allows for thorough review by the MAP and other stakeholders of all measures under consideration.

Comment: Some commenters suggested that CMS consider developing additional outcomes measures specific to colonoscopies and consider developing a measure of whether or not colonoscopy patients remain cancer free, specifically suggesting that we work with stakeholders to improve existing measures.

Response: We thank the commenter for their recommendations and will consider these types of measures in future years.

We also thank all commenters for providing their views and we will consider them as we develop future measures for the ASCQR Program.

7. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures.

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we continue to develop the ASCQR Program. The manuals that contain specifications for the previously

adopted measures can be found on the QualityNet Web site at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754>.

Many of the quality measures used in Medicare and Medicaid reporting programs are NQF-endorsed. We note that two of the measures previously adopted for the ASCQR Program are not NQF-endorsed, and NQF endorsement is not a program requirement. However, for those measures that are NQF-endorsed, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years as part of its regular maintenance process for NQF-endorsed performance measures. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with the NQF on an annual basis. The NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

We note that the NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to measures in order to maintain endorsement status. Other non-NQF measures may undergo maintenance changes as well. We believe that it is important to have in place the subregulatory process that we have adopted for the ASCQR Program to incorporate nonsubstantive updates into the measure specifications for measures so that the measure specifications remain current. We also recognize that some changes to measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41049), we did not propose any changes to this policy.

8. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. When available, these data will be displayed at the CCN level; we intend to make data collected under the ASCQR program publicly available in CY 2015. In the CY 2015 OPPS/ASC proposed rule (79 FR 41049), we did not propose any changes to this policy.

Comment: One commenter urged CMS to make the data submitted by ASCs available to the public after giving ASCs an opportunity to preview the data.

Response: We thank the commenter for their comment, and note that in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. These data will be displayed at the CCN level. We did not propose any changes to this policy (79 FR 41049).

C. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XV.C.1. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131 through 75132) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI-U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI-U update factor is the Consumer Price Index for all urban consumers (CPI-U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI-U is a negative number, the CPI-U would be held to zero. Under the ASCQR Program, any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this final rule with comment period.

available. We also do not agree that reporting of measure data by some ASCs and not others under voluntary reporting would affect the validity of data reported for this Web-based measure because this situation is no different than any other measure where not all ASCs had cases.

Comment: Many commenters requested that CMS remove the ASC–11 measure from the program entirely, rather than delaying implementation and allowing voluntary reporting. These commenters reiterated similar concerns expressed in the CY 2014 OPPTS/ASC final rule with comment period regarding associated burden, suitability for ASCQR Program versus PQRS, program alignment of this measure, nonstandardization of collected information, NQF endorsement, MAP recommendation, and coordination challenges faced by facilities.

Response: We continue to believe this measure addresses the importance area of care coordination and responsibility for monitoring patient outcomes between performing physicians, practitioners that assess visual function, and facilities where procedures are performed; therefore, we are not removing ASC–11 from the ASCQR Program measure set for the CY 2017 payment determination and subsequent years.

With respect to the concerns raised by commenters about the measure, we refer commenters to the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75124 through 75126, 75129, and 75138 through 75139) where we previously have responded to these concerns.

After consideration of the public comments we received, for the reasons discussed above, we are finalizing our proposal to allow voluntary data collection and reporting of this measure for the CY 2017 payment determination and subsequent years. We also are finalizing our proposal to exclude the measure entirely from the CY 2016 payment determination measure set. ASCs will be able to begin reporting with January 1, 2015 services as described above in section XIV.E.3. of this final rule with comment period. For ASCs that choose to submit data, we request that they submit such data using the means and timelines finalized in the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75138 to 75139). ASCs will not be subject to a payment reduction for failing to report this measure during the period of voluntary reporting. Data voluntarily submitted will be publicly reported.

4. Claims-Based Measure Data Requirements for the New Measure for the CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPTS/ASC proposed rule (79 FR 41046–41048), we proposed to adopt the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is a claims-based measure that does not require any additional data submission apart from standard Medicare FFS claims. In the CY 2015 OPPTS/ASC proposed rule (79 FR 41051), we also proposed that, for this measure, which uses ASC Medicare claims data as specified in the ASCQR Specifications Manual and does not require any additional data submission such as QDCs, we would use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. Thus, we stated, for the CY 2017 payment determination for this measure, claims from July 1, 2014 to June 30, 2015 would be used. We noted that we proposed to adopt this measure under the ASCQR Program as well as the Hospital OQR Program, as described in section XIII.H.2.c. of the proposed rule. We stated that this ASCQR Program time period provides for the timeliest data possible while aligning the proposed data submission requirements with our Hospital OQR Program proposal, which would use the claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years that we adopted in the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75111 through 75112).

We invited public comment on this proposal.

Comment: Many commenters expressed concern that, if finalized, the ASC–12 measure's data collection period would begin July 1, 2014, several months before adoption of the measure is finalized. Several commenters recommended that data collection begin July 1, 2015.

Response: As we stated above in section XIV.B.5. of this final rule with comment period, we are finalizing the adoption of ASC–12 for the CY 2018 payment determination and subsequent years instead of the CY 2017 payment determination and subsequent years as proposed. We are finalizing the data submission time period for ASC–12 to use paid Medicare FFS claims from the calendar year 2 years before the payment determination calendar year. For the CY 2018 payment determination, we will use paid

Medicare FFS claims from January 1, 2016 to December 31, 2016. We believe the reliability of the measure using 1 year of data is sufficiently reliable.

While we believe that measure reliability may be further improved by using a longer time period, we must balance the reliability of the measure with the timeliness of the measure. At this time, we believe that 1 year of data appropriately balances these competing interests, but we will continue to assess this belief during the dry run.

After consideration of the public comments we received, we are not finalizing our proposal to use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. Instead, we will use paid Medicare FFS claims from the calendar year 2 years before the payment determination calendar year. Specifically, with respect to the CY 2018 payment determination, for calculating ASC–12, we will use paid Medicare FFS claims from January 1, 2016 to December 31, 2016.

5. Data Submission Requirements for ASC–8 (Influenza Vaccination Coverage Among Healthcare Personnel) Reported via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination and Subsequent Years

a. Previously Adopted Requirements for the CY 2016 Payment Determination

We refer readers to the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74510) and the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75139 through 75140) for a complete discussion of the ASC–8 measure (Influenza Vaccination Coverage among Healthcare Personnel) (NQF #0431), including the data collection timeframe and the data reporting standard procedures for the CY 2016 payment determination.

In the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75139 through 75140), we finalized our proposal to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site for detailed procedures for enrollment (<http://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html>), set-up (<http://www.cdc.gov/nhsn/ambulatory-surgery/setup.html>), and reporting (<https://sams.cdc.gov>) (user authorization through Secure Access Management Services (SAMS) is required for access to NHSN). We note

with comment period, we are finalizing our proposal to exclude OP-31 from the CY 2016 payment determination measure set. Therefore, we estimate that there will be no burden for reporting OP-31 for the CY 2016 payment determination, and an overall reduction in burden of 160 hours ((40 hours per quarter for reporting \times 4 quarters) + 0.167 hours per year for reporting via the Web-based tool) per hospital for the CY 2016 payment determination.

Combining the estimated reductions in burden for all three of these measures, we estimate a total reduction in burden of 240 hours (40 hours + 40 hours + 160 hours) per hospital for the CY 2016 payment determination due to delayed data collection for OP-29 and OP-30 and the exclusion of OP-31. We estimate that approximately 3,300 hospitals will participate in the Hospital OQR Program for the CY 2016 payment determination. Therefore, we estimate a total reduction in burden of 792,000 hours (240 hours \times 3,300 hospitals) for the CY 2016 payment determination from our original estimate of 1.6 million hours (160 hours/measure \times 3 measures \times 3,300 hospitals) as discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171 through 75172) for all hospitals participating in the Hospital OQR Program based on the data collection delays for OP-29 and OP-30 and the exclusion of OP-31. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated that these measures would result in a financial burden of \$30 per hour. Therefore, we estimate that the changes to these three measures will result in a reduction in financial burden of \$23.8 million (\$30/hour \times 792,000 hours) for the CY 2016 payment determination from our original estimate of \$76.8 million (\$1.6 million \times \$30) as discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171 through 75172).

b. Hospital OQR Program Requirements for the CY 2017 Payment Determination and Subsequent Years

As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for the particular payment determination. For the reasons stated in that rule, we believe that the burden associated with these requirements is 42 hours per hospital or 138,600 hours for all hospitals for the CY 2017 payment determination and subsequent years. We estimate a financial burden for these

requirements of \$4.2 million (\$30/hour \times 138,600) for all hospitals.

(1) Claims-Based Measures for the CY 2017 and CY 2018 Payment Determinations and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530) for detailed discussions of the information collection requirements for the previously finalized claims-based measures (OP-8, OP-9, OP-10, OP-11, OP-13, OP-14, and OP-15). In section XIII.E. of this final rule with comment period, we are finalizing our proposal to adopt one additional claims-based measure, OP-32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, but are finalizing its inclusion in the measure set for the CY 2018 payment determination and subsequent years instead of for the CY 2017 payment determination and subsequent years as proposed. Before publicly reporting this measure, however, we will conduct a dry run (a preliminary analysis) for facilities to review their performance and provide feedback. For more detailed information about the dry run, we refer readers to our discussion in section XIII.E. of this final rule with comment period.

As we noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530) and consistent with the modifications we are finalizing in this final rule with comment period, we calculate claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions.

(2) Chart-Abstracted Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530 through 68531) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) for detailed discussions of the information collection requirements for the previously finalized chart-abstracted measures (OP-1, OP-2, OP-3, OP-4, OP-5, OP-6, OP-7, OP-18, OP-20, OP-21, OP-22, OP-23, OP-29, OP-30, and OP-31).

In the CY 2015 OPPS/ASC proposed rule (79 FR 41034), we proposed to remove three chart-abstracted measures from the Hospital OQR Program beginning with the CY 2017 payment determination, OP-4: Aspirin at Arrival (NQF # 0286); OP-6: Timing of Prophylactic Antibiotics; and OP-7: Perioperative Care: Prophylactic Antibiotic Selection for Surgical

Patients (NQF # 0528). In section XIII.C.3. of this final rule with comment period, we are finalizing our proposal to remove two of these measures (OP-6 and OP-7) from the Hospital OQR Program for the CY 2017 payment determination and subsequent years. We are not finalizing our proposal to remove OP-4 and refer readers to section XIII.C.3. of this final rule with comment period for a detailed discussion. We previously estimated that each participating hospital will spend 35 minutes (or 0.583 hours) per case to collect and submit the data required for the chart-abstracted measures finalized for the CY 2015 payment determination and subsequent years (OP-1, OP-2, OP-3, OP-4, OP-5, OP-6, OP-7, OP-18, OP-20, OP-21, OP-22, and OP-23) (78 FR 75171). Because we are finalizing our proposals to remove two of these measures, we believe that the time to chart-abstract measures will be reduced by 16.7 percent (2 of 12 measures) per case. Therefore, we estimate that hospitals will spend approximately 29 minutes (0.483 hours) per case to collect and submit these data.

Data submitted for the CY 2014 payment determination indicate that the average hospital will submit approximately 1,266 cases per year for these measures. Therefore, as a result of our removal of 2 chart-abstracted measures, we estimate that the time it will take for the average hospital to abstract data for all of the chart-abstracted measures will be 612 hours per year (1,266 cases \times 0.483 hours). We estimate that there will be approximately 3,300 hospitals that participate in the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Therefore, we estimate that the chart-abstracted measures for the CY 2017 payment determination and subsequent years will result in a burden of 2.02 million hours (612 hours \times 3,300 hospitals) for all participating hospitals, for a total financial burden of approximately \$61 million (2.02 million hours \times \$30/hour).

In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated that OP-29 and OP-30 would require 25 minutes (0.417 hours) per case per measure to chart-abstract. We also estimated that hospitals would abstract 384 cases per year for each of these measures. Our estimate for the CY 2017 payment determination and subsequent years has not changed from last year's estimate (although, as noted above, we have changed our estimate for the CY 2016 payment determination based on the delay of reporting OP-29 and OP-30).

based outcome measures would be nominal for the CY 2017 payment determination and for subsequent years.

In section XIV.B.5. of this final rule with comment period, we are finalizing our proposal to add one additional claims-based measure to the ASCQR Program, but are finalizing its inclusion in the measure sets for the CY 2018 payment determination and subsequent years, instead of the measure set we proposed for the CY 2017 payment determination and subsequent years. Before publicly reporting this measure, we plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to section XIV.B.5 of this final rule with comment period for a detailed discussion of the dry run.

Because this measure, ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, will be computed by CMS based on paid Medicare FFS claims, and will not require ASCs to submit QDCs, we do not anticipate that this measure would create additional burden to ASCs during the dry run or for the CY 2018 payment determination and subsequent years.

d. Web-Based Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174) for detailed discussions of the information collection requirements for the five previously-adopted Web-based measures, excluding ASC-11, which we proposed for voluntary inclusion in the ASCQR Program for the CY 2017 payment determination and subsequent years. The five previously adopted measures are: ASC-6: Safe Surgery Checklist Use; ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF # 0431); ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF # 0658); and ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF # 0659).

For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC-6: Safe Surgery Checklist Use and the ASC-7: ASC

Facility Volume measures would be 1,756 hours (5,260 ASCs \times 2 measures \times 0.167 hours per ASC) and \$52,680 (1,756 hours \times \$30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure would be 18,005 hours and \$540,150 (18,005 hours \times \$30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for ASCs with a single case per ASC for the chart-abstracted ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF # 0658) and ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF # 0659) measures would be 3,067 hours and \$92,010 (3,067 hours \times \$30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

In section XIV.E.3.c. of this final rule with comment period, we are finalizing our proposal that data collection and submission be voluntary for the CY 2017 payment determination and subsequent years for ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536), meaning we would not subject ASCs to a payment reduction with respect to this measure during the period of voluntary reporting. We continue to believe this measure addresses an important area of care, and anticipate that many facilities will report this measure on a voluntary basis. In the CY 2014 ASC/OPPS final rule with comment period (78 FR 75173), we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data for this measure, making the total estimated burden for ASCs with a single case per ASC 3,067 hours (5,260 ASCs \times 0.583 hours per case per ASC) annually. We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization. We estimate that approximately 20 percent of ASCs would elect to report this measure on a voluntary basis; therefore, we estimate the total estimated burden for ASCs with a single case per ASC to be 613 hours (1,052 ASCs \times 0.583 hours

per case per ASC) and \$18,390 (613 hours \times \$30.00 per hour) annually for the CY 2017 payment determination and subsequent years.

e. Extraordinary Circumstances Extension or Exemptions Process

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140) for a complete discussion of our extraordinary circumstances extension or waiver process under the ASCQR Program. In the CY 2015 OPPS/ASC proposed rule, we did not propose to make any substantive changes to this process. However, in the future, we will refer to the process as the extraordinary circumstances extensions or exemptions process. In section XIV.E.7. of this final rule with comment period, we note that we intend to make certain changes to the form to ensure that the form is consistent across CMS quality reporting programs. We do not anticipate that these minor changes would affect the burden estimates for this process.

f. Reconsideration

While there is burden associated with filing a reconsideration request, the regulations at 5 CFR 1320.4 for the PRA (44 U.S.C. 3518(c)(1)(B)) exclude collection activities during the conduct of administrative actions such as reconsiderations.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments on this burden.

XX. Waiver of Proposed Rulemaking and Response to Comments

A. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on a proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I codes (CPT codes) and Level II codes that are intended to provide uniformity to coding procedures,

TABLE 53—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2014 TO CY 2015 AS A RESULT OF THE CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$42 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	\$42 million.

d. Effects of Requirements for the Hospital OQR Program

In section XIII. of this final rule with comment period, we are finalizing policies affecting the Hospital OQR Program. Of 3,325 hospitals that met eligibility requirements for the CY 2014 payment determination, we determined that 88 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (70 of the 88) chose not to participate in the Hospital OQR Program for the CY 2014 payment determination. We estimate that approximately 90 hospitals will not receive the full OPD fee schedule increase factor for the CY 2017 payment determination and subsequent years.

In section XIII.E. of this final rule with comment period, we are finalizing our proposal to add one claims-based quality measure, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, for the Hospital OQR Program for the CY 2018 payment determination and subsequent years, instead of the CY 2017 payment determination and subsequent years as proposed. Because this measure is claims-based, it will not require additional burden from data reporting or other action on the part of the hospitals. Therefore, we do not anticipate that this measure will cause any additional facilities to fail to meet requirements the Hospital OQR Program for the CY 2018 payment determination and subsequent years.

In section XIII.C.3. of this final rule with comment period, for the CY 2017 payment determination and subsequent years, we are finalizing our proposal to remove OP–6 and OP–7 from the Hospital OQR Program. However, we are not finalizing our proposal to remove OP–4 and are retaining that measure in the Hospital OQR Program for reasons discussed in section XIII.C.3. In sections XIII.D.3.b. and c. of this final rule with comment period, we are also finalizing our proposal to exclude OP–31 from the CY 2016 payment determination measure set and to change that measure from required to voluntary for the CY 2017 payment determination and subsequent years.

Hospitals will not be subject to a payment reduction with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting.

We anticipate a reduction in burden of approximately 840,517 hours or \$25.2 million across participating hospitals from the two measures we are removing and the measure we are making voluntary, as further detailed in sections XIII.C.3. and XIII.D.3.c. of this final rule with comment period, respectively, and the information collection requirements in section XIX.C.1. of this final rule with comment period. We refer readers to the information collection requirements section of this final rule with comment period (section XIX.C.1. of this final rule with comment period) for a detailed discussion of the financial burden of the requirements of the Hospital OQR Program.

The validation requirements that we are finalizing for the CY 2017 payment determination and subsequent years will result in medical record documentation of approximately 6,000 cases per quarter (up to 12 cases per quarter for 500 hospitals) submitted to the designated CMS contractor. In section XIII.H.3.e. of this final rule with comment period, we are finalizing our proposal to allow hospitals to submit medical record documentation for validation using either of two methods: (1) Through paper medical records; or (2) by securely transmitting electronic versions of medical information by either (a) downloading or copying the digital image (that is, a PDF) of the patient chart onto CD, DVD, or flash drive and shipping the electronic media following instructions specified on the QualityNet Web site; or (b) securely submitting digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site.

As stated in prior rulemaking (76 FR 74577), we will pay for the cost of sending paper medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately \$1.00 per case for postage. For both new electronic methods, we are finalizing our proposal in the information

collection requirements section of this final rule with comment period to reimburse hospitals for sending medical records electronically at a rate of \$3.00 per patient chart.

As we stated in the CY 2014 OPPI/ASC final rule with comment period (78 FR 75192), we have found that an outpatient medical chart generally contains up to 10 pages. However, because we do not yet know how many hospitals will choose to submit data electronically or through paper, we cannot estimate the total cost of expenditures and are unable to estimate the number of hospitals that will fail the validation documentation submission requirement for the CY 2017 payment determination. Because we will pay for the data collection effort, we believe that a requirement for medical record documentation for up to 12 cases per quarter for 500 hospitals for CY 2015 represents a minimal burden to Hospital OQR Program participating hospitals.

e. Effects of CY 2015 Policies for the ASCQR Program

In section XIV. of this final rule with comment period, we are adopting policies affecting the ASCQR Program. Of 5,260 ASCs that met eligibility requirements for CY 2014, we determined that 116 ASCs did not meet the requirements to receive the full annual payment update.

In section XIV.B.5. of this final rule with comment period, we are finalizing the adoption of one claims-based quality measure, ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, for the ASCQR Program beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed. The measure is claims-based and will not require additional data reporting or other action by ASCs. Therefore, we do not anticipate that this measure will cause any additional ASCs to fail to meet the ASCQR Program requirements. We present the time and burdens associated with our finalized policies and proposals in section XIX.C.2. of this final rule with comment period.

In section XIV.E.3.b. of this final rule with comment period, we noted the 3-