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September 6, 2013

Ms. Marilyn B. Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1601-P  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals

Dear Ms. Tavenner:

On behalf of the more than 79,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the calendar year (CY) 2014 proposed rule: *Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals* published in the *Federal Register* on July 19, 2013. Our comments on issues of interest to ACS will first address the outpatient prospective payment system (OPPS) proposals, followed by the ambulatory surgical center (ASC) proposals. We also provide comments on the Hospital Outpatient Quality Reporting (OQR) Program updates and the ASC Quality Reporting (ASCQR) Program.

## I. PROPOSED UPDATES AFFECTING OPPS PAYMENTS

The OPPS currently packages medical devices, medical and surgical supplies, surgical dressings, and implantable biologicals into the related procedure. For CY 2014, CMS proposes to expand the existing packaging policy for implantable biologicals to unconditionally package all drugs and biologicals,



including skin substitutes, that function as supplies or devices in a surgical procedure.

The Centers for Medicare & Medicaid Services (CMS) states that “skin substitutes” refers to a category of products that are commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers, described by Current Procedural Terminology (CPT) codes 15271-15278. The ACS agrees with CMS that CPT codes 15271-15278 require the use of at least one skin substitute product to properly perform the procedure. However, the ACS believes that CMS is proposing to incorrectly adopt the term “skin substitute” and is creating a broad definition for products that are used to treat clinically different wounds.

CMS states that skin substitutes described by CPT codes 15271-15278 do not function like human skin that is grafted onto a wound and instead are various types of wound dressings that stimulate the host to regenerate lost tissue and replace the wound with functional skin. The ACS strongly disagrees with this assessment. The products described by codes 15271-15278 do not function as “covers,” “biologic wound dressings,” “wound dressings,” or “surgical dressings.” A dressing is a material that is utilized for covering and protecting a wound. Although it may be incorporated into the wound, the goal of a dressing is to protect a wound from contamination, to manage the wound conditions such as exudate, necrotic tissue, or excess dryness without exerting any direct biological effect in the wound bed.<sup>1</sup> In 2012, the American Medical Association CPT Editorial Panel, the ACS, and several other medical associations worked to develop new skin substitute CPT codes. As a result, codes 15271-15278 were created to describe the work of placing skin substitute grafts. A new subheading titled “definitions” was added to the 2012 CPT Manual that provides a more thorough explanation of surgical preparation, autografts/tissue cultured autografts, and skin substitute grafts. CPT states that skin substitute grafts include non-autologous human skin (dermal or epidermal, cellular and acellular) grafts (such as homograft, allograft), non-human skin substitute grafts (for example, xenograft), and biological products. CPT explicitly states that codes 15271-15278 are not used to report the application of non-graft wound dressings (e.g., gel, ointment, foam, and liquid) or injected skin substitutes. The ACS believes that the definitions in the CPT Manual accurately represent the use of codes 15271-15278 and CMS’ assumption that these products are various types of wound dressings is inaccurate. We urge CMS to correct the definition of skin substitutes so that it is accurate and to

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<sup>1</sup> Jones, Vanessa, Joseph E. Grey, and Keith G. Harding. “ABC of wound healing.” *BMJ*. 2006 April 1; 332(7544): 777–780.

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review the CPT definitions and guidelines for the use of these codes and the products associated with them.

CMS also states that packaging payment for skin substitutes into the Ambulatory Payment Classification payment for the related surgical procedures would result in a total payment that is more reflective of the average resource costs for the procedure because these products vary significantly from product to product. However, a range of skin substitutes exists and not all able to be used interchangeably to treat different types of chronic wounds. The ACS believes that the proposed policy will provide a greater incentive to hospital outpatient departments to limit the types of skin substitutes available to surgeons, thereby restricting them to less expensive options that may not be the best treatment for the patient's chronic wound.

For example, there is a significant difference in cost between the product Biobrane, which is a synthetic membrane, and Apligraf, which is a biologic skin substitute. In some clinical instances Biobrane is appropriate and may decrease length of patient stay, increase speed of healing, and decrease pain. However, there are clinical conditions that require the more costly product Apligraf. Although, the cost of the procedure is significantly more for Apligraf patients, the wound may respond better and the patient's quality of life may be improved.

We urge CMS not to implement this policy because flexibility is needed in choosing the most medically appropriate skin substitute to treat chronic wounds in order to support optimal healing and quality outcomes. Rather, the ACS supports additional evidence-based research on the use of skin substitutes and the development of guidelines and provider education materials using the Food and Drug Administration indications and CPT definitions.

## II. PROCEDURES THAT WOULD BE PAID ONLY AS INPATIENT PROCEDURES

CMS did not identify any procedures for removal from the inpatient list and proposes no changes to the list for CY 2014. We restate our previous comments regarding our request to add the following eight laparoscopic colectomy-related CPT codes to the inpatient list:

- **44202** (Laparoscopy, surgical; enterectomy, resection of small intestine, single resection and anastomosis)
- **44203** (Laparoscopy, surgical; each additional small intestine resection and anastomosis)

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- **44204** (Laparoscopy, surgical; colectomy, partial, with anastomosis)
- **44205** (Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy)
- **44206** (Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure))
- **44207** (Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis))
- **44208** (Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy)
- **44213** (Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy).

These eight codes are currently assigned status indicator “T,” meaning they are payable under either the inpatient or outpatient payment systems. We urged CMS to add these codes to the inpatient list because it is unsafe to perform these procedures in the outpatient setting.

Below we address the five criteria that CMS uses to identify procedures that may appropriately be removed from the inpatient list. Although these eight laparoscopic codes are not currently on the inpatient list, it is clear that none of the five criteria apply to the eight codes at issue. Because a convincing argument cannot be made that it is appropriate for these eight codes to be payable in the outpatient setting based on CMS’ criteria, it is clear that they should be added to the inpatient list.

**Criterion 1: Most outpatient departments are equipped to provide the services to the Medicare population.**

Most outpatient departments are not equipped to provide the services described by codes 44202-44208 and 44213 to the Medicare population due to the length of stay and risk of complications associated with these procedures. Codes 44202 and 44203 describe laparoscopic removal of the small intestine, codes 44204-44208 describe laparoscopic partial colectomy services, and code 44213 is a separately billable code for the mobilization of the splenic flexure that must be billed with a laparoscopic partial colectomy. A laparoscopic colectomy almost always requires a stay more than one Medicare utilization day (CMS’ recently finalized guidance on the length of time appropriate for the presumption of an inpatient admission), with most studies showing the average length of stay no less than four days at the very least.<sup>2</sup> If a laparoscopic

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<sup>2</sup> See David P. Eisenberg et al., *Short- and Long-term Costs of Laparoscopic Colectomy are Significantly Less than Open Colectomy*, *Surg. Endosc.*, Jan. 14, 2010,



colectomy were performed in the outpatient setting, that patient would be admitted as an inpatient immediately following the surgery for the next several days. As such, the length of stay associated with these procedures is far too long for the outpatient setting.

Performing these procedures in the outpatient setting is a waste of hospital resources and an unnecessary drain on the healthcare system, but also has a detrimental impact on patients. A patient could potentially be moved or experience a delay in care as their status is transferred from outpatient to inpatient. In addition, there is always a risk that the laparoscopic colectomy may require a conversion to an open colectomy. Although that risk has decreased since laparoscopic colectomy was first described in 1991, between five and 21 percent of laparoscopic colectomies are still converted to open.<sup>3</sup> Hospital outpatient departments are not equipped to provide open colectomies to the Medicare population. Furthermore, the Medicare population is at higher risk of complications because of a higher incidence of comorbidities. Despite the fact that some complications maybe lower for laparoscopic colectomy compared to open colectomy, approximately 21 percent of laparoscopic colectomy Medicare patients experience complications, primarily bleeding, ileus, and gastrointestinal complications.<sup>4</sup> In addition, among the Medicare population, approximately 25 percent of patients are monitored in the intensive care unit (ICU) following laparoscopic colectomies.<sup>5</sup> Although the rate of ICU monitoring is lower following laparoscopic compared to open colectomies, this rate is far too high for these procedures to be performed safely in the outpatient setting.

Patients who receive services described by codes 44203-44308 and 44213 in the outpatient as opposed to the inpatient setting also suffer a greater financial burden. Although the outpatient copayment for a single outpatient service may not be more than the inpatient deductible, the total copayments for all

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<http://link.springer.com/article/10.1007%2Fs00464-010-0909-1> (average length of stay for laparoscopic colectomy was **5.2 days**;  $p < 0.0001$ )

See Jensen T.C. Poon et al., *Impact of the Standardized Medial-to-Lateral Approach on Outcome of Laparoscopic Colorectal Resection*, 33 *World J. Surg.* 2177 (2009) (average length of stay for laparoscopic colectomy was **between 4 and 7 days**;  $p < 0.001$ ).

See M.S. Vlug, et al., *Systematic Review of Laparoscopic vs. Open Colonic Surgery within an Enhanced Recovery Programme*, 11 *Colorectal Disease* 335, 339 (2009) (average length of stay for laparoscopic colectomy for the significant studies in this paper had a median of **between 4 and 8 days**;  $p < 0.05$ ).

<sup>3</sup> Linda C. Cummings, et al., *Laparoscopic Versus Open Colectomy for Colon Cancer in an Older Population: a Cohort Study*, 10 *World J. of Surg. Onc.* 31 (2012).

<sup>4</sup> *Id.* (complication rates were 21.5 percent for laparoscopic colectomy patients ( $p = 0.03$ )).

<sup>5</sup> *Id.* (ICU monitoring rates were 25.2 percent for the laparoscopic colectomies).

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outpatient services could exceed the inpatient deductible. In addition, a patient who is admitted immediately following outpatient surgery could be required to pay the outpatient copayment in addition to the inpatient deductible. Patients could also pay more for self-administered drugs, which are not covered in the outpatient setting, but are covered for inpatients. In addition, time spent as a hospital outpatient does not count toward the three-day qualifying inpatient stay for Medicare Part A coverage of care in a skilled nursing facility (SNF). Consequently, patients who receive these services in the outpatient rather than the inpatient setting are exposed to both a physical and financial risk of harm with no added benefit.

In summary, because these procedures require a hospital stay of at least several days, carry a risk of the laparoscopic procedure leading to a conversion to open, a risk of other complications or need for ICU treatment, in addition to the risk of financial harm to the patient and the healthcare system, it is clear that criterion 1 is not met.

**Criterion 2: The simplest procedure described by the code may be performed in most outpatient departments.**

The simplest procedure described by codes 44202-44208 and 44213 may not be safely performed in an outpatient department. Because every patient and every procedure is different, there could be cases described by each of these codes that are not the same level of complexity. For example, some procedures described by 44206 could be more complicated than others that are also billed using 44206. However, as discussed above, all of the procedures described by 44202-44208, and 44213 are inherently complex, requiring a hospital stay of several days, possibly in the ICU, and with a risk of complications and potential conversion to open. It is unsafe to perform any procedure described by these codes in any outpatient department, so criterion 2 is not met.

**Criterion 3: The procedure is related to codes that CMS has already removed from the inpatient list.**

The eight laparoscopic codes are not related to codes that CMS has recently removed from the inpatient list. We reviewed the codes that CMS has removed from the inpatient list over the past 10 years and could not find codes that are similar to the four codes at issue. Although CMS has removed some laparoscopic procedures, CMS has not removed any laparoscopic colectomy codes or any type of colon-related procedure. Consequently, criterion 3 is not met.

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**Criterion 4: A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.**

The eight laparoscopic procedures are performed infrequently on an outpatient basis. Based on 2011 American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) data, none of the codes are performed more than 5.7 percent of the time in the outpatient setting. It is possible that even this small percentage is due to miscoding or other errors. As such, the data show that these procedures are being performed in very few hospitals on an outpatient basis, relative to the frequency that they are being performed in the inpatient setting. As such, criterion 4 is not met.

**Table 1: Site of Service Frequency of Laparoscopic Partial Colectomy Codes**

Code	Descriptor	Place of Service Frequency
44202 (T)	Laparoscopy, surgical; enterectomy, resection of small intestine, single resection and anastomosis)	Inpatient: 93.40% <b>Outpatient: 5.64%</b> Physician office: 0.51% ASC: 0.11% ER: 0.34%
44203 (T)	Laparoscopy, surgical; each additional small intestine resection and anastomosis	Inpatient: 96.88% <b>Outpatient: 3.13%</b> Physician office: No RUC data ASC: No RUC data ER: No RUC data
44204 (T)	Laparoscopy, surgical; colectomy, partial, with anastomosis	Inpatient: 94.29% <b>Outpatient: 5.33%</b> Physician office: 0.24% ASC: 0.10% ER: 0.04%
44205 (T)	Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy	Inpatient: 94.90% <b>Outpatient: 4.672%</b> Physician office: 0.25% ASC: 0.12% ER: 0.05%
44206 (T)	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)	Inpatient Hospital: 95.60% <b>Outpatient Hospital: 4.12%</b> Physician Office: 0.09%



		ASC: 0.09% ER: 0.09%
44207 (T)	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)	Inpatient Hospital: 94.73% <b>Outpatient Hospital: 4.98%</b> Physician Office: 0.19% ASC: 0.10% ER: 0.00%
44208 (T)	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy	Inpatient Hospital: 95.40% <b>Outpatient Hospital: 4.20%</b> Physician Office: 0.20% ASC: 0.20% ER: No RUC data
44213 (T)	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)	Inpatient Hospital: 94.89% <b>Outpatient Hospital: 4.91%</b> Physician Office: 0.09% ASC: 0.08% ER: 0.03%

**Criterion 5:** A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by CMS for addition to the ASC list.

The four laparoscopic partial colectomy codes are currently not on the ambulatory surgical center (ASC) list of covered surgical procedures. Currently there is no CMS proposal to add these codes to this list. Based on Table 1, above, these procedures are performed with a frequency of 0.2 percent or less in an ASC and this small percentage is likely due to coding errors. CMS' policy is to only include procedures on this list if they do not pose a safety risk to Medicare beneficiaries and would not require an overnight stay if performed in an ASC. These procedures, however, would pose a significant risk of safety to the Medicare population if performed in an ASC due to the complexity of the procedures and as discussed under Criterion 1, would almost always require an overnight stay of several days. For these reasons it is unlikely that these codes would ever be proposed or included on the ASC list of covered surgical procedures so criterion 5 is not met.



Therefore, we urge CMS to add codes 44202-44208 and 44213 to the inpatient list. We see only a benefit to CMS, providers, health systems, and primarily patients, to adding these codes to the inpatient list. We are happy to provide any additional information on this issue, if needed.

### III. PROPOSED NONRECURRING POLICY CHANGES

CMS anticipates that it will end its nonenforcement policy for direct supervision of outpatient therapeutic services in critical access hospitals (CAHs) and small rural hospitals. This will result in CAHs and small rural hospitals being required to comply with the CMS supervision policy that requires direct supervision of therapeutic services, except for those that CMS identifies as appropriate for general supervision.

We support the end of the nonenforcement policy. While we share the concerns of CAHs and small rural hospitals regarding the shortage of general surgeons across the country, the ACS believes supervision requirements must be applied uniformly across all care settings for reasons of patient safety. We support CMS' policy regarding not establishing different supervision requirements for CAHs/small rural hospitals and OPPS hospitals for the same services.

### IV. PROPOSED UPDATES TO THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

#### a. Proposed Covered Surgical Procedures Designated as Office-Based

CMS annually reviews volume and utilization data to identify "office-based" procedures that are added to the ASC list of covered surgical procedures. These procedures are performed more than 50 percent of the time in physicians' offices and CMS's medical advisors believe they are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Based on its review of CY 2012 data, CMS proposes to permanently identify the following three additional procedures as office-based.

Code	Descriptor
26341	Manipulation, palmar fascial cord (i.e., dupuytren's cord), post enzyme injection (e.g., collagenase), single cord
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
36595	Mechanical removal of pericatheter obstructive material (e.g., fibrin sheath) from central venous device via separate venous access

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The ACS is concerned about the designation of CPT code 37761 as office-based because we believe that CMS data indicating that this code is performed more than 50 percent of the time in the office is a result of inaccurate coding. Consequently, we do not believe that the procedure described by the code is performed more than 50 percent of the time in the office. The procedure described by CPT code 37761, *Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg*, is a 90-day global procedure established in 2010 to describe a less radical open approach to perforating veins. It is an open vascular surgical operation requiring a direct incision over the perforator vein, dissection of the subcutaneous tissue for exposure, and direct ligation of a visualized vessel below the fascia. The vein is ligated with a suture ligature. In this condition the vein is abnormally enlarged and fragile, and a significant amount of care is needed when performing this procedure as not to injure the vein or adjacent nerve. The procedure may be done several times for each vein that requires treatment. As such, the ACS does not believe the procedure described by CPT code 37761 is truly performed 50 percent of the time or more in the office, and we urge CMS not to designate this code as office-based. Instead, the ACS supports the creation of provider education material on the appropriate use of code 37761 and is happy to work with CMS to develop the necessary material to promote accurate coding.

**b. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates**

CMS proposes to continue its policy of updating the ASC conversion factor by a measure of inflation in the Consumer Price Index for Urban Consumers (CPI-U). We urge CMS to adopt the hospital market basket instead of the CPI-U to update ASC payment rates for inflation.

In the CY 2013 OPPS/ASC final rule, CMS acknowledged that stakeholders have in the past urged CMS to use the hospital market basket as the measure of ASC cost increases. CMS responded that the hospital market basket does not align with the cost structures of ASCs. CMS indicated that a much wider range of services, such as room and board and emergency services, are provided by hospitals but are not reflective of costs associated with providing services in ASCs.

There is broad agreement that the CPI-U measures inflation in a basket of consumer goods that is atypical of what ASCs purchase and is therefore flawed for the purposes of the ASC payment system. The CPI-U measures costs of goods purchased by typical consumers, which reflects the types and weights of

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categories typical of an American household, rather than an outpatient surgical provider, or even any type of healthcare facility. The hospital market basket, on the other hand, is an available proxy for ASC costs and is superior to the use of the CPI-U. The hospital market basket reflects producer price inputs and measures health care delivery-related costs. The hospital market basket is also used to update the OPSS payment rates. Because the OPSS cost structure looks much like the cost structure of ASCs, if the hospital market basket is appropriate for updating OPSS payment rates, it is also appropriate for updating ASC payment.

In addition, aligning the ASC and OPSS update and productivity factors will help minimize the silos around settings of care. As such, we urge CMS to use the hospital market basket to update the ASC conversion factor because the hospital market basket more closely reflects the cost structure of ASCs compared to the CPI-U.

#### **V. HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM UPDATES AND PROPOSED REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTERS QUALITY REPORTING PROGRAM**

##### ***CY 2016 Payment Determination for both Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Reporting Program***

CMS proposes to add several new measures to the Hospital Outpatient Quality Reporting (OQR) program and the Ambulatory Surgical Center Quality Reporting (ASCQR) program for CY 2016 payment determination, two of which are addressed below.

- Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

CMS states that in the average-risk population, colonoscopy screening is recommended in current guidelines at 10-year intervals, and performing colonoscopies too frequently increases patients' exposure to risk of procedural harm. CMS also states that the proposed measure assesses the percentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. However, the rule also indicates that the measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to

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receive a repeat colonoscopy in an interval that is *less* than the recommended amount of 10 years.

We request clarification on whether the intent of the measure is to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is *at least* 10 years or *less* than 10 years. It appears that that intent is to measure compliance with the current guidelines of repeat colonoscopies every 10 or more years, but the language of the rule seems contradictory.

Although we support this measure as it is currently used in the Physician Quality Reporting Program (PQRS), we have concerns with including it in the Hospital OQR and ASCQR programs because it is currently a physician-level measure and has not been specified or tested as a facility-level measure. We also agree with the Measure Applications Partnership (MAP) that inclusion of this measure in the Hospital OQR and ASCQR should be delayed until this time-limited measure is fully endorsed by the National Quality Forum (NQF).

- Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps – Avoidance of Inappropriate Use

CMS states that colonoscopy is the recommended method of surveillance after the removal of adenomatous polyps because it has been shown to significantly reduce subsequent colorectal cancer incidence. CMS also indicated that, based on a randomized trial, follow-up colonoscopy at three years detects important colonic lesions as effectively as follow-up colonoscopy at both one and three years. For this reason, CMS proposes to include this measure, which assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of three or more years since their last colonoscopy documented in the colonoscopy report.

Similar to the previous measure, we support this measure as it is currently used in PQRS, but we have concerns with including it in the Hospital OQR and ASCQR programs because it is currently a physician-level measure and has not been specified or tested as a facility-level measure. We also agree with the MAP that inclusion of this measure in the Hospital OQR and ASCQR should be delayed until this time-limited measure is fully endorsed by the NQF.

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## VI. PROPOSED CHANGES TO THE CONDITIONS FOR COVERAGE FOR ORGAN PROCUREMENT ORGANIZATIONS

Under current regulations Organ Procurement Organizations (OPOs) must meet three outcome measures, specified by CMS at CFR 486.318. CMS proposes to modify the regulations to allow OPOs to only be required to meet two of the three outcome measures. The ACS agrees with the American Society of Transplant Surgeons in their separately submitted letter that the three outcome measures serve an important role in providing an incentive for improved performance. Instead of finalizing the proposal, we urge CMS to strike a more nuanced balance between the need to avoid the chaos that would result from decertifying a substantial proportion of the current OPOs and the equally important need to provide incentives for poorly performing OPOs to improve their donation rates, yields, and organ quality. As such, we believe that implementing a “mitigating circumstances” process similar to the process that has been made available to transplant centers that do not meet CMS outcomes requirements strikes a more appropriate balance than scaling back OPO outcomes requirements. Making available a “mitigating circumstances” process would enable CMS to review the circumstances of underperforming OPOs individually to determine whether certification should be extended and, if so, for how long and under what conditions. Specific benchmarks for improved performance could be set, and CMS would retain the authority to take appropriate action if performance does not improve.

We appreciate the opportunity to provide comments regarding this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Bob Jasak, Deputy Director for Regulatory and Quality Affairs in our Division of Advocacy and Health Policy. He can be reached at [bjasak@facs.org](mailto:bjasak@facs.org) or at (202) 672-1508.

Sincerely,

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