

# PRT Questions from first review of: Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance, submitted by Digestive Health Network

## Questions to the Submitter

### *Questions on Model Design*

- 1. The Model Overview presented important data stating that three fifths of US adults age 50-75 are not up to date on their colonoscopy screenings. Yet, the rest of the document doesn't specifically address approaches to improving this failure. In a one-year episode payment approach, which does not seem to include any role for patient assignment to particular providers, specifically how does the payment model address this significant underuse?**

We are unclear what reference the PRT is citing that three-fifths of US adults are not up to date on the colonoscopy screenings. According to the American Cancer Society, in 2010, of people age 50 or older, for whom screening is recommended, 59% reported having received colorectal cancer testing consistent with current guidelines.<sup>1</sup>

We agree with the PRT that population health measures to improve CRC screening rates need to start at the level of the primary care practitioner – family practice, gynecology, internal medicine, geriatrician, etc. According to Medicare's data regarding who performs colonoscopy for CRC screening, gastroenterologists, surgeons, family practitioners, and internal medicine specialists are the specialties who primarily provide these services. The majority of the practitioners who provide this service are not part of an integrated delivery system. Therefore, before attempting to solve the population health issue, we believe it is important to first identify and address the barriers inherent in the current system.

The goals of this proposal are to eliminate waste and overuse in the performance of colonoscopy for colorectal cancer screening, surveillance, and diagnosis, and to reduce the barriers patients currently encounter while receiving this life-saving service. The Affordable Care Act (ACA) removes financial barriers for patients to receive preventive services which receive a grade of A or B from the US Preventive Services Task Force (USPSTF). However, Medicare has determined that for asymptomatic patients with positive findings on colorectal screening by a method such as a stool test, the otherwise asymptomatic beneficiary's colonoscopy is now considered as a diagnostic procedure when they are referred to the endoscopist for colonoscopy. This means that the service is no longer preventive, but rather a diagnostic procedure (with co-pays and deductibles) which can add

---

<sup>1</sup> See Colorectal Cancer Facts and Figures 2014-2016, American Cancer Society. Available at <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2014-2016.pdf>. Accessed February 5, 2016.

hundreds of dollars of cost to the patient. Although legislation has been introduced in Congress attempting to “fix” this situation, it has failed to pass. Our proposal is designed to address this barrier to patients receiving cost-effective CRC screening and diagnostic follow-up.

There are many other impediments to reaching the goal of increasing colorectal screening rates in the population. This proposal seeks to address and resolve several important barriers: patient fear of the procedure, the bowel preparation required, and the cost of the procedure. Our proposal creates opportunities for direct communication with patients, addressing their concerns and fears in a culturally and linguistically appropriate manner and explaining to the patient the importance in following the preparation protocol<sup>2</sup>. Further, this proposal addresses the unanticipated costs accruing to the beneficiary which result when a screening colonoscopy becomes a therapeutic exam when a lesion is found.

**Conversely, available data finds that overuse produced by too frequent follow-up screening and surveillance colonoscopies do not occur within the one year of the bundled episode but rather a number of years out.<sup>3</sup> How does a one-year bundle address the incentive for too frequent examinations, which occur outside of the payment episode window?**

We have proposed that collection of four quality measures from Medicare’s Quality Payment Program be incorporated as essential components of this model<sup>4</sup>.

- Age Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (quality ID 320, NQF 0658)
  - Percentage of patients aged 50 to 75 years of age receiving a 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
- Age Appropriate Screening Colonoscopy (quality ID 439)
  - The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31
- Colonoscopy Interval for Patients with a history of Adenomatous Polyps – Avoidance of Inappropriate Use (quality ID 185, NQF 0659)
  - Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous

---

<sup>2</sup> See Jones RM, Devers KJ, Kuzel AJ, Woolf SH. “Patient-reported barriers to colorectal cancer screening: a mixed-methods analysis.” *Am J Prev Med.* 2010 May;38(5):508-16.

<sup>3</sup> See Kruse, G.R., Kahn, S.M., Zaslavsky, A.M. *et al*, “Overuse of Colonoscopy for Colorectal Cancer Screening and Surveillance, *Journal of General Internal Medicine*, September 30, 2014:277-283.

<sup>4</sup> Further information on the quality measures, numerator and denominator descriptions are available at <https://qpp.cms.gov/measures/quality>.

colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy

- Screening Colonoscopy Adenoma Detection Rate (quality ID 343)
  - The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy

Collection of quality data for CMS QPP measures 320, 439, and 185 addresses the PRT’s question of ensuring that surveillance intervals are performed at appropriate intervals. Our proposal to incorporate these quality measures is consistent with our support of the Choosing Wisely recommendation which states “Do not repeat colorectal cancer screening (by any method) for 10 years after a high-quality colonoscopy that does not detect neoplasia.”<sup>5</sup>

CMS has the capability to audit performance at a beneficiary and provider level. We welcome input from the PRT on how to ensure that the Choosing Wisely recommendations and CMS QPP measures are incorporated into the performance criteria for this model.

- 2. The flow of funds under the proposed payment model is unclear. Specifically, which provider receives the payment? In addition, how is the payment allocated to other team members? Finally, who has overall management and is responsible for recovering funds from team members if performance targets are not met, or could that be accomplished through some form of payment withhold?**

Thank you for your question. The endoscopist – whether gastroenterologist, surgeon, internist, or primary care physician – would be the individual who receives the payment. The endoscopist has the responsibility of allocating payment to other team members, which we call the “associated team members”. We propose that associated team members– anesthesiologist, radiologist, pathologist, emergency physician – are initially paid on a fee-for-encounter basis when their services are required. Working with our actuarial consultant, we have analyzed the Medicare 5% files for CY 2012, 2013, and 2014, and calculated a prospective per-procedure payment which includes full payment for associated team members providing anesthesia, radiology, pathology, emergency department, evaluation & management, and observation services. As part of this model, payments and utilization would be reconciled after one year. If savings are achieved, and the associated team members have chosen to enter into a risk-sharing agreement with the endoscopists, the savings would be distributed proportionally to participants. If performance targets are not met, then funds are recovered from the endoscopist and those associated team members having chosen to participate in risk sharing, subject to the limitation on downside risk.

---

<sup>5</sup> See <http://www.choosingwisely.org/clinician-lists/american-college-surgeons-colorectal-cancer-screening-every-ten-years/>, accessed February 5, 2017.

Following our analysis of the Medicare 5% file, we have calculated the percentage of beneficiaries who:

- Undergo a repeat colonoscopy within 1 year of the index procedure
- Have an emergency department (ED) visit within 7 days of the index procedure
- Have an outpatient observation claim within 7 days of the index procedure
- Have an inpatient admission within 7 days of the index procedure

Working with our actuarial consultants, we have calculated a stop-loss premium which could be incorporated into the per-procedure payment under this model. We believe this would provide an incentive for the endoscopist AND associated team members to participate in upside and downside risk-sharing, while aligning all healthcare professionals and providers to provide the highest quality services to beneficiaries who require colonoscopy for CRC screening, diagnosis and surveillance.

**3. The payment approach described on pages 13-15 involves a combination of a one-time payment to cover a number of activities and a prospectively-based bundled payment. How would you price out these payments? Do you have any estimates of their size?**

As noted in our response to question #2, we have engaged an actuarial consultant to assist us in reviewing the Medicare 5% file. Our analysis used the ICD-9 codes identified in the proposal which are taken from the CMS National Coverage Determination for colorectal cancer screening. This has allowed us to calculate the non risk-adjusted Medicare costs per beneficiary, whether the index colonoscopy service is performed in the hospital outpatient department (HOPD) or ambulatory surgery center (ASC). We used this information to develop a prospective bundled payment for the service. Because the analysis is proprietary, we cannot share the actual findings from the analysis, but would be pleased to share our analysis with the PRT and CMS once confidentiality is assured.

The analysis looks at the paid claims costs of the following components, broken out by professional and facility claims:

- Index Colonoscopy
  - Colonoscopy
  - Anesthesia
  - Moderate Sedation
  - J-codes
  - Radiology
  - Capsule Endoscopy
  - Pathology
  - Other Facility Cost (including prep agents)
- Repeat Colonoscopy

- Colonoscopy
- Anesthesia
- Moderate Sedation
- J-codes
- Radiology
- Capsule Endoscopy
- Pathology
- Other Facility Cost (including prep agents)
- % of patients undergoing repeat colonoscopy within 1 year of index procedure
- Emergency room (post index, 7-days)
  - % of patients having ED visit
  - % of patients with observation stay
  - % of patients with inpatient stay
- Emergency room (post repeat colonoscopy, 7-days)
  - % of patients having ED visit
  - % of patients with observation stay
  - % of patients with inpatient stay
- Evaluation and management, 30 days pre-index
- Evaluation and management, 1 year post-index

We are unclear of the PRT's request regarding "estimates of size" and would appreciate further clarification.

Based on our analysis of the Medicare 5% file for the three years, representing approximately 90,000 ± 2000 beneficiaries each year, we believe the total payment (incorporating the above components) for a procedure performed in the HOPD setting, is approximately \$1500. Of this, professional fees are approximately \$430, while the facility fees are approximately \$1050.

We believe that the total payment for a similar procedure performed in the ASC setting is approximately \$1050. Of this, the professional fees are approximately \$500 while the facility fees are approximately \$550. We believe the increase in professional fees represents higher utilization of anesthesia professionals in the ASC setting.

As noted in our proposal, 2014 Medicare data indicates that ASC utilization for the most common colonoscopy procedures is G0105-51.16%, G0121-43.77%, 45378-32.76%, 45380-44.06%, 45384 – 39.07%, and 45385-45.13%. In this model, we proposed to increase ASC utilization to 60% for applicable colonoscopy procedures in the first year, with a subsequent 5% increase per year until an ASC utilization of 75% is achieved in year four.

In our response to question #16, we identified the number of yearly colonoscopies performed for colorectal cancer screening, diagnosis, and surveillance in Medicare beneficiaries, based on claims and ICD-9 data. We calculated that the number of CRC

related colonoscopies for the most common colonoscopy procedures is 1,199,924, or approximately 1.2M procedures. We estimated that the current blended ASC utilization rate is approximately 45%. According to our analysis, the cost savings when the procedure is moved from the HOPD to ASC is \$450 / procedure. Increasing ASC utilization to 60% through migrating 180,000 colonoscopy procedures currently performed in the HOPD to the ASC setting would save \$81,000,000 for Medicare. Additional savings would be realized in subsequent years as we move towards the model's goal of 75% ASC utilization.

<b>Code</b>	<b>Description</b>	Medicare claims	CRC related claims
<b>45378</b>	Colonoscopy	461645	41502
<b>45380</b>	Colon, biopsy	963491	119810
<b>45384</b>	Colon, hot biopsy	121535	19671
<b>45385</b>	Colon, polypectomy	781487	538132
<b>G0105</b>	Colon, screen, high risk	231556	231556
<b>G0121</b>	Colon, screen, not high risk	249253	249253

As discussed in the proposal, CMS determined effective January 1, 2015 that anesthesia for patients undergoing colonoscopy for CRC screening was part of the preventive service covered without patient co-pay or deductible. We anticipate that the cost of anesthesia services may increase when the final prospective bundled payment is calculated.

Additional findings:

- The data suggests that approximately 1.1% of patient have an ED visit within 7 days of the index colonoscopy. This rate increases to 1.7% of patients within 7 days of the repeat colonoscopy.
- A slightly higher number of patients requiring observation were initially seen in the HOPD setting, while a higher number of patients requiring inpatient admission were initially seen in the ASC setting. We have not delved into the data to further understand the meaning of this data, but believe that this finding indicates the need for appropriate patient selection based on ASA status and other criteria to identify the right setting for the service for the right patient.
- Approximately 20% of patients have an E/M visit within the 30 days prior to the index procedure, and approximately 14% of patients have an E/M visit within 1 year of the index procedure. For this reason, we believe it is important to incorporate an E/M visit into the financial modeling for the one-time payment

- As discussed more fully in our responses to questions #11+12, we do not agree with the PRT's suggestions that all beneficiaries can receive pre-procedure counseling solely through an open-access model.

Please note that our analysis is based on Medicare national payment amounts. The calculations have not been adjusted for Medicare GPCI locality, nor do they include the one-time payment for care management and coordination activities. We look forward to correlating our data with Medicare's internal analysis.

With regards to the one-time payment, the costs for these services were determined by practice administrators, as discussed in our responses to questions #11+12. Our data indicates that it takes approximately 27-36 minutes for the office personnel to evaluate and inform a patient under an open access model, in addition to the practice expense staff times that are currently captured in the colonoscopy procedure reimbursement. While this remains a proprietary analysis, we are prepared to discuss this further with the PRT and CMS to identify an appropriate cost for the services, perhaps using a methodology similar to other CMS prospective care management models.

**4. The proposal emphasizes change of place of service from OPD to ASC, and page 15 specifically - refers to establishment of ASC utilization targets. Wouldn't it be easier to set the payment rates at the ASC price for both venues rather than expecting hospital-based clinicians to actually move their colonoscopy site of service (an approach briefly alluded to in the Flexibility section but not developed)?**

We agree with the PRT that it would be ideal if hospitals would agree to a site-neutral payment that is the same as the payment for when the procedure is performed in the ASC setting. We note that MedPAC has made similar comments in recent years. However, hospitals have been unwilling to negotiate a payment less than the Medicare OPPS fee schedule. We would welcome input from the PRT as to how the model could be constructed to encourage the hospital community to accept a site-neutral payment. In the absence of site-neutral payment, we have developed our model in a manner that would encourage the movement of patients from the HOPD to ASC setting, when clinically appropriate, and when the ASC setting is available.

As Medicare data suggests that the ASC setting is underutilized for the performance of this procedure, we have established ASC utilization targets which increase over a four-year period. We recognize that a percentage of patients will, for clinical reasons, still need to have their procedures performed in the HOPD setting.

This proposed model is voluntary, not mandatory. This model is not exclusive to gastroenterologists. There is nothing that requires endoscopists to participate in this model; if the endoscopist does not have access to an ASC setting then it would be their choice to not participate in the model.

5. **What are the total cost savings the proposal is attempting to achieve?**

If the targets are achieved, the costs savings can be summarized as follows:

- Movement of patients from HOPD to ASC setting should achieve a savings of approximately \$425 / procedure
- Reducing follow-up procedures from 15% to 7% should achieve a savings of approximately \$125 / procedure

We address this further in our response to question #3. These potential savings do not account for the one-time management fee in the proposal, nor do they account for the potential increase in anesthesia utilization effective January 1, 2015. Also, it is important to note that our savings calculations would not encourage the physician to skimp on care or require the patient to be denied medically necessary care. The proposed per-procedure price accounts for the patient to receive sedation, preparation, pathology, emergency department, observation, and evaluation & management services as necessary.

6. **On page 11, bottom, is any follow-up done if the PHQ-2 is positive? For example, do you go onto PHQ-9? If so, is PHQ-9 included in the bundle? If not, why? What provisions would there be for appropriate referral for positive screening? Is there a clinical or other rationale for selecting depression screening as a worthy added service the model can support, as opposed to, perhaps, blood pressure screening and referral? Is it simply related to the contribution of depression to poor procedure preparation? What other factors, such as cognitive impairments, could contribute to poor preparation and why did you not include them as well?**

We identified PHQ-2 because of preliminary data which suggest that depression is an unrecognized factor which could contribute to patients not undergoing recommended CRC screening and possibly contributing to poor preparation. We believe that screening for and addressing depression could lead to timely referral to the primary care provider for further intervention as well as potentially avoidable repeat procedures.

During 2016, we met with Majority and Minority staff members for the Senate Finance Committee. Collectively, they identified a need for specialists to be more involved in total patient care, citing PHQ-2 as a representative example. Based on their suggestions, we incorporated PHQ-2 into this proposal.

We concur that endoscopic proceduralists might not be the ideal physicians to diagnose and manage depression; however, we believe that encounters associated with screening colonoscopy may be opportunities to identify health issues where intervention may benefit our patients. PHQ-2 was selected as a simple depression screening tool (unlike PHQ-9) which can be administered quickly and efficiently by staff during preprocedure intake. As with other screening activities, patients testing positive would be referred back to their primary provider for further evaluation and management. We hypothesize that depression

may be one factor impacting poor procedure preparation and post-procedure complications and plan to examine this relationship. It is not the intent of this proposal, however, to exhaustively investigate all the variables which may impact colon preparation.

We would appreciate feedback from the PRT on the proposal to incorporate a PHQ-2 into the model. If the PRT does not recommend inclusion of such, we welcome their insight on other quality measures that would be part of this model. In our proposal, we identified these additional quality measures which would be part of the normal pre-surgical checklist.

- Preventive care and screening: body mass index (BMI) screening and follow-up plan (quality ID 128, NQF 0421)
- Preventive care and screening: tobacco use: Screening and cessation intervention (quality ID 226, NQF 0028)
- Preventive care and screening: screening for high blood pressure and follow-up documented (quality ID 317)
- Preventive care and screening: unhealthy alcohol use: screening and brief counseling (quality ID 431, NQF 2152)

We respectfully disagree with a comment submitted by one of the Gastroenterology societies, “Recommend removal of screening and counseling for obesity, tobacco and alcohol use (page 11) in this bundle. Although these are important services for our patients, they should not be the primary responsibility of the gastroenterologist, many of whom will be performing the screening colonoscopy in an open access system.”<sup>6</sup> The endoscopist is a physician. In our opinion, the physician should be responsible for evaluation of the entire patient, not simply the colon, rectum and anus.

#### *Other Questions*

- 7. The proposal focuses on hospital and ASC-based colonoscopies. However, these procedures are also provided in physician office settings – in Medicare 4-5% of the time for some of the codes. How would physician office-based colonoscopies be addressed in this proposal?**

According to Medicare data, office-based endoscopy is performed approximately 4-5% of the time, primarily in states such as New York, Illinois, Virginia, and Puerto Rico, where certificate of need laws historically restricted access to / development of more cost-effective models for the provision of endoscopic services. Not all physicians have the equipment to perform endoscopic services in their office setting, and not all office endoscopy settings have the equipment and staff to safely perform endoscopic procedures on ASA II-III patients.

---

<sup>6</sup> See [http://www.gastro.org/news\\_items/aga-supports-physician-focused-payment-models](http://www.gastro.org/news_items/aga-supports-physician-focused-payment-models), accessed February 5, 2017

Further, we are perplexed that Medicare's calculations of the payment for anesthesia services for gastrointestinal endoscopic procedures - code 00740 (Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum) and code 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum) - does not include any practice expense for the staff, supplies, and/or equipment to provide anesthesia in the office (non-facility) setting. As there is no mechanism for accounting for the staff, equipment, and supplies to safely provide anesthesia in the non-facility setting, we did not believe that we had the data to price this service in the office setting. We note that a coding change proposal to address this situation (practice expense costs of anesthesia in the non-facility setting) was brought to the CPT Editorial Panel during 2016, but the Panel did not elect to proceed with the request to establish a practice-expense only CPT code for this cost.

Recognizing these caveats, we do not see a problem if physicians who are currently equipped to provide office-based endoscopy wish to participate in this model, but would need to work with CMS and the actuaries to calculate a separate payment to accommodate for the costs of providing the service in the non-facility setting.

- 8. The proposal notes that the model can be expanded after several years of data collection (e.g. to other colonoscopy procedures). What is the clinician group that is being proposed to test this model? Is your proposal limited to DHN clinicians/patients only? Is it limited to gastroenterologists only?**

Thank you for the opportunity to clarify this point. Our proposal is not limited solely to DHN clinicians and/or their patients. We welcome and would encourage other endoscopists to participate in the model and data collection. To date, over 1000 Gastroenterologists in 12 states have identified a pressing need to develop a model with the goals of removing barriers to eligible patients receiving medically necessary CRC screening services, and promoting elimination of potentially avoidable / unnecessary services. As previously noted, almost 25% of colonoscopies are performed by physicians other than gastroenterologists, including colorectal surgeons, endoscopic surgeons, general surgeons, family practitioners, internal medicine, and other specialties. This model would be open to all who perform this procedure and who have an interest in achieving better care for their patients.

- 9. Please provide more information on the patient population that is being proposed to test the model. For example, is it centered on a specific geographic area, or set of demographic characteristics?**

Practices in the following geographic areas have indicated an interest in participating in the testing of this model. All practices see a mix of Medicare, Medicaid, and commercial patients. While practices are located in urban or suburban areas, some practices provide services in rural areas as well.

- Arizona
- California
- Colorado
- Florida
- Georgia
- Illinois
- Maryland
- Minnesota
- New Jersey
- Ohio
- Tennessee
- Texas

**10. On page 12, 3rd paragraph there is discussion of data sharing. How would EHR data be shared? This paragraph also indicates that data would be incorporated from several sources to support total cost of care. It is unclear what role of total care analysis plays in colonoscopy payment. Please explain.**

At present, data resides in several silos, including the hospital, ASC, and endoscopist offices. In addition, quality data is collected and reported through EHR, QCDR and claims data. We believe these separate repositories may represent barriers to data sharing, and that addressing colonoscopy in a bundled program presents an opportunity to promote interoperability across data systems, incorporating both clinical and quality performance data to support total cost of care.

As noted in our response to question #3, we have proposed collecting and reporting on data which would allow participating physicians, whether at their group or geographic level, to compare their performance with other participating physicians at a geographic and national level.

**11. The proposal and other literature document the problem of poor bowel preparations as a cause of suboptimal adenoma detection rates. Yet, available literature finds that for US commercial and Medicare patients, reported rates of inadequate bowel preparation are 15-25%, but the rates of repeat colonoscopy are much lower, presumably leading to a substantial under-detection of adenomas.<sup>7</sup> Yet, this happens in a fee schedule environment with presumably no financial disincentive to order repeat exams, with better preps. Why wouldn't a bundled payment approach that pays nothing for a repeat colonoscopy exacerbate the problem of too few repeats even when indicated because of poor preps? How exactly do you plan to reward better attention to bowel preparation, especially since you have measurement targets for decreasing the rate of repeat exams?**

---

<sup>7</sup> See Salz, T., Weinberger, M, Ayanian, J.Z. *et al*, "Variation in use of surveillance colonoscopy among colorectal cancer survivors in the United States", *BMC Health Service Research*, 2010, 10:256-63.

**Are you assuming that the greater attention to instructions about proper preps is enough to obviate the need for repeat exams due to poor preps?**

The PRT reviewer opens an important discussion points: how to ensure that patients receive appropriate services, and that pre-procedure preparation be suitable to enable the physician to perform a high quality examination, consistent with the Choosing Wisely recommendations. We believe that our actuarial analysis has already helped us to identify opportunities for improvement. We would appreciate the assistance of the PRT in obtaining the QRUR data for adenoma detection rates (ADR) from physician practices who participate in the model to determine whether there is under-detection of adenomas.

We believe that a period of 1 year with non-payment to the physician for the repeat procedure removes the financial incentive under the current system of bringing the patient back several times during the year *because they can*. Better attention to ensuring adequate bowel prep on the first visit reduces the potential for gaming the system.

**12. Is there evidence that a visit to the scoping physician prior to the actual day of the procedure actually would improve clinical quality and produce better bowel preparation? Wouldn't patients see the requirement for such a visit as an unnecessary inconvenience? Wouldn't provision of instruction videos work better and be lower cost, whether under classic fee for service or bundled episode payment, with an actual visit reserved for those patients with cognitive impairments (and their caregivers), chronic bowel conditions, etc.?**

This proposal recognizes the need to improve patient education (multi-lingual), provide consistent instructions for prep, ensure consistent physician recommendations after poor prep and/or technical limitations, monitor of prep quality and its relationship to adenoma detection rates. Patient engagement, interactive web tools have been tested and hold promise in prep education and prep assistance, procedure informed consent, anesthesia informed consent, and procedure process familiarity. On-line utilization of materials can be monitored to confirm use of these tools, allowing additional patient contacts for reminders, and software can notify the physician when patients have neglected to complete education for focused live contacts.

Certainly, every patient does not require a pre-procedure visit. Our analysis of Medicare claims indicates that 20% of patients require an E/M visit during the 30 days prior to the index procedure. Direct access will be the goal for those patients that clear a screening (partly web-based and phone contact). Live patient educators using telephone or web may be clinically appropriate for a percentage of the 80% that could avoid the office visit but for medical issues. Live assistance in patient's preferred language can provide further assistance during preps and answer diet and other questions, thereby improving prep quality, decreasing cancellations and repeat procedures, and improving quality.

As addressed in our response to question #13, CMS requires a pre-procedure history and physical (H&P) for all cases with documentation in the procedure chart. While this H&P can be performed on the day of the procedure or at an office visit within 30 days, the work is still required.

- 13. On page 15, 1st sub-bullet indicates a set of activities that would be covered under the one-time payment. Please provide more information on what communication and engagement activities would be covered under this one-time payment. Further, the proposal notes that Medicare beneficiaries typically do not meet the practitioner until immediately before their colonoscopy. How much does an in-person visit with the practitioner prior to colonoscopy reduce poor preparation in comparison to other methods (e.g. receiving instructions over the phone)?**

Please see our response to question #12. Historically, the reported rates of poor bowel prep are approximately 15%. As part of this model, we recommend the incorporation of a standardized protocol to identify those patients who can safely receive instructions without a physician visit. Practice expense needs to be accounted for in the proposal in order to ensure a high quality examination for the patient. Such a program incurs a cost to the office in terms of development of the video materials, office staff time, screening of patients, and identification of those patients who require in-person instructions. Medicare's State Operations Manual and accreditation entities (Joint Commission, AAAHC, AAAASF, DNV) require review of the history + physical and examination of the patient by the endoscopist on the date of service<sup>8</sup>. In addition, addressing patient expectations is critical, for example, reinforcing the need for an escort after the procedure, since it would not be safe for the patient who received sedation or anesthesia to take a taxi or Uber home afterwards.

- 14. On the topic of too many biopsies to increase revenues, what is the basis for establishing a ceiling of 2 per procedure – empirical or normative? Doesn't the fixed bundled payment actually provide an incentive for too few biopsies, assuming the practice receiving the bundle is at risk for such spending? Wouldn't the perverse incentive to over-biopsy be addressed more simply by banning self-referral of pathology, such that the practitioner performing the colonoscopy would be financially indifferent to the number of specimens generated?**

The recommendation on the average number of pathology bottles is based on a previous study.<sup>9</sup> Our subsequent data analysis with the actuaries will allow us to propose a per-

---

<sup>8</sup> See CMS State Operations Manual Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R71SOMA.pdf>. Accessed February 5, 2017

<sup>9</sup> See Milliman White Paper Medicare anatomic pathology utilization: 2009 through 2013 Robert M. Damler, FSA, MAAA Jennifer L. Gerstorff, FSA, MAAA, February 27, 2015, available at

procedure cost which incorporates pathology services across all patients, regardless of whether pathology is performed or not, for the patients identified with the ICD9 / ICD10 codes as identified by CMS in the national coverage determination. We disagree with the reviewer's comment that self-referral of pathology should be banned, as the purpose of this model is to ensure cost-effective, value-driven, and appropriate care for patients.

- 15. The proposal emphasizes that a bundled payment would reduce the incidence of post-procedure emergency room visits. However, the data provided finds that the rate of ER visits within 7 days of procedure is <0.1%, a trivial spending and quality concern. Isn't the issue of avoidable ER visits a "red herring," to suggest there is logic to extending to one year an episode that predominantly consumes only 2 days – prep and procedure, especially given that the real problem of over- and under-provision of colonoscopy occurs outside of the one-year episode payment window?**

As noted in our response to question #3, based on our review of the Medicare 5% files for 2012, 2013, and 2014, the rate of ED visits after colonoscopy is >1%. Our analysis of the Medicare 5% file revealed that the inpatient hospitalization rate after the ED visit is as high as 43% for beneficiaries who underwent the index and a follow-up colonoscopy within 1 year in the HOPD setting.

We respectfully acknowledge the PRT's comments regarding the question of whether provision of services occurs outside of the one year payment window. Please see our response to question #6 regarding quality measures that address this concern.

- 16. We have several questions concerning Table 1 on page 6. This table appears to show the distribution of diagnostic codes for selected procedure codes. However, we are not completely sure of this. Please clarify the content of this table by labeling the columns, defining the CPT codes, etc. Also we are not sure exactly what you are trying to convey with this table. Please elaborate.**

**Table 1:** 2014 Medicare data, frequency of colonoscopy procedures. The claims column lists the total number of claims for that service paid by Medicare in 2014. The ICD-9 codes related to CRC screening, diagnosis, surveillance are:

- V10: personal history of malignant neoplasm of large intestine or rectum
- V12: personal history of colon polyps
- V16: family history of malignant neoplasm of GI tract
- V76: special screening for malignant neoplasm of large intestine or rectum
- 211: Benign neoplasm of colon or rectum

For example, for code 44388 (colonoscopy through stoma), there were 5,136 claims paid by Medicare. Of these claims, 25.56% were for a personal history of malignant neoplasm of the large intestine or rectum.

Two columns are added to the table. The first is a description of the CPT code. The second new column, entitled "CRC", represents the number of Medicare claims that we believe were performed for CRC diagnostic, screening, or surveillance purposes that would be eligible for the model. The sum of column CRC is 1,212,276 procedures, which represents 41.5% of the total number, 2,918,903 colonoscopy procedures listed.

Code	Description	Claims	V12	211	V76	V16	V10	CRC
44388	Colon thru stoma	5136					25.56%	1312
44389	Colon, stoma, biopsy	2343		22.22%			14.82%	872
44391	Colon, stoma, control bleed	197						267
44392	Colon, stoma, hot biopsy	521		51.28%				
44394	Colon, stoma, polypectomy	1595		38.89%			18.06%	908
45378	Colonoscopy	461645	8.99%					41502
45380	Colon, biopsy	963491	11.44%	36.42%	12.43%			119810
45381	Colon, injection	76334	10.38%	50.38%	10.35%			7961
45382	Colon, control bleed	23810		17.45%	4.26%			1032
45384	Colon, hot biopsy	121535	11.05%	56.12%	16.13%			19671
45385	Colon, polypectomy	781487		52.57%	16.29%			538132
G0105	Colon, screen, high risk	231556	56.50%		18.13%	13.11%	6.42%	231556
G0121	Colon, screen, not high risk	249253	1.85%		94.47%			249253

**17. Please clarify the last paragraph on page 8. Some of the statistics do not seem consistent. For example, the proposal indicates that 1.81M Medicare beneficiaries account for 60% of colonoscopies (implying that the total number of colonoscopies is about 3.02M). However the next sentence states that 12M colonoscopies were performed in 2012 and Medicare accounted for about 25% of these). Are the 1.81M beneficiaries a share of all beneficiaries that received colonoscopies or something else? Specifically, what does the 1.81M refer to?**

In 2014, Medicare paid for approximately 3.02 million colonoscopies. Of these, approximately 1.21 million (not 1.81 million) colonoscopies were performed for CRC

screening, diagnostic, or surveillance indications. 1.81M refers to the number of colonoscopies for all indications for the identified CPT codes which might ultimately be eligible for this model. We have excluded advanced therapeutic procedures such as endoscopic mucosal resection, endoscopic ultrasound, stricture dilation, decompression, ablation, placement of stents, and banding of hemorrhoids from the current, or if a future model were expanded to include additional indications other than CRC screening, diagnosis, and surveillance. We regret the confusion.

Data from a variety of sources indicates that approximately 12 million colonoscopies were performed in 2012. Medicare paid for approximately 3 million colonoscopies in 2012. Thus, Medicare beneficiaries accounted for approximately 25% of the colonoscopies performed that year.

**18. On page 9, there is reference to \$3 million in savings that Horizon BCBS of New Jersey realized under a shared savings program. Can you tell us what share of this \$3Million reflects savings from colonoscopies, rather than higher cost joint replacements, etc.?**

A representative from Horizon BCBS responded that “We paid \$3M in 2014 across a number of episodes. Colonoscopy shared savings that year were approximately \$300k, and about \$700k in 2015.”

**19. On page 5, the 1<sup>st</sup> full paragraph there is reference to concerns about whether physicians are addressing incomplete procedures due to poor prep and/or “technical limitations.” Please elaborate on these technical limitations. Also, what are they and what is their relative importance?**

Several potential limitations impacting successful completion of colonoscopy include preparation factors (discussed in responses to Questions 12 and 13), endoscopist factors, equipment factors, and anatomic/physiologic factors. The endoscopist needs to be aware of the potential to miss lesions, especially in the cecum, around sharp angulations and in the rectal ampulla.

Some of the challenges to colonoscopy, and the techniques for overcoming them, relate to the instrument characteristics. The tendency for the colonoscope to flex when it is pushed can result in insertion becoming increasingly difficult (and painful) as loops inevitably form. Adhesions, such as occurring after hysterectomy or endometriosis, may fix the pelvic colon and can cause sharp angulation making colonoscopy difficult.

Data collection will provide meaningful information regarding these technical limitations which can be used to foster improved outcomes.

**20. What share of the 90% ASA I-II cited in the 4<sup>th</sup> paragraph on page 10 is for diagnostic screening?**

The authors of the cited study evaluated 958,428 colonoscopy procedures which were performed for standard indications, including screening, surveillance, and diagnosis of symptoms. The authors found no difference in the odds ratio for serious adverse events between patients rated ASA Class II vs I (odds ratio 0.98, 95% CI 0.68-1.43). The percentage of patients undergoing colonoscopy for screening versus other indications was not specified in this study. We believe that this data supports the assertion that colonoscopies for ASA I or II patients can be safely moved to the ASC setting, regardless of indication, and at significantly lower cost.

## Second set of PRT Questions from review of: Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance, submitted by Digestive Health Network

### Questions to the Submitter

- 1. Page 15 of the proposal mentions the reconciliation of services among participating and nonparticipating providers and facilities. Please provide additional information regarding payment for nonparticipating providers and facilities. What would happen, for example, if the endoscopist is unable to contract with a pathologist to participate in the model? Would the bundled payment be downward adjusted to reflect the separate payment that was made to the pathologist?**

We propose that claims data is used to develop a per-procedure target price for the services encompassed under the model, and that associated team members be paid initially on a fee-for-encounter basis when their services are required. If the endoscopist is unable to contract with a pathologist (for example) to participate in the model, we do not believe that adjusting the bundled payment downward would be appropriate, as this calls into question whether the endoscopist is truly offering a comprehensive model for this condition.

Some have raised the question regarding the creation of a “bundle lite”, where the endoscopist is only responsible for developing a fixed fee for a select group of services, e.g. endoscopy, sedation, facility, for the date of service. We have concerns that this format might not engage all the team members to work in a coordinated manner to ensure that appropriate services are provided to the patient in the most cost-efficient, high quality manner, with appropriate risk for minimizing unnecessary services, complications, and too-early follow-up procedures. As the proposed model is voluntary, we would not recommend the endoscopist enter into the model if they are not able to contract with facilities and associated team members to provide coordinated and comprehensive care.

We believe a mechanism needs to be created for Medicare and third-party payors to recognize which patients are participating in the model, and which providers are participating in the model. We continue to believe that HCPCS codes or modifiers would be the mechanism for addressing this situation. In those unique and special situations where, for example, tissue was obtained that required outside referral of the specimen to a second pathologist for consultation, availability of a modifier would allow the pathologist to identify that the service being provided is outside of the model.

- 2. Please provide more information regarding the one-time payment referenced on page 15 of the proposal (and page 7 of your responses to the first set of PRT questions). Clarify whether it is factored into the bundled payment or whether it is a separate payment from the bundled payment.**

The one-time payment would be factored into the payment for the episode. This payment would address the administrative costs incurred by the endoscopist office for providing appropriate preparation education and consent, 24/7 access to staff for patients and family

members with questions about the procedure preparation and medications, coordinating services with associated team members and facilities so that they know the patient is part of the model, contracting with associated team members and facilities, data integration and coordination across associated team members and facilities, post-procedure care coordination, quality reporting, 24/7 access to staff for post-procedure inquiries, and internal data analysis. Unsatisfactory bowel preparation has been reported in up to 33% of screening colonoscopies.<sup>1</sup> As noted in our first set of responses, the one-time payment would incorporate patient-centered educational videos and other web-based interactive tools which have been shown to improve bowel preparation quality.

The payment would include an amortized amount for the approximately 20% of patients who cannot be managed solely through interactive tools, and who require an evaluation and management visit during the 30 days prior to the procedure.

Our analysis of the Medicare 5% sample for years 2012-2013-2014 suggests that approximately 1.3% of beneficiaries will have an emergency room visit within 7 days of an index colonoscopy procedure, which increases to 2.2% for those who undergo a follow-up colonoscopy procedure. These rates are similar to a recent analysis of 2010 Medicare data which analyzed unplanned hospital visits within 7 days after colonoscopy<sup>2</sup>. In our analysis, the most common reasons for emergency department visits within seven days post colonoscopy reveals these are for conditions unrelated to the procedure, namely hypertension, hyperlipidemia, medication reconciliation and diabetes. We do not believe it would be feasible to establish a real-time mechanism to determine which diagnoses would or would not be part of the episode, as we are concerned this would create a significant administrative burden for the emergency department and the endoscopist's office. Incorporating access to endoscopist office staff as part of the one-time payment could help to reduce potentially avoidable visits to the emergency department.

Approximately 1.5% of patients seen in the emergency department are admitted for observation. In the model, we proposed to include payment for observation services. The one-time payment would include a stop-loss premium to account for the costs of emergency department regardless of the diagnosis, and observation services if incurred.

- 3. The proposal indicates that there is yearly retrospective reconciliation with downward payment adjustment based on failure to meet (1) the colonoscopy re-do target, (2) the ASC utilization target, and (3) the quality criteria for surveillance follow-up intervals? Can you please clarify how this works? Would the APM entity have to pay money back to Medicare? Or is this retrospective reconciliation only referring to money paid back to the endoscopist from associated team members? If the former is true, how much downward adjustment results from failure to meet each of the targets/quality criteria? In addition, which specific follow-up interval measures are used?**

---

<sup>1</sup> Hayat U, Lee PJW, Lopez R, et al. Online Educational Video Improves Bowel Preparation and Reduces the Need for Repeat Colonoscopy Within Three Years. *Am J Med* 2016; 129: 1219.e1–1219.e9

<sup>2</sup> Ranasinghe I, Parzynski CS, Searfoss R, et al. Differences in Colonoscopy Quality Among Facilities: Development of a Post-Colonoscopy Risk-Standardized Rate of Unplanned Hospital Visits. *Gastroenterology* 2016; 150: 103-113

The targets identified above (re-do rate, ASC utilization, quality criteria) are the responsibility of the endoscopist. We propose that retrospective reconciliation of data occurs at a predetermined time; if targets are not met, the endoscopist would pay money back to Medicare.

We propose the following downward adjustment resulting from failure to meet the following targets / quality criteria:

- Re-do rate: 4%
- ASC utilization (payment) rate: 4%
- Surveillance intervals: 4%

It has been brought to our attention that not all physicians who perform colonoscopy have access to an ambulatory surgical center (ASC) setting. To encourage participation in the proposed model, we would support allowing the hospital outpatient department to contract at the established ASC payment rate as part of the model, and for that arrangement to be counted towards meeting the ASC utilization rate goals. We believe that allowing the hospital such latitude would encourage the provision of services in the setting that is the safest for the patient based on their ASA risk assessment and at the most cost-effective rate. We would not want to penalize those physicians who have an interest in participating in the model but who do not have access to an ASC setting, if they are able to negotiate with a hospital an ASC-equivalent reimbursement rate for those patients whose colonoscopies could be performed in an ASC setting, if one were available.

The recommendations for follow-up interval are based on specialty society consensus guidelines published during this decade:

- Lieberman DA, Rex DK, Winawer SJ, et al. **Guidelines for Colonoscopy Surveillance After Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer.** GASTROENTEROLOGY 2012;143:844–857 (table 1)
- Kahi CJ, Boland CR, Dominitz JA, et al. **Colonoscopy surveillance after colorectal cancer resection: recommendations of the US multi-society task force on colorectal cancer** GASTROINTESTINAL ENDOSCOPY 2016; 83: 489-498 (table 2)
- Shergill AK, Lightdale JR, Bruining DH, et al for the ASGE Standards of Practice Committee. **The role of endoscopy in inflammatory bowel disease** GASTROINTESTINAL ENDOSCOPY 2015; 81: 1101-21 (table 3)
- Giardiello FM, Allen JI, Axilbund JE, et al. **Guidelines on Genetic Evaluation and Management of Lynch Syndrome: A Consensus Statement by the US Multi-Society Task Force on Colorectal Cancer** GASTROINTESTINAL ENDOSCOPY 2014; 80: 192-220 (table 4)

Table 1: surveillance and screening intervals, individuals with baseline average risk

**Table 1.** 2012 Recommendations for Surveillance and Screening Intervals in Individuals With Baseline Average Risk

Baseline colonoscopy: most advanced finding(s)	Recommended surveillance interval (y)	Quality of evidence supporting the recommendation	New evidence stronger than 2006
No polyps	10	Moderate	Yes
Small (<10 mm) hyperplastic polyps in rectum or sigmoid	10	Moderate	No
1–2 small (<10 mm) tubular adenomas	5–10	Moderate	Yes
3–10 tubular adenomas	3	Moderate	Yes
>10 adenomas	<3	Moderate	No
One or more tubular adenomas $\geq$ 10 mm	3	High	Yes
One or more villous adenomas	3	Moderate	Yes
Adenoma with HGD	3	Moderate	No
Serrated lesions			
Sessile serrated polyp(s) <10 mm with no dysplasia	5	Low	NA
Sessile serrated polyp(s) $\geq$ 10 mm	3	Low	NA
OR			
Sessile serrated polyp with dysplasia			
OR			
Traditional serrated adenoma			
Serrated polyposis syndrome <sup>a</sup>	1	Moderate	NA

NOTE. The recommendations assume that the baseline colonoscopy was complete and adequate and that all visible polyps were completely removed.

Table 2: surveillance intervals, individuals with colorectal cancer

**APPENDIX. Summary of recommendations**

We recommend that patients with CRC undergo high-quality perioperative clearing with colonoscopy. The procedure should be performed preoperatively or within a 3- to 6-month interval after surgery in the case of obstructive CRC. The goals of perioperative clearing colonoscopy are detection of synchronous cancer and detection and complete resection of precancerous polyps.
We recommend that patients who have undergone curative resection of either colon or rectal cancer receive their first surveillance colonoscopy 1 year after surgery (or 1 year after the clearing perioperative colonoscopy). Additional surveillance recommendations apply to patients with rectal cancer (see " <a href="#">Additional Considerations in Surveillance of Rectal Cancer</a> ").
We recommend that, after the 1-year colonoscopy, the interval to the next colonoscopy should be 3 years (ie, 4 years after surgery or perioperative colonoscopy), and then 5 years (ie, 9 years after surgery or perioperative colonoscopy). Subsequent colonoscopies should occur at 5-year intervals, until the benefit of continued surveillance is outweighed by diminishing life expectancy. If neoplastic polyps are detected, the intervals between colonoscopies should be in accordance with the published guidelines for polyp surveillance intervals. These intervals do not apply to patients with Lynch syndrome.
Patients with localized rectal cancer who have undergone surgery without total mesorectal excision, those who have undergone transanal local excision (transanal excision or transanal endoscopic microsurgery) or endoscopic submucosal dissection, and those with locally advanced rectal cancer who did not receive neoadjuvant chemoradiation and then surgery using total mesorectal excision techniques are at increased risk for local recurrence. In these situations, we suggest local surveillance with flexible sigmoidoscopy or EUS every 3–6 months for the first 2–3 years after surgery. These surveillance measures are in addition to recommended colonoscopic surveillance for metachronous neoplasia.
In patients with obstructive CRC precluding complete colonoscopy, we recommend CTC as the best alternative to exclude synchronous neoplasms. Double-contrast barium enema is an acceptable alternative if CTC is not available.
There is insufficient evidence to recommend the routine use of FIT or fecal DNA for surveillance after CRC resection.

Table 3: surveillance intervals, individuals with inflammatory bowel disease

TABLE 4. American Society for Gastrointestinal Endoscopy 2014 recommendations for screening and surveillance in patients with IBD		
Eligible patients	Screening	Surveillance
UC: Left-sided or extensive colitis CD: Involving at least 1/3 of colon * Ideally, surveillance colonoscopy should be performed when colonic disease is in remission.	All patients at 8 y, with restaging biopsies	<ul style="list-style-type: none"> <li>• Every 1-3 y</li> <li>• Optimal surveillance interval not defined.</li> <li>• Presence of these risk factors merits annual surveillance: active inflammation, anatomic abnormality (stricture, multiple pseudopolyps), history of dysplasia, family history of CRC in first-degree relative, PSC.</li> <li>• In patients with endoscopically and histologically normal mucosa on <math>\geq 2</math> surveillance colonoscopies, the surveillance interval can be lengthened.</li> </ul>

*IBD, inflammatory bowel disease; UC, ulcerative colitis; CD, Crohn's disease; CRC, colorectal carcinoma; PSC, primary sclerosing cholangitis.*

Table 4: surveillance intervals, individuals with Lynch syndrome

TABLE 10. Guidelines for Screening At-Risk or Affected Persons With Lynch Syndrome		
Intervention	Recommendation	Strength of recommendation
Colonoscopy	Every 1–2 y beginning at age 20–25 y or 2–5 y younger than youngest age at diagnosis of CRC in family if diagnosis before age 25 y Considerations: Start at age 30 y in MSH6 and 35 in PMS2 families Annual colonoscopy in MMR mutation carriers	Strong recommendation: Level of evidence (III): well-designed and conducted cohort or case-controlled studies from more than 1 group with cancer GRADE rating: moderate

While we propose that the model period encompasses one year, we are concerned that waiting 1+ years to provide information to the model participants may represent a missed opportunity. In our experience with commercial models, feedback has been provided within three-six months of initiation, with quarterly feedback thereafter. We suggest that feedback information is provided to the model participants within six months of initiation and quarterly thereafter, so that spending can be reconciled against the prospective episode payment. Providing feedback data in a prompt and regular manner would allow model participants to identify opportunities to adjust and modify their activities as early as possible.

A concern that has been brought to our attention involved referral of patients for elective surgical (open or laparoscopic) removal of lesions. A review of 2014 Medicare claims data revealed that 6.37% of claims for code 44140, *Colectomy, partial; with anastomosis*, were for ICD-9 211, *Benign neoplasm other digestive system*. We recommend that referral rates for this circumstance be reviewed and a baseline established for the endoscopist participating in the

model. Referral rates for endoscopic mucosal resection and open or laparoscopic removal of benign lesions should be monitored on an ongoing basis to ensure that patients attributed to the model receive safe, effective, and appropriate care.

**4. Please describe how patients are attributed to the model. Would endoscopists attribute patients (e.g. based on the use of the proposed CPT code)?**

Endoscopists, regardless of specialty, would attribute patients to the model. At this time, the CPT Editorial Panel has not provided their determination regarding our proposal to establish a CPT code that would allow the endoscopist, associated team members, and facility to indicate participation in the model for the attributed patient. We continue to recommend that a coding mechanism, either through HCPCS / CPT codes or modifiers, is needed for the endoscopist, facility, and other associated team participants to indicate their participation on behalf of the patient in question who is attributed to the model.

**5. Does the bundled payment amount vary based on whether the patient is ASA Class I vs. III? Does the bundled payment amount vary for any other reasons?**

The bundled payment amount does not vary depending on the patient's ASA class. There will be patients who for safety or other clinical reasons will require the procedure to be performed in the hospital outpatient setting. While a 2013 study estimated that 6.9% of patients undergoing colonoscopy were ASA physical status class III, we do not know what the actual rate is in Medicare beneficiaries<sup>3</sup>. Analysis of claims data should help to establish what that percentage actually is, which would be reflected in establishing a fixed per-procedure payment.

In our analysis of the 5% Medicare claims, we have identified instances when a patient undergoing colonoscopy for CRC screening, diagnosis, or surveillance might undergo a second endoscopic procedure on the same date of service. We believe this circumstance can be addressed through the use of a modifier. If confidentiality can be assured, we would be pleased to share with the PTAC the analysis of the 5% Medicare claims that we and our actuarial consultants have developed to inform our assumptions and recommendations regarding this situation.

We have considered whether the bundled amount should vary for other reasons, such as:

- High-risk patient with inflammatory bowel disease or Lynch syndrome requiring significant, multiple biopsies
- Patient with a large lesion requiring staged removal
- Patient on anticoagulation with removal of a lesion requiring placement of a clip

Based on assessment of the Medicare 5% sample, we do not recommend variation of the bundled payment amount for these reasons. Establishing modifiers would allow the participants to indicate that an unusual circumstance is outside of the episode.

---

<sup>3</sup> Enestvedt BK, Eisen GM, Holub J, et al. Is ASA classification useful in risk stratification for endoscopic procedures? *Gastrointest Endosc.* 2013;77(3):464-71