

December 28, 2016

Proposal for a Physician-Focused Payment Model: Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance

Attached, please find a submission from the Digestive Health Network for a Physician-Focused Payment Model, entitled the **Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance**

If you have any questions related to the model, please contact:

Joel V. Brill, MD FACP AGAF FASGE FACG

Chief Medical Officer

Predictive Health, LLC

3639 E. Denton Lane

Paradise Valley, AZ 85253

(602) 418-8744

joel.brill@gmail.com

Please also copy:

Scott R. Ketover, MD AGAF

President & CEO

Minnesota Gastroenterology, PA

P.O. Box 14909

Minneapolis, MN 55414

(612) 870-5408

sketover@mngastro.com

Charles Accurso, MD FACG

President

Digestive HealthCare Center

511 Courtyard Dr.

Hillsborough, NJ 08844

(908) 218-9222

Chasa57@aol.com

DIGESTIVE HEALTH NETWORK, INC.

December 29, 2016

Physician-Focused Payment Model Technical Advisory Committee
C/o U.S. DHHS Asst. Sec. of Planning and Evaluation Office of Health Policy
200 Independence Avenue S.W.
Washington, DC 20201
PTAC@hhs.gov

Letter of Support – Comprehensive Colonoscopy Advanced Alternative Payment Model for
Colorectal Cancer Screening, Diagnosis and Surveillance

Dear Committee Members:

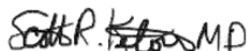
On behalf of the more than 1,000 physicians whose clinics make up the Digestive Health Network, Inc., a Delaware stock corporation, we would like to express our strong support for the accompanying proposal for a Physician-Focused Payment Model, which we are submitting to the PTAC for review.

The Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance seeks to provide novel incentives and tools for both improving the quality of care and reducing costs. The model is an outpatient, prospective episode-based model with retrospective reconciliation. Financial risk is attributed to teams of providers based on their individual role in providing care to the patient. The model incorporates a rigorous quality measurement framework and will adjust payments based upon the quality of care delivered. It is our intention that the proposal meets MACRA Advanced APM requirements.

Our patient-focused approach is based on the team-based nature of care for the patient undergoing colorectal cancer screening, diagnosis and surveillance using colonoscopy. The model creates a comprehensive and coherent framework for evaluating clinically meaningful performance in quality, efficiency, and value to improve colorectal cancer screening. The model provides information and tools to individual providers and group that help them target cost drivers and improve quality.

Thank you for the opportunity to submit this proposal and for your consideration of its merits. If you have any questions about the attached proposal, please contact Scott Ketover MD at sketover@mngastro.com or Joel V. Brill MD at joel.brill@gmail.com.

Sincerely



Scott R. Ketover, MD AGAF
President
Digestive Health Network, Inc.

Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance

Advanced Alternative Payment Model

A Physician-Focused Payment Model Submitted by the Digestive Health
Network

December 2016

Table of Contents

| | |
|---|----|
| I. Background and Model Overview | 1 |
| A. Colorectal Cancer: Incidence..... | 1 |
| B. Colorectal Cancer: Screening and Surveillance..... | 3 |
| C. Model Overview | 5 |
| II. Scope of Proposed PFPM | 8 |
| III. Quality and Cost | 10 |
| IV. Payment Methodology | 13 |
| V. Value Over Volume | 15 |
| VI. Flexibility | 15 |
| VII. Ability to be Evaluated | 17 |
| VIII. Integration and Care Coordination | 17 |
| IX. Patient Choice | 18 |
| X. Patient Safety | 19 |
| XI. Health Information Technology | 20 |
| XII. Supplemental Information | 20 |

Abstract

We are pleased to propose a comprehensive prospective bundled payment advanced alternative payment model to more effectively manage patients who require colonoscopy for colorectal cancer (CRC) screening and surveillance, for evaluation of a positive finding on other CRC screening modalities as recommended by the US Preventive Services Task Force^{1 2}, and for other diagnostic purposes. This prospective dual-risk model, built upon the knowledge gained from retrospective models with upside only risk and prospective 'day-of-procedure' fixed price models, will establish incentives to pay for higher-value care, will be flexible, and improve quality at a lower overall cost (42 CFR Sec. 414.1465).

¹ Screening for Colorectal Cancer. US Preventive Services Task Force Recommendation Statement. *JAMA* 2016; 315 (23): 2564-2575

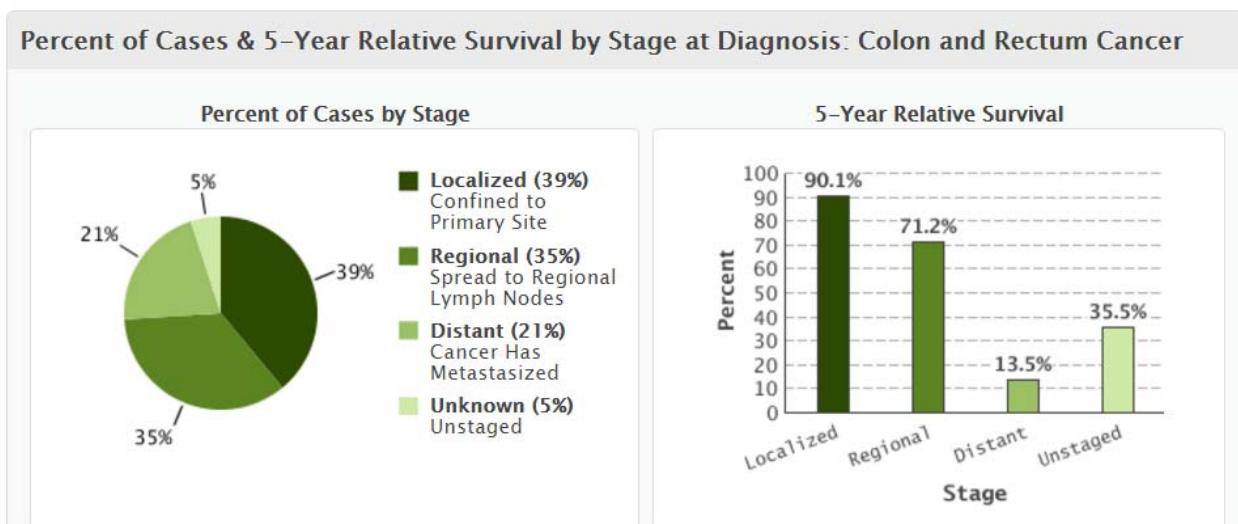
² HEDIS 2017 Volume 2 Technical Update. Released October 3, 2016.

Background and Model Overview

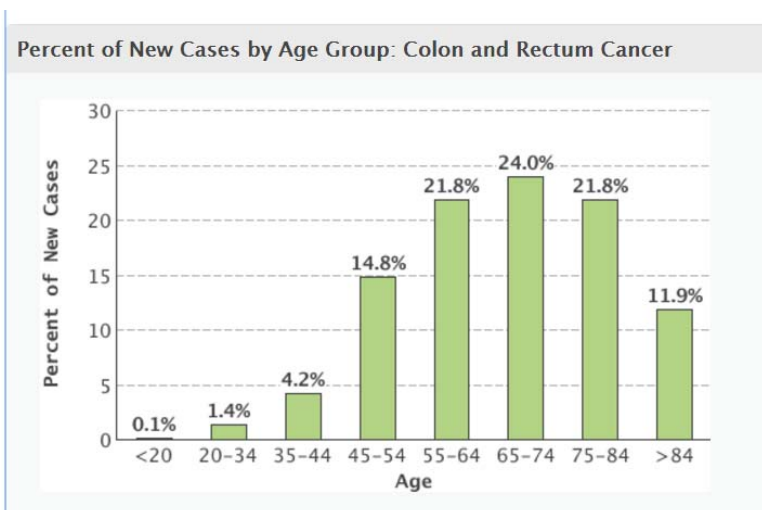
A: Colorectal Cancer: Incidence

There were an estimated 134,490 new cases of colorectal cancer in 2016, which represents 8.0% of all new cancer cases³. Colorectal cancer is the fourth most common cancer in the United States, where the number of new cases of colon and rectum cancer is 41.0 per 100,000 men and women per year.

The earlier colon and rectum cancer is detected, the greater chance a person has of surviving five years after being diagnosed. For colon and rectum cancer, 39.4% are diagnosed at the local stage. The 5-year survival for localized colon and rectum cancer is 90.1%.



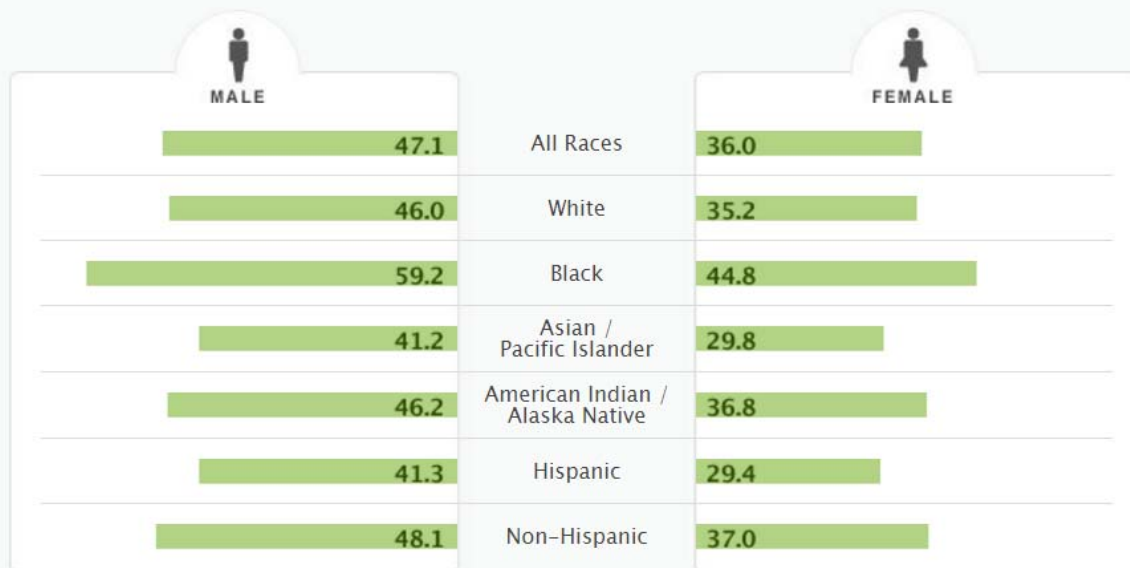
Colon and rectal cancer is most frequently diagnosed in people aged 65-74.



³ Howlader N, Noone AM, Krapcho M, et al. SEER Cancer Statistics Review, 1975-2013, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2013/, based on November 2015 SEER data submission, posted to the SEER web site, April 2016, updated September 2016. Accessed December 26, 2016

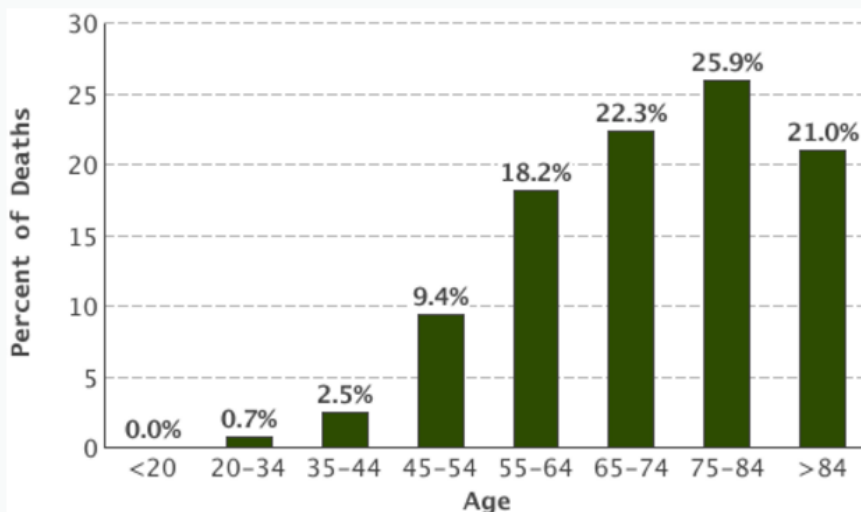
The number of new cases of colon and rectum cancer was 41.0 per 100,000 men and women per year. Colorectal cancer is more common in men than women and among those of African American descent.

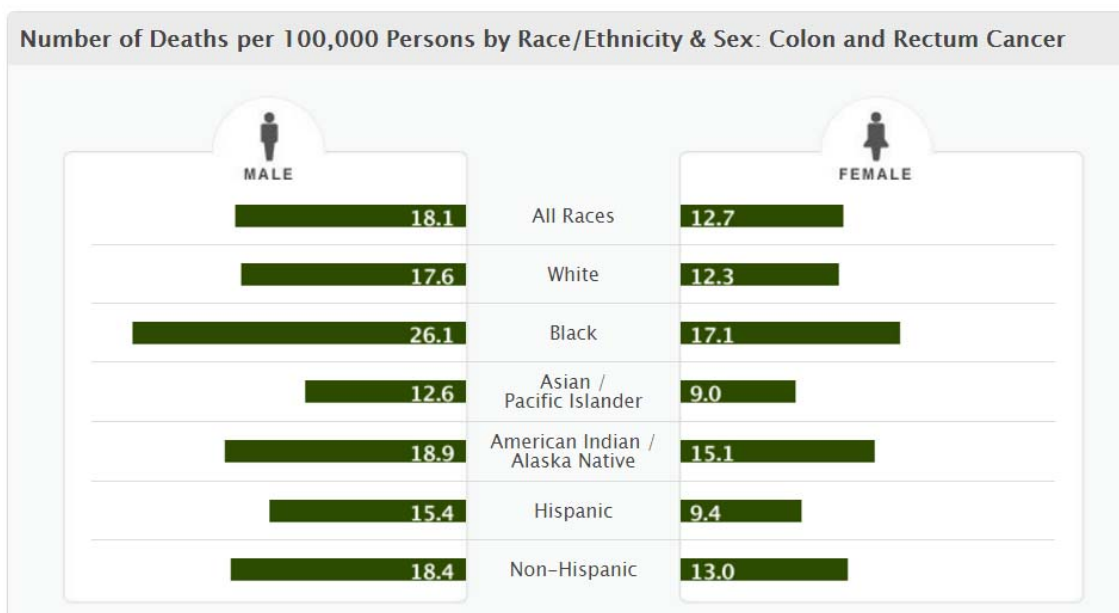
Number of New Cases per 100,000 Persons by Race/Ethnicity & Sex: Colon and Rectum Cancer



Approximately 49,190 people will die from colorectal cancer during 2016, which represents 8.3% of all cancer deaths. Colon and rectum cancer is the second leading cause of cancer death in the United States; the number of deaths is 15.1 per 100,000 men and women per year and the five-year survival rate is 65.1%. The median age at death is 73. The percent of colon and rectum cancer deaths is highest among people aged 75-84.

Percent of Deaths by Age Group: Colon and Rectum Cancer





The average total all-cause Medicare Fee-For-Service spending for Colorectal Cancer for 2015, based on the CMS 5% Limited Data Sets is:

| Chronic Condition | Number of Beneficiaries (1,000s) | Average Monthly Payments (\$) per Beneficiary | Spending (\$) by Percentile | | | | |
|-------------------------------|----------------------------------|---|-----------------------------|------------------|---------|------------------|------------------|
| | | | 5 th | 25 th | Median | 75 th | 95 th |
| Colorectal Cancer | 411 | \$2,780 | \$86 | \$319 | \$1,233 | \$3,576 | \$10,049 |
| Condition only | 14 | \$977 | \$13 | \$80 | \$165 | \$589 | \$5,607 |
| With other chronic conditions | 396 | \$2,846 | \$96 | \$344 | \$1,312 | \$3,653 | \$10,187 |

Part A

| | | | | | | | |
|-------------------------------|-----|---------|-----|-----|-------|---------|---------|
| Colorectal Cancer | 416 | \$1,715 | \$0 | \$0 | \$332 | \$1,991 | \$7,466 |
| Condition only | 15 | \$251 | \$0 | \$0 | \$0 | \$0 | \$1,557 |
| With other chronic conditions | 401 | \$1,769 | \$0 | \$0 | \$394 | \$2,092 | \$7,603 |

Part B

| | | | | | | | |
|-------------------------------|-----|---------|------|-------|-------|---------|---------|
| Colorectal Cancer | 399 | \$1,080 | \$89 | \$269 | \$556 | \$1,187 | \$3,880 |
| Condition only | 107 | \$1,000 | \$69 | \$259 | \$605 | \$1,257 | \$3,285 |
| With other chronic conditions | 4 | \$359 | \$12 | \$46 | \$121 | \$336 | \$1,464 |

B: Colorectal Cancer Screening and Surveillance

Early screening is an important tool in fighting colorectal cancer, but only three fifths of U.S. adults age 50 to 75 overall are up to date on their screenings, and serious disparities persist^{4 5}. While intense outreach can increase screening and save lives, gaps exist. This alternative advanced payment model will result in improved quality of care and increased cost savings

⁴ Baker DW, Brown T, Buchanan DR, et al. Comparative Effectiveness of a Multifaceted Intervention to Improve Adherence to Annual Colorectal Cancer Screening in Community Health Centers. A Randomized Clinical Trial. *JAMA Intern Med.* 2014;174(8):1235-1241

⁵ American Cancer Society Colorectal Cancer Facts and Figures 2014-2016

relative to the current fee-for-service model for performance of colonoscopy for colorectal cancer screening, diagnosis or surveillance, whether through a stoma or the rectum⁶.

Understanding the history of colonoscopy for colorectal cancer screening and surveillance is critical to understanding the potential of this proposed advanced alternative payment model to address payment policy in a new way. Appreciating the importance of early detection in preventing deaths from colorectal cancer, in 1997 Congress enacted the Balanced Budget Act, which provided coverage of FOBT and flexible sigmoidoscopy to Medicare beneficiaries 50 or older at average risk for the disease. Colonoscopy was also covered, but only for high-risk individuals⁷. In December 2000, Congress enhanced this basic coverage by expanding colonoscopy coverage to average risk individuals, effective July 1, 2001^{8 9}. Medicare currently covers either a screening colonoscopy every 10 years or a flexible sigmoidoscopy every 4 years for average risk individuals, and a colonoscopy every 2 years for beneficiaries at high risk. However, as Congress did not extend coverage of this preventive service to include evaluation and counseling of the patient and assessing clinical status prior to undergoing sedation for the colonoscopy procedure, Medicare does not cover the pre-procedure evaluation of the asymptomatic patient prior colonoscopy¹⁰. Thus, an open access model has evolved where Medicare beneficiaries receive instructions on their procedure preparation via mail, phone, or internet but typically do not meet the endoscopist until immediately before their examination¹¹, which has resulted in an estimated 10-15% rate of incomplete procedures due to poor prep and/or technical limitations¹².

Colonoscopy is one of the most frequently performed procedures; in 2015, Medicare paid for almost 2,895,000 procedures for non-therapeutic indications such as colorectal cancer screening and diagnostic evaluation of gastrointestinal bleeding, abdominal pain, and change in bowel habits. Increases in colorectal cancer screening have been associated with a decrease in colorectal cancer incidence¹³, and there is a correlation between adenoma detection rate (ADR) and decreased CRC incidence¹⁴.

In 2015, CMS expanded the waiver of coinsurance and deductible to include a separately payable anesthesia service in conjunction with a screening colonoscopy¹⁵. Under the Affordable Care Act, the facility and pathology for screening colonoscopy are preventive for Medicare beneficiaries; non-Medicare patients also have preventive coverage of the pre-procedure

⁶ Brill JV, Jain R, Margolis P et al. A bundled payment framework for colonoscopy performed for colorectal cancer screening or surveillance. *Gastroenterology*. 2014 Mar;146(3):849-853.e9.

⁷ Balanced Budget Act of 1997, (Pub.L. 105–33, 111 Stat. 251, enacted August 5, 1997)

⁸ H.R.5661 - Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, incorporated in Pub L 106 - 554 – Consolidated Appropriations Act, 2001

⁹ Congressional Research Service. Medicare Provisions in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, P.L. 106-554). May 24, 2001

¹⁰ Honorable Benjamin L. Cardin, Colon Cancer Screen for Life Act of 2002, Congressional Record, V. 148, Pt 1, page 938, February 8, 2002

¹¹ Baron TH, Kimery BD, Sorbi D, et al. Strategies to address increased demand for colonoscopy: guidelines in an open endoscopy practice. *Clin Gastroenterol Hepatol* 2004;2:178-82

¹² Lebowhl B, Kastrinos F, Glick M, et al. The Impact of Suboptimal Preparation on Adenoma Miss Rates and the Factors Associated with Early Repeat Colonoscopy. *Gastrointestinal Endoscopy*. 2011;73(6):1207-1214.

¹³ American Cancer Society Colorectal Cancer Facts and Figures 2014-2016

¹⁴ Corley DA, Jensen CD, Marks AR, et al. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. *N Engl J Med* 2014; 370:1298-1306

¹⁵ CMS Manual System Pub 100-04 Medicare Claims Processing. Transmittal 3232 April 3, 2015

evaluation and management visit and the prep for the procedure¹⁶. However, if another CRC screening test (e.g. FIT, Cologuard, flexible sigmoidoscopy, etc.) is positive, even if the patient is otherwise asymptomatic, Medicare considers the resulting colonoscopy to be diagnostic, not preventive, with the beneficiary responsible for copayments and deductibles¹⁷.

Concerns whether physicians are appropriately following guidelines for surveillance intervals¹⁸, addressing incomplete procedures due to poor prep and/or technical limitations¹⁹, performing the procedure in a lower cost ASC rather than a higher cost HOPD setting²⁰, and reducing or eliminating patient financial responsibility when the asymptomatic patient is referred for colonoscopy as a result of another CRC screening test collectively represent opportunities for improvement through improved quality of care and increased cost savings relative to the current fee-for-service model.

C: Model Overview

This comprehensive bundled payment model for colorectal cancer screening, diagnosis, or surveillance; incorporating colonoscopy, anesthesia, moderate sedation, pathology, radiology, and evaluation and management services, incorporates the following CPT / HCPCS services during a 1-year episode framework:

- Colonoscopy through stoma 44388, 44389, 44391, 44392, 44394, 44403, 44404
- Colonoscopy 45378, 45380, 45381, 45382, 45384, 45385, 45390, G0105, G0121
- Anesthesia 00810, 008X1, 008X2
- Moderate sedation 99152, 99153, 99156, 99157, G0500
- Radiology 74261, 74262, 74270, 74280
- Capsule endoscopy 0355T
- Pathology 88305, 88313, 88341, 88342
- Evaluation and Management 99201-99205, 99211-99215, 99241-99245
- Emergency Room 99281-99285
- Facility (hospital outpatient, ambulatory surgical center)

A one-year episode period was chosen rather than a 90-day episode to avoid the potential for physicians / healthcare professionals to ‘game’ the system by bringing the patient back for a follow-up examination (due to poor preparation or incomplete visualization) after the episode period.

The colonoscopy episode includes:

- Pre- and post-procedure evaluation and management services

¹⁶ United States Department of Labor. Coverage of Preventive Services. See <http://www.dol.gov/ebsa/faqs/faq-aca29.html> and <http://www.dol.gov/ebsa/faqs/faq-aca31.html>. Accessed December 11, 2016

¹⁷ Andrews M. When a Screening Test For Colon Cancer Leads To A Pricey Follow-Up. Kaiser Health News / National Public Radio August 30, 2016. Available at <http://www.npr.org/sections/health-shots/2016/08/30/491839847/when-a-screening-test-for-colon-cancer-leads-to-a-pricey-follow-up>

¹⁸ Goodwin JS, Singh A, Reddy N, et al. Overuse of Screening Colonoscopy in the Medicare Population. *Arch Intern Med.* 2011;171(15):1335-1343

¹⁹ Staff DM, Saeian K, Rochling F, et al. Does open access endoscopy close the door to an adequately informed patient? *Gastrointestinal Endoscopy* 2000;52:212-7.

²⁰ Avalere Health. Medicare Payment Differentials Across Outpatient Settings of Care. February 2016

- Anesthesia and/or moderate sedation
- Anatomic pathology
- Radiology procedures such as barium enema or CT colonography, or capsule endoscopy of the colon, which might be required to be performed to complete the examination of the colon
- Emergency room visit to evaluate complications within 7 days of the colonoscopy procedure, consistent with CMS quality measures ASC-12: *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* and OP-32: *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy*²¹
- Facility costs (ASC, HOPD)
- Preparation agent
- Pharmaceutical agents for sedation (e.g. Demerol, Fentanyl, Versed, Propofol)
- Quality reporting measures

The episode does not include:

- Other CRC screening tests with a grade of A or B as recommended by the US Preventive Services Task Force and/or covered by CMS (e.g. FOBT, FIT, stool DNA, septin-9, CT colonography, barium enema, flexible sigmoidoscopy)
- Inpatient hospitalization because of a complication which warrants surgical intervention and/or observation.
- Surgery, chemotherapy, radiation oncology, and/or molecular diagnostic testing for a patient with colorectal neoplasm

Table 1: 2014 Medicare data, frequency of colonoscopy procedures:

| Code | Claims | V12 | 211 | V76 | V16 | V10 |
|-------|--------|--------|--------|--------|--------|--------|
| 44388 | 5136 | | | | | 25.56% |
| 44389 | 2343 | | 22.22% | | | 14.82% |
| 44391 | 197 | | | | | |
| 44392 | 521 | | 51.28% | | | |
| 44394 | 1595 | | 38.89% | | | 18.06% |
| 45378 | 461645 | 8.99% | | | | |
| 45380 | 963491 | 11.44% | 36.42% | 12.43% | | |
| 45381 | 76334 | 10.38% | 50.38% | 10.35% | | |
| 45382 | 23810 | | 17.45% | 4.26% | | |
| 45384 | 121535 | 11.05% | 56.12% | 16.13% | | |
| 45385 | 781487 | | 52.57% | 16.29% | | |
| G0105 | 231556 | 56.50% | | 18.13% | 13.11% | 6.42% |
| G0121 | 249253 | 1.85% | | 94.47% | | |

We propose that the episode would be applicable to the following ICD-9 / ICD-10 diagnoses, based on the CMS Internet-Only Medicare Claims Processing Manual, Publication 100-04,

²¹ Mathematica Policy Research. 2016 Measure Updates and Specifications Report Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy: A Quality Measure for Profiling Facility Performance Using Claims Data. May 4, 2016

Chapter 18 Preventive and Screening Services, Section 60, Colorectal Cancer Screening²², CMS National Coverage Determination (NCD) for Fecal Occult Blood Test (190.34)²³, National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3)²⁴, and CMS Transmittal 3436 (effective December 30, 2015)²⁵

ICD-9 diagnosis codes:

- V10.05 Personal history of malignant neoplasm of large intestine
- V10.06 Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus
- V12.72 Personal history of colon polyps
- V16.0 Family history of malignant neoplasm of gastrointestinal tract
- V18.51 Family history of colonic polyps
- V76.41 Screening for malignant neoplasms of rectum
- V76.50 Special screening for malignant neoplasms of intestine, unspecified
- V76.51 Special screening for malignant neoplasms of intestine
- V84.09 Genetic susceptibility to other malignant neoplasm
- 211.3 Benign neoplasm of colon
- 211.4 Benign neoplasm of rectum and anal canal
- 555 Regional enteritis (Crohn's disease)
- 556 Ulcerative colitis
- 558.2 Toxic gastroenteritis and colitis
- 558.9 Other and unspecified non-infectious gastroenteritis and colitis

ICD-10 diagnosis codes:

- K50 – Crohn's disease
- K51 – ulcerative colitis
- K52.1 – toxic gastroenteritis and colitis
- K52.89 – other specified noninfective gastroenteritis and colitis
- K52.9 – noninfective gastroenteritis and colitis, unspecified
- Z85.038 – personal history of other malignant lesion of large intestine
- Z85.048 – personal history of other malignant lesion of rectum, rectosigmoid junction, and anus

²² <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c18.pdf>. Accessed December 26, 2016

²³ https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=167&ncdver=1&DocID=190.34&type=ncd&page=index_section.asp&ncd_sections=40&where=index_section.asp%257c40&ncd_id=190.34&ncd_version=1&basket=ncd*3a%24190.34*3a%241*3a%24Fecal+Occult+Blood+Test+%252528FOBT%252529&bc=gAAAAAgAAAAAA%3D%3D&. Accessed December 26, 2016

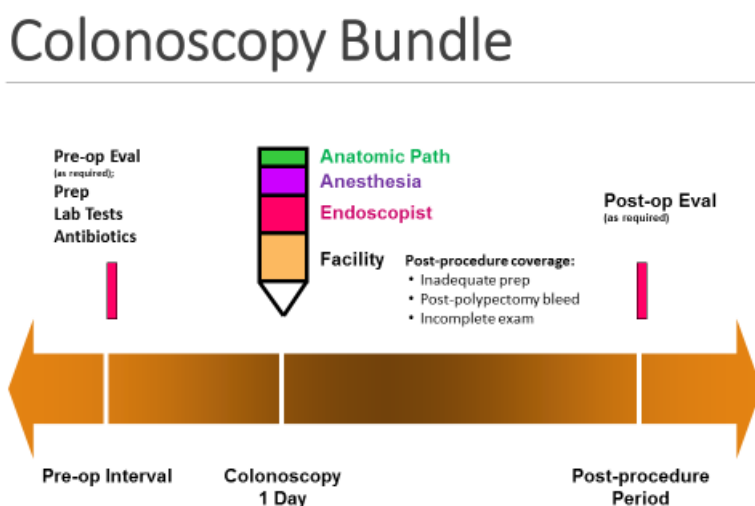
²⁴ [https://www.cms.gov/medicare-coverage-database/\(S\(v0cxhe45alguxjupvix24zai\)\)/details/ncd-details.aspx?NCDId=281&ncdver=5&CALId=97&ver=5&CalName=Prothrombin+Time+and+Fecal+Occult+Blood+\(Revision+of+ICD-9-CM+Codes+for+Injury+to+Gastrointestinal+Tract\)&bc=gAgAAAAAgAIAAA%3D%3D&](https://www.cms.gov/medicare-coverage-database/(S(v0cxhe45alguxjupvix24zai))/details/ncd-details.aspx?NCDId=281&ncdver=5&CALId=97&ver=5&CalName=Prothrombin+Time+and+Fecal+Occult+Blood+(Revision+of+ICD-9-CM+Codes+for+Injury+to+Gastrointestinal+Tract)&bc=gAgAAAAAgAIAAA%3D%3D&). Accessed December 26, 2016

²⁵ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3436CP.pdf>. Accessed December 26, 2016

- D12.6 – benign neoplasm of colon, unspecified
- Z12.11 – encounter for screening for malignant neoplasm of colon
- Z12.12 – encounter for screening for malignant neoplasm of rectum
- Z15.09 – genetic susceptibility of other malignant neoplasm
- Z80.0 – family history of malignant neoplasm of digestive organs
- Z83.71 – family history of colonic polyps
- Z86.010 – personal history of benign neoplasm of colon

Scope of the Proposed PFPM

The episode can be visualized as follows:



Any physician that performs colonoscopy and can align / contract with the other components of the bundle. Medicare 2014 claims data indicates that physician specialties who perform colonoscopy and represent at least 1% of claims for colonoscopy procedures include Gastroenterology, General and Endoscopic Surgery, Colorectal Surgery, Internal Medicine and Family Practice.

There are approximately 11,500 gastroenterologists, 3,500 colorectal surgeons, 6,000 endoscopic surgeons, 18,000 general surgeons, 35,000 anesthesiologists, 35,000 certified registered nurse anesthetists, 18,000 pathologists, and 209,000 primary care physicians who could participate if the model was expanded to scale. Based on Medicare claims data, this could apply to approximately 1.81M Medicare beneficiaries, which represents approximately 60% of colonoscopies performed. Approximately 12 million colonoscopies were performed in the US in 2012, which suggests that Medicare represents approximately 25% of colonoscopy procedures²⁶. Of the remaining 9 million colonoscopies, if 60% of colonoscopy procedures are related to colorectal cancer screening, diagnosis and surveillance, this model could be expanded to an additional approximately 5.4M patients in Medicaid, commercial, Tricare, and other programs.

²⁶ Joseph DA, Meester RGS, Zauber AG, Manninen DL, Wings L, Dong FB, Peaker B, van Ballegooijen M. Colorectal cancer screening: Estimated future colonoscopy need and current volume and capacity. Cancer 2016. DOI: 10.1002/cncr.30070.

Forty-two Gastroenterology practices representing 1000+ physicians has organized as the Digestive Health Network (DHN) to submit this physician focused bundled payment service advanced APM proposal, and has submitted a Coding Change Proposal to the AMA CPT Editorial Panel to create a category III tracking code that would support tracking, participation, coverage, and reimbursement for this model. Establishment of a tracking category III CPT code, if successful, would ensure that DHN participation would not be required for physicians to participate in this model.

The proposed model should work the same regardless of whether the physician is independent or employed, whether in a small or large practice, whether in a single or multi-specialty practice. The physician's compensation should go down (downside risk) if the physician has a high incidence of repeat procedures due to poor preparation, too-early follow-up, etc.

Variations of this model have been implemented on a prospective basis by practices in several states under direct contracts with self-funded employer and Taft-Hartley trusts, with good success. A retrospective variation of this model with upside-only risk has been implemented by Horizon Blue Cross Blue Shield of New Jersey; in the first year of implementation the plan paid out almost \$3M to 51 practices participating in their shared savings Episodes of Care program for colonoscopy and other procedures.²⁷

The costs or financial risks associated with the payment model are feasible for small practices. While the concept of a "focused factory" was first described in 1997²⁸, the endoscopist does not need to have all the entities (facility, anesthesia, pathology) under one roof. This model provides a framework for the solo or small practice to evaluate their own practice, and to contract with other providers to establish a prospective payment for services.

Patients who are eligible for colorectal cancer screening, diagnosis, and surveillance through colonoscopy are expected to benefit from this model. Services from different healthcare professionals and settings are coordinated and incented to provide high-quality, complete examination of the colon on the initial study, reducing the potential risks of repeat procedures. Patients are protected through ensuring that their anesthesia status and risks are ascertained, they receive interactive patient-specific instructions on high quality split-dose preparation, and services are scheduled in the most cost-efficient setting. One co-pay for the entire episode of care is proposed, as applicable, thus reducing the unintended consequences of beneficiary financial burden and responsibility when an otherwise asymptomatic patient undergoes colonoscopy as a result of another CRC screening test, or a screening service becomes a procedure. Patients are protected against unintended consequences and less than optimal outcomes, knowing that if a repeat procedure was required during the episode period due to a post-polypectomy bleed or poor prep, the second procedure would be covered without additional patient financial responsibility.

Physician engagement is an important component in achieving performance improvement goals. Experience has shown that gradual, continuous improvement with timely feedback on

²⁷ See <https://www.horizonblue.com/about-us/news/company-news/results-show-doctors-patients-and-horizon-bcbsnj-members-all-win-from-company-s-innovative-episodes>. Accessed December 26, 2016

²⁸ R.Herzlinger, *Market-Driven Health Care* (Reading, Mass.: Addison-Wesley, 1997)

performance is preferable to an ‘all-or-none’ approach^{29 30}. Based on published literature approximately 15% of colonoscopies performed are incomplete; data from the DHN practices suggests this rate is 9%. We propose to reduce repeat procedures to 7% in the first year of this APM, with a subsequent 1% reduction per year until a 96% complete procedure rate is achieved in year four and beyond³¹.

Available 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%, and 45385-45.13%. Facility payment differs depending on whether the hospital outpatient department (HOPD) or ambulatory surgical center (ASC) is the site of service. In this APM, we propose 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 and beyond.

The overall anticipated impacts on Medicare spending are to limit repeat procedures, reduce the number of procedures being repeated too early, support performance of procedures in a lower cost ASC rather than a higher cost HOPD setting, establish a cap on the number of pathology specimens, reduce patient barriers to obtaining life-saving colorectal cancer screening, and save money for the trust funds.

Quality and Cost

In a prospective episode payment model for a self-limited procedure such as colonoscopy, care delivery is expected to improve to achieve savings and improve quality. Medicare claims data indicates that approximately 52% of colonoscopy procedures are performed in the HOPD setting, while approximately 43% are performed in the ASC setting. Published literature suggests that close to 90% of patients undergoing colorectal cancer screening, diagnostic, or surveillance colonoscopy are American Society of Anesthesiologists (ASA) physical status classification I or II³². We believe most ASA I-II patients can be safely moved from the HOPD to the ASC setting, and ASA III if anesthesia support is available in the ASC setting, with a reduction in 2017 facility costs of \$306.92 for screening / diagnostic and \$403.41 for procedural services.

Table 2: Medicare facility reimbursement, by setting, colonoscopy procedures

| Code | 2016 HOPD | 2016 ASC | 2017 HOPD | 2017 ASC |
|--------------|-----------|----------|-----------|----------|
| G0105 | \$752.76 | \$420.93 | \$667.40 | \$360.48 |

²⁹ Herzer KR, Pronovost PJ. Motivating physicians to improve quality: Light the intrinsic fire. *Am J Med Qual.* 2014;29(5):451–453

³⁰ Herzer KR, Pronovost PJ. Physician Motivation: Listening to What Pay for Performance Programs and Quality Improvement Collaboratives are Telling Us. *Joint Commission journal on quality and patient safety.* 2015;41(11):522-528.

³¹ MacPhail ME, Hardacker KA, Tiwari A, et al. Intraprocedural cleansing work during colonoscopy and achievable rates of adequate preparation in an open-access endoscopy unit. *Gastrointestinal Endoscopy* 2015; 81 (3): 525-30

³² Enestvedt BK, Eisen GM, Holub J, Lieberman DA. Is ASA classification useful in risk stratification for endoscopic procedures? *Gastrointestinal endoscopy.* 2013;77(3):10.1016/j.gie.2012.11.039. doi:10.1016/j.gie.2012.11.039.

| | | | | |
|--------------|----------|----------|----------|----------|
| G0121 | \$752.76 | \$420.93 | \$667.40 | \$360.48 |
| 44388 | \$752.76 | \$420.93 | \$667.40 | \$360.48 |
| 44389 | \$752.76 | \$420.93 | \$877.23 | \$473.82 |
| 44394 | \$752.76 | \$420.93 | \$877.23 | \$473.82 |
| 45378 | \$752.76 | \$420.93 | \$667.40 | \$360.48 |
| 45380 | \$752.76 | \$420.93 | \$877.23 | \$473.82 |
| 45385 | \$752.76 | \$420.93 | \$877.23 | \$473.82 |

Quality will be improved, and Medicare expenditures reduced, by reducing inappropriate surveillance procedures at an early interval. Goodwin, et al. reported that 46.2% of Medicare patients underwent a repeated examination in fewer than 7 years, and in 42.5% of these patients there was no clear indication for the early repeated examination. This APM incorporates public reporting of physician performance on the following MIPS quality measures:

- 185 (Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use)
- 320 (Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)
- 439 (Age Appropriate Screening Colonoscopy)

Public reporting aligned with physician participation in this episode is anticipated to result in a 90% reduction in surveillance procedures performed at an inappropriately early interval.

Further, quality will be improved by reporting and acting on the following MIPS quality measures as part of this episode:

- 128 (Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan)
- 130 (Documentation of Current Medications in the Medical Record)
- 226 (Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention)
- 343 (Screening Colonoscopy Adenoma Detection Rate)
- 425 (Photodocumentation of Cecal Intubation)
- 431 (Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling).

In addition, we propose to obtain a PHQ-2 screen for depression at the pre-procedure assessment to ascertain whether unrecognized depression contributes to poor procedure preparation and post-procedure complications.

This APM proposes to use the following measurements of beneficiary experience of care:

- Overall satisfaction with experience
- Professionalism of the non-medical office staff
- Communication with physician being easy to understand
- Included in decision making related to your care
- Information provided on what to expect during and after the colonoscopy procedure
- Preparation for the colonoscopy procedure
- Likelihood to recommend
 - The physician
 - The practice

- The site of service where the procedure was performed

The greatest barrier to a prospective model's success is the inability of payers to prevent duplicate payment for services billed outside of the bundle, such as anesthesia or pathology. We address that through our concurrent proposal to establish a CPT category III tracking code which could be reported along with the index colonoscopy procedure (see supplemental information). A category III CPT tracking code could be implemented by Medicare, Medicaid, and commercial payors to 1) indicate participation in this alternative APM episode and 2) prevent duplicate payment for services. A second barrier is promoting a fixed price model for an episode of care involving an outpatient procedure which is viewed as a 000-day global procedure. The projections and payment assumptions in this APM are based upon data obtained from the DHN physicians, with annual payment increases limited to CMS changes to the MPFS and OPFS fee schedules. Targets to reduce potentially avoidable repeat procedures and utilize cost-efficient sites of service are incrementally increased over years 1 through 4 of the APM.

As we gain experience and data, in future years we may propose to extend this model to include 1) additional colonoscopy procedures, 2) additional indications, 3) addressing inpatient hospitalization risk, and 4) incorporating additional CRC screening services to move to a population health model of care for CRC screening.

The QCDR used most frequently in gastroenterology practices, GIQuIC³³, has an installed base focusing on endoscopic procedures. Reporting quality data using a QCDR that has been adopted by many solo and small GI practices would help to facilitate wider adoption of this APM, noting that this episode expands measurement of quality and appropriateness to the HOPD and office setting. This APM leverages existing multi society guidelines on appropriateness of care and follow up intervals, incorporates cross-cutting and specialty specific MIPS measures, and propose to publicly report this information by physician NPI and by group TIN to provide patients and beneficiaries with the ability to compare physicians in geographic regions and across the country. Data from multiple sources will be incorporated to support total cost of care, resource utilization, and clinical quality metrics through sharing data from the EHRs of all clinicians who provide relevant care for the attributed patient population. Auditing of participants should occur on a regular basis to ensure quality of care. The Digestive Health Network has partnered with a consulting actuary to perform statistical analyses and to estimate the impact of the model on spending and quality of care.

Improving lesion detection and removal of pre-cancerous lesions is a key component of CRC screening. A limitation of colonoscopy is that it relies on the ability of the endoscopist to identify a lesion. Variation in performance has been linked to important outcome measures; for example, interval cancers are more common in low adenoma detectors as compared with high adenoma detectors³⁴. Deep learning, which can help researchers to analyze medical data to treat diseases and to enhance doctors' ability to analyze medical images, could be applicable to this model by

³³ <http://giquic.gi.org/>

³⁴ Robertson DJ, Kaminski MF, Bretthauer M. Effectiveness, training and quality assurance of colonoscopy screening for colorectal cancer. *Gut*. 2015 Jun;64(6):982-90

providing a large and publicly available annotated database for automated classification of colonic polyps and lesions³⁵.

Payment Methodology

The genesis of this APM began in early 2016, when over 1000 physicians in 42 gastroenterology practices across the country identified the value-based need for an episode payment for colonoscopy for CRC screening, diagnosis, and surveillance. The model has been tested at a local level, initially in prospective date of procedure models with self-funded employer groups, with a recognition that the model needs to be expanded to an episode of care model to ensure quality, promote provision of services in the cost-efficient setting most appropriate for the individual patient, and reduce potentially inappropriate services.

The DHN obtained data from its practices to construct the payment methodology:

- How many colonoscopies did your practice perform (inpatient vs outpatient) for the 12 months Oct 1, 2015 thru Sept 30, 2016
- How many Outpatient colonoscopies are scheduled as screening? (44388, 45378, G0105, G0121).
- Of those procedures which started as screening exams, what % result in
 - Biopsy (cold) 45380, 44389
 - Biopsy (hot) 45384, 44392
 - Polypectomy 45385, 44394
 - Endoscopic mucosal resection 45390, 44403
 - Injection 45381, 44404
- How many outpatient colonoscopies were diagnostic based on another CRC screening test (blood, stool, imaging, FS)? Of these procedures, what % result in
 - Biopsy (cold) 45380, 44389
 - Biopsy (hot) 45384, 44392
 - Polypectomy 45385, 44394
 - Endoscopic mucosal resection 45390, 44403
 - Injection 45381, 44404
- What % of colonoscopies are performed for CRC surveillance (follow-up after previous study)? Of these procedures, what % result in
 - Biopsy (cold) 45380, 44389
 - Biopsy (hot) 45384, 44392
 - Polypectomy 45385, 44394
 - Endoscopic mucosal resection 45390, 44403

³⁵ Ribeiro E, Uhl A, Wimmer G, Häfner M. Exploring Deep Learning and Transfer Learning for Colonic Polyp Classification. *Computational and Mathematical Methods in Medicine*. 2016;2016:6584725. doi:10.1155/2016/6584725.

- Injection 45381, 44404
- What % of outpatients undergo repeat colonoscopy, or follow-up at an earlier interval, due to poor prep?
- What % of outpatient colonoscopies are
 - Incomplete and had to undergo a second procedure
 - Had an ER/Urgent Care visit within 7 days of colonoscopy
 - Had a post polypectomy bleed requiring a second procedure
- What % of your outpatient colonoscopies are ASA I, ASA II, ASA III?
 - Where do you perform screening, diagnostic, surveillance colonoscopy on an ASA III patient?
- In what % of colonoscopies is cancer diagnosed, requiring referral to a surgeon and oncologist for management?
- What % of colonoscopies are performed for patients with inflammatory bowel disease? Lynch syndrome or other polyposis disorders?

The data obtained from the practices revealed:

Why is colonoscopy performed:

- 47% are de novo for screening
- 8% are diagnostic resulting from another CRC screening test
- 45% are for surveillance

Where are procedures performed:

- 52% ASC
- 1% office
- 47% HOPD

What is the procedure mix:

- Diagnostic: 27%
- Biopsy: 35%
- Injection: 1%
- Polypectomy: 37%

What is the ASA classification:

- ASA I: 16%
- ASA II: 61%
- ASA III: 23%

Rate of ER visits within 7 days of procedure: <0.1%

Rate of post-polypectomy bleed requiring repeat procedure: 0.3%

Average number of biopsy jars / procedure: 2.1

Percentage of pathology procedures requiring special stains: 22%

Re-do rate (includes poor prep and inability to completely visualize colon): 9%

Procedures performed for Lynch syndrome / inherited polyposis disorders: 2%

Procedures performed in patients with IBD: 7%

Average number of anesthesia units per procedure: 8.7

Incorporating CPT coding, site of service, analysis of current performance, and proposed goal performance, we propose a payment model which would need to be correlated with CMS data:

- A prospective payment which incorporates the services identified in Model Overview (page 5), adjusted yearly by the proposed rate of re-do procedures and rate of ASC utilization as outlined in Scope of the Proposed PFPM (page 10)
- Incorporate a one-time payment which includes:
 - Communication and engagement with patient regarding pre-procedure evaluation, assessment of ASA status, medication management, and preparation instruction aspects of care
 - Review of patient status including review of laboratory and other studies
 - Collection of health outcomes data and registry documentation
 - Providing patients with 24/7 access to physicians or other qualified healthcare professionals or clinical staff to address urgent needs
 - Post-procedure evaluation and management services, as indicated
 - Stop-loss premium for emergency department / urgent care visits and observation services within 7 days of the endoscopic procedure
 - Endoscopist office reconciliation of services amongst participating and non-participating providers and facilities.
- Incorporate the quality measures identified in Quality and Cost (page 12)
- One co-payment amount for all the services received by a Medicare beneficiary who require diagnostic or procedural services; beneficiaries who receive screening services would continue to have zero co-pay and deductible as a Preventive service.
- Yearly retrospective reconciliation, with downside payment adjustment for those providers who 1) fail to meet the re-do target for the calendar year (CY), 2) fail to meet the ASC utilization target for the CY, and/or 3) fail to meet the quality criteria for surveillance follow-up intervals based on endoscopic and pathology findings.
- A safe harbor designation from federal anti-kickback and Stark laws that would facilitate this coordinated care model across different practices and facilities.

Value over Volume

This payment model is applicable to other payers in addition to Medicare, and if the CPT coding change application is approved, should not require new methodology. While this is proposed as a prospective model, a retrospective methodology will be required which would provide the

physician with their information and target performance goals at the beginning of each model year. Risk adjustment is achieved through limiting participation to outpatients who are ASA class I-III. A fixed payment for each patient ASA class I-III who undergoes colonoscopy, regardless of the method of sedation, site of service, number of pathology specimens used, and no payment for repeat procedures, is expected to sustain the expected changes in care delivery over time.

As noted above, the targets for this APM are defined as reducing the poor prep / in complete procedure rate initially to 7%, with a subsequent 1% reduction per year until a 4% repeat procedure rate is achieved in year four and beyond, while keeping complications (as measured by ASC-12 and OP-32) minimal. Quality measurement incorporates both procedure specific and population health measures, while encouraging performance of the procedure in the most cost-efficient setting and manner. The penalties for failure are that all physicians and qualified healthcare professionals involved – endoscopist, anesthesia, pathologist - and facilities (HOPD, ASC) lose revenue if they are 1) not paid for potentially avoidable repeat procedures and 2) fail to achieve the financial goals of the model, resulting in a downside adjustment. Those who do not achieve these goals will be at financial risk for their portion of care within the framework of the model.

The proposed payment methodology differs from current Medicare payment methodologies / Center for Medicare and Medicaid Innovation (CMMI) models for physicians or other eligible professionals as it is a specialty specific model that is physician driven, based on an outpatient procedure, involves multiple specialties, and geared towards improving public health. Unless the physicians are currently part of a multi-specialty group operating under 1 TIN number, there is no way to address care coordination across multiple providers and facilities with different TIN numbers. Our CPT proposal addresses the accuracy and consistency of identification / coding of diagnoses and conditions, clinical appropriateness of the payment unit, and accurately assigning claims for payment to the episode of care.

Flexibility

A fixed price for the bundle will encourage physicians and other eligible professionals to deliver high-value health care. Physicians will be encouraged to provide services in the most clinically appropriate, cost effective setting for most patients, namely an ASC rather than the HOPD setting. Hospitals that wish to participate would have an incentive to lower its outpatient procedure price to match the ASC price, as demonstrated in several marketplaces³⁶. A bundled payment for colonoscopy could reduce the incentives for physicians to take potentially unnecessary biopsies. Experience with Horizon BCBS and others have demonstrated improvement in colorectal cancer screening at an overall decrease in costs. Practices that have not participated in the program are publicly identified as ‘non-participants’ with patients having to pay a higher co-pay to use those practices and facilities.

The proposed model can be adapted to accommodate the full spectrum of differences in clinical settings and patient subgroups. Most physicians lack the complete claims data (medical,

³⁶ New Choice Health. Minneapolis, MN Colonoscopy Cost Comparison. <https://www.newchoicehealth.com/places/minnesota/minneapolis/colonoscopy/colonoscopy>. Accessed December 26, 2016

hospital, pharmacy, etc.) to establish a cost profile of each patient, including the costs of hospitalizations, complications, etc. Few physician groups have the data capabilities to analyze ICD-9 or ICD-10 codes to identify which emergency department services after colonoscopy were or were not likely related to the index procedure into their contracting efforts with payors³⁷. For these reasons, we recommend that this model start with colonoscopy for CRC screening, diagnosis, surveillance; after several years of collecting data the model can be expanded to other colonoscopy procedures such as dilation, foreign body removal, stent placement, etc.

In the future, once we gain adequate data and experience, we believe that this model could serve as a basis for expansion into a population model for CRC screening. Further, this model could accommodate changing technology, should CMS determine in the future that other technologies for CRC screening such as CT colonography, colon capsule endoscopes, and/or blood tests meet the CMS definition of ‘reasonable and necessary’ for coverage as a CRC screening service under Section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)).

We have identified that practices will incur infrastructure needs to implement the proposed model. While some of the data collection will be based upon information contained in electronic medical records (EMR) and endoscopy writer software (endowriters), we believe that cloud based clinical decision support (CDS) tools will be required to integrate with the patient’s EMR. Further, our experience is that patients will benefit from the provision of patient-specific tools to reinforce preparation instructions in a culturally sensitive and linguistically specific manner. These operational burdens and reporting requirements that result from the proposed payment model will need to be accounted for within the episode payment, which is addressed in Payment Methodology (page 15).

We have excluded coverage of hospitalization events related to this model. One reason is that the incidence of complications post colonoscopy is, thankfully, small³⁸. Another reason, though, is that incorporating hospitalization events into the model could be financially devastating to the solo, small, and/or rural practitioner participating in the model. We have explored whether participants in this model could obtain stop-loss reinsurance to ‘insure’ against such an unlikely occurrence, and believe that CMS will need to clarify that participation as a ‘virtual group’ under MACRA, which has currently been proposed for solo and small practices to combine their reporting as a group across all four MIPS performance categories, would also be applicable for an APM to allow solo and small groups to combine for the purposes of purchasing stop-loss reinsurance³⁹. Under that assumption, we have engaged actuaries to identify the per-case premium for stop-loss, which would be incorporated into the payment for the episode.

Ability to be Evaluated

In this proposal, we have addressed how the impact of the colonoscopy advanced APM on metrics included as part of the proposed model can be evaluated. In addition to measuring rates

³⁷ Spector JM, Studebaker B, Menges EJ. Provider Payment Arrangements, Provider Risk, and Their Relationship with the Cost of Health Care. The Society of Actuaries 2015

³⁸ 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 Jan;150(1):103-13

³⁹ Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114 10, enacted April 16, 2015)

on MIPS measures and patient satisfaction measures, participants will be measured and held accountable for rates of site-of-service utilization, method of sedation, incomplete procedures, adequacy of colonoscopy preparation, utilization of pathology, surveillance intervals, and episode cost of care. We have proposed to incorporate a PHQ-2 depression screen and selected population health measures as part of our data collection efforts. The evaluable goals for this model will be at both the individual physician NPI and provider entity TIN level.

Ultimately, the goal is to expand CRC screening at a population health level, decreasing the rate of colorectal cancer, and improving detection of CRC at early stages. Increasing CRC screening rates to 80% by 2018 would reduce CRC incidence rates by 17% and mortality rates by 19% during short-term follow-up and by 22% and 33%, respectively, during extended follow-up. These reductions would amount to a total of 277,000 averted new cancers and 203,000 averted CRC deaths from 2013 through 2030⁴⁰.

Integration and Care Coordination

The types of physicians and qualified healthcare professionals likely to be included in the implementation of this model to achieve desired outcomes would include gastroenterologists, surgeons, primary care providers, pathologists, anesthesiologists and CRNAs, radiologists, and nurse practitioners and physician assistants who are part of the gastroenterologist's, surgeon's, or primary care endoscopist's practice. Noting that the Departments of Labor, Treasury, and HHS have clarified that the preparation for the screening colonoscopy is a covered service without patient financial responsibility, pharmacists could also participate in the model, incident-to the endoscopist's service, for the purposes of 1) colonoscopy prep instructions, and 2) medication reconciliation. The proposed model would not result in significant changes in workforce requirements compared to more traditional arrangements. The data collaboration and collection, use of the category III tracking CPT code, and capture of MIPS quality measures should lead to greater integration and care coordination among practitioners and across settings.

Contractual arrangements will be key to the success of the model. For Medicare, we envision that payment for the model will be set based on the Medicare allowable payment for the professional and facility services incorporated in the model, adjusted by the applicable geographic practice cost index (GPCI) for the practitioners, as addressed in the Payment Methodology section (page 15). Contract arrangements will need to be executed between the endoscopist, pathologist, and anesthesia professional for participation in the model, as well as with hospitals and ambulatory surgical centers. In the design of the model, as we have identified that solo and small practices could have issues with cross-coverage in the event of complications, program requirements around care processes will need to be established to address potential savings and losses.

Patient Choice

⁴⁰ Meester RGS, Doubeni CA, Zauber AG, et al. Public Health Impact of Achieving 80% Colorectal Cancer Screening Rates in the United States by 2018. *Cancer*. 2015;121(13):2281-2285. doi:10.1002/cncr.29336.

Patient choice is preserved under this model by accommodating individual differences in patient characteristics (including social needs, etc.), conditions, and health-related preferences while furthering population health outcomes. While there is no mandate for the patient to participate in this model, the financial and quality considerations should be appealing to the patient compared to the traditional fee-for-service model. Incorporating payment for pre-procedure services prior to colonoscopy under CMMI's authority to test various payment and service delivery models that aim to achieve better care for patients and smarter spending would ensure appropriate assessment of sedation risks, encourage performance of the procedure in the most cost-effective setting based on the beneficiary's individual clinical circumstance, and provide preparation instructions in a culturally sensitive and linguistically specific manner.

Expansion of this model to address disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography depends on the economics of the model and the willingness of the endoscopist, other physicians, and hospital / ASC facilities to participate in the data collection and financial terms of the model. A retrospective version of this model has already been implemented by several commercial payors, and a prospective version of this model has been implemented by self-funded employers and Taft-Hartley trusts. CMS inclusion of this model as an advanced APM would expand the demographic and geographic diversity of participation in alternative payment models beyond existing CMS / CMMI models in specialty care, addressing a chronic condition (colorectal cancer) which has a disproportionate impact on Black, American Indian / Alaska Native, and non-Hispanic groups.

Patient Safety

The proposed model incorporates numerous quality measures - MIPS, ASC, and outpatient hospital - to ensure that patients are not harmed by efforts to achieve savings or to improve specific aspects of quality/outcomes. The initial 1000+ physicians who have already indicated interest in participating in this model have collected rates of service information as outlined previously in the section on payment methodology, including rates of repeat procedures and ER visits within seven days of a colonoscopy procedure. Once a baseline is established, this information would be collected on a prospective basis to ensure the provision of necessary care and monitor for any potential stinting of care after implementation.

We believe that it is important that the proposed model ensure the integrity of its intended benefits. In addition to the embedded monitoring under consideration, we propose that public reporting of individual physicians including both FFS and Medicare Advantage should be included to monitor whether unintended or other incongruent behaviors occur. While this advanced APM proposal addresses Medicare beneficiaries, patients, payers and purchasers have a significant interest in the cost of colonoscopy procedures^{41 42}, and we are prepared to support a transparency initiative that includes cost and quality data on all patients who participate in this advanced APM initiative, not just FFS Medicare beneficiaries.

⁴¹ Rosenthal E. The \$2.7 Trillion Medical Bill. Colonoscopies Explain Why U.S. Leads the World in Health Expenditures. New York Times. June 1, 2013. Available at http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html?pagewanted=all&_r=0. Accessed December 26, 2016

⁴² Pinder J. How Much Is My Colonoscopy Going to Cost? \$600? \$5,400?. The Health Care Blog. August 27, 2014. Available at <http://thehealthcareblog.com/blog/2014/08/27/how-much-is-my-colonoscopy-going-to-cost/>. Accessed December 26, 2016

Many gastroenterology practices already participate in clinical research. We have considered whether a data monitoring board including external, non-professional participants should be established to ensure no stinting of services.

Health Information Technology

Patients' privacy of health information will be protected. No new providers or caregivers will have access to personal health information (PHI) compared to the baseline. All professional and facility participants will be governed by HIPAA. The proposed APM facilitates transparency related to cost and quality of care to patients and other stakeholders through external data collection and reporting.

Data for colonoscopy procedures and associated services may reside in several information silos, e.g. endoscopist, primary care, surgeon, anesthesiologist, pathology, radiology, facility. This APM incorporates a CPT category III code to facilitate participation, tracking and payment in the model. As the endoscopist is the fulcrum of the model, interoperability of electronic health records would help but is not essential in guiding better decision-making.

The proposed APM presumes the incorporation of patient-focused technology innovations to support improved outcomes, improve the consumer experience, and enhance the efficiency of the care delivery process. A number of practices already have experience with SonarMD, a patient engagement application which incorporates clinical decision support tools and has demonstrated reduction in emergency department visits, inpatient hospitalizations, and overall cost savings for patients with inflammatory bowel disease⁴³, and SmartClinic, a patient engagement application which provides patient preparation protocols, treatment instructions, appointment reminders, and compliance tracking for patients undergoing colonoscopy⁴⁴. Both applications were developed by Gastroenterologists who attempted to address and solve inefficiencies in their existing practice environment. We envision incorporating patient engagement tools into this APM, and reporting on whether patient engagement facilitates improvement in procedures and outcomes.

Supplemental Information

The Physician-Focused Payment Model Technical Advisory Committee notes that proposals submitted for consideration will be made available to the public for comment. However, the American Medical Association states that the application for a category III CPT code is considered to be confidential and is not available for review⁴⁵. We look forward to working with both entities to identify a method whereby we can provide a copy of the category III CPT code proposal to the PTAC for review, without violating the AMA's confidentiality processes.

⁴³ <https://www.sonarmd.com/>

⁴⁴ <http://www.smartclinicapp.com/>

⁴⁵ <https://www.ama-assn.org/practice-management/cpt-application-frequently-asked-questions>

Supplemental Information: Proposed Payment Methodology

There are challenges inherent in an episode payment model which incorporates coordination of services provided by multiple practitioners in a variety of settings. We have identified that solo and small practices may face greater challenges in implementing this APM, as they might not have the internal resources for coordination of services and after-hours / cross coverage to support this model.

The goals of this model are:

- To reduce potentially avoidable repeat procedures due to poor preparation / inability to perform a complete screening procedure
- To encourage utilization of this service in the most cost-effective setting
- To support surveillance intervals in accordance with both specialty society guidelines and Medicare coverage policies
- To address concerns regarding potential overuse of services
- To ensure that beneficiaries are not surprised when CRC screening in the asymptomatic individual becomes diagnostic

Published literature suggests that the repeat rate (re-do) for colonoscopy procedures is 10-15%. Data from our practices suggests that this rate varies but may be as high as 9%. We propose to set a 7% goal for re-do in the first year, with a reduction by 1% per year in subsequent years until a 4% rate is achieved.

In addition, there is an opportunity for beneficiaries to undergo colonoscopy in a cost-effective setting.

To achieve the goals of this APM, the endoscopist who contracts with CMS to participate in this model will need to receive information from CMS on the Medicare allowable amounts for hospitals and ASCs in their geographic area. A legal structure which allows the physician to directly contract with the ASC and hospital as well as other providers, including waiver of payment if a repeat procedure is required during the episode period, will need to be addressed.

Once that is available, the endoscopist would establish a prospective payment which would incorporate:

- Yearly target re-do rate
- One-time payment for care coordination services
- Endoscopic procedures
- Anesthesia / moderate sedation. Anesthesia professional indicates they are participating in model
- Pathology (88305) capped at 2 bottles / procedure.
- Pathology special stains (88313, 88341, 88342) capped at 20% of procedures (44389, 44392, 44394, 44403, 45380, 45384, 45395, 45390) where pathology specimens are obtained.

- Imaging procedures (74261, 74262, 74270, 74280 when required to complete examination of the colon). Radiologist indicates they are participating in model.
- Capsule endoscopy (0355T)
- Facility payment based on target ASC / HOPD utilization

The re-do target for the endoscopist, anesthesia professional would be set at the yearly target re-do rate (e.g. 107% in year one). This includes payment for repeat procedures for post-polypectomy bleeding. Payment for pathology services are fixed. Claims for capsule endoscopy and imaging procedures are paid and reconciled against the episode payment. If re-do rate is less than target (e.g. 105% in year one), then the savings (e.g. 2%) are distributed to the endoscopist and anesthesia professional. If re-do rate is greater than target, then the endoscopist and anesthesia professional are subject to a withhold of up to 4%.

The facility target for the endoscopist and facility would be set at the yearly target ASC utilization rate (e.g. 60% in year one). If the ASC utilization is greater than the target rate, then the endoscopist receives a 5% incentive bonus for all procedures performed in the ASC setting. If the ASC utilization is worse than the target rate, the endoscopist is subject to a withhold of up to 4%.

Emergency department (ED) charges are paid and reconciled against the episode payment. The APM assumes an emergency department utilization rate of 0.1% within 7 days of the index procedure. If ED utilization is >0.1%, this reconciliation amount is withheld against the endoscopist's incentive payment.

Quality indicators for surveillance intervals are audited using a statistical sampling of claims. Less than 90% adherence to recommended intervals for surveillance will result in a 2% withhold to the endoscopist.