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1300 North 17<sup>th</sup> Street • Suite 900  
Arlington, Virginia 22209  
Tel: 703.841.3200  
Fax: 703.841.3392  
www.medicalimaging.org

Dear Committee Members,

The Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the Proposal for a Physician-Focused Payment Model: Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance.

\* \* \* \*

Colorectal cancer (CRC) is the second most common cancer diagnosed in United States and the third leading cause of cancer death even though it has a roughly 90% 5-year survival rate when detected early<sup>1</sup>. Unfortunately, as indicated in a May 2015 report from the Centers for Disease Control and Prevention, CRC screening is dramatically underutilized.<sup>2</sup> While we support the aim of the proposed colonoscopy alternative payment model (APM), we are concerned that it will not capture colorectal cancer screening and diagnostic episodes that are initiated with computed tomography colonography (CTC).

CTC consists of low-dose standard abdomen and pelvis computed tomography (CT) imaging combined with display protocols to optimally visualize the colon.<sup>3-13</sup> Since its introduction into clinical practice around the year 2000, CTC has been implemented by over 1,000 radiology facilities in the US as well as a large number of global practices. Scientific studies on CTC have been published in almost 2,000 articles worldwide since its inception.

In June 2016, the United States Preventive Services Task Force endorsed CTC, awarding it and other CRC screening services an “A” grade.<sup>14</sup> Further, the Task Force has recognized that CTC is at least as sensitive as optical colonoscopy (OC) in identifying colorectal cancers and large adenomas.<sup>15</sup> CTC has significantly higher sensitivity and specificity in identifying precursor polyps compared to stool-based tests.<sup>16</sup> CTC is inherently better at visualizing colonic anatomy than OC.<sup>17</sup> CTC imaging visualizes all segments of the colon and produces highly diagnostic 2D and 3D volumetric images that can be manipulated, magnified, enhanced, and viewed from multiple angles on dedicated workstation computers to ensure that all colonic detail is visualized. The power of modern CT computers allows for a 3D virtual “fly through” of the entire colon in both retrograde and antegrade fashion.

CTC performs exceptionally well in colorectal cancer screening and, as utilization increases, will play an even more significant role in preventing CRC. For this reason, we believe that any CRC screening, diagnosis and surveillance APM should include at least all direct visualization methods as episode initiating procedures and should be open to radiology practices and facilities performing CTC.

\* \* \* \*

If you have any questions, please contact Peter Weems at 703-841-3238 or email at [pweems@medicalimaging.org](mailto:pweems@medicalimaging.org).

Thank you,



Patrick Hope  
Executive Director, MITA

*MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.*

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<sup>1</sup> <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-survival-rates>

<sup>2</sup> [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a4.htm?s\\_cid=mm6417a4\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a4.htm?s_cid=mm6417a4_w)

<sup>3</sup> Chang KJ, Heisler MA, Mahesh M, Baird GL, Mayo-Smith WW. CT colonography at low tube potential: using iterative reconstruction to decrease noise. Clin Radiol. 2015;70(9):981-988.

<sup>4</sup> Lambert L, Danes J, Jahoda J, Masek M, Lisy J, Ourednicek P. Submillisievert ultralow-dose CT colonography using iterative reconstruction technique: a feasibility study. Acta Radiol. 2015; 56(5):517-525.

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<sup>6</sup> Lambert L, Ourednicek P, Jahoda J, Lambertova A, Danes J. Model-based vs hybrid iterative reconstruction technique in ultralow-dose submillisievert CT colonography. Br J Radiol. 2015; Apr;88 (1048) :20140667.

<sup>7</sup> Lubner MG, Pickhardt PJ, Kim DH, Tang J, del Rio AM, Chen GH. Prospective evaluation of prior image constrained compressed sensing (PICCS) algorithm in abdominal CT: a comparison of reduced dose with standard dose imaging. Abdom Imaging.

<sup>8</sup> Lubner MG, Pooler BD, Kitchin DR, et al. Sub-millisievert (sub-mSv) CT colonography: a prospective comparison of image quality and polyp conspicuity at reduced-dose versus standard-dose imaging. Eur Radiol. 2015;25(7):2089-2102.

<sup>9</sup> Millerd PJ, Paden RG, Lund JT, et al. Reducing the radiation dose for computed tomography colonography using model-based iterative reconstruction. Abdom Imaging. 2015;40 (5):1183-1189.

<sup>10</sup> Nagata K, Fujiwara M, Kanazawa H, et al. Evaluation of dose reduction and image quality in CT colonography: comparison of low-dose CT with iterative reconstruction and routine-dose CT with filtered back projection. Eur Radiol. 2015;25(1):221-229.

<sup>11</sup> Shen H, Liang D, Luo M, et al. Pilot study on image quality and radiation dose of CT colonography with adaptive iterative dose reduction three-dimensional. PLoS one. 2015;10(1):e0117116.

<sup>12</sup> Shin CI, Kim SH, Lee ES, et al. Ultra-low peak voltage CT colonography: effect of iterative reconstruction algorithms on performance of radiologists who use anthropomorphic colonic phantoms. Radiology. 2014;273(3):759-771.

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- <sup>13</sup> 43 Yamamura S, Oda S, Imuta M, et al. Reducing the Radiation Dose for CT Colonography: Effect of Low Tube Voltage and Iterative Reconstruction. *Acad Radiol*. 2015 Apr 11. pii: S1076-6332(15)00130-0. doi: 10.1016/j.acra.2015.03.009. [Epub ahead of print].
- <sup>14</sup> <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/colorectal-cancer-screening2>
- <sup>15</sup> <https://www.uspreventiveservicestaskforce.org/Page/Document/evidence-summary/colorectal-cancer-screening2>
- <sup>16</sup> Levin B, Lieberman D, McFarland B, et al. Screening and Surveillance for the Early Detection of Colorectal and Adenomatous Polyps, 2008. *CA Cancer J Clin* 2008;58:1-31
- <sup>17</sup> Pickhardt PJ, Nugent PA, Mysliwiec PA, et al. Location of Adenomas Missed by Optical Colonoscopy. *Ann Intern Med* 2004; 141:352-359..

January 25, 2017

Physician-Focused Payment Model Technical Advisory Committee  
c/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201  
[PTAC@hhs.gov](mailto:PTAC@hhs.gov)

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

To: The Physician Focused Payment Model Technical Advisory Committee

I am writing this letter in support of The Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance; a proposal currently under consideration by the PTAC. This proposal aims to broaden CMS' APM portfolio by addressing an issue in payment policy in a new manner by including APM entities whose opportunities to participate in APMs have been limited. Additionally, this project fills an existing need for a way to bundle payments for Colonoscopy. It promotes a value-based approach to Colorectal Cancer Screening and will ultimately lead to lower cost/procedure. The current coding structure does not allow for coordination of payments for Colonoscopy and leads to excess costs.

Sincerely,

Lawrence R. Kosinski, MD, MBA, AGAF, FACG  
Clinical Practice Councilor: American Gastroenterological Association  
Managing Partner: Illinois Gastroenterology Group  
745 Fletcher Drive  
Elgin, Illinois 60123  
(847)370-8878



# COLLEGE of AMERICAN PATHOLOGISTS

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January 25, 2017

Ann Page, Office of Health Policy, Assistant Secretary for Planning and Evaluation (ASPE) and Designated Federal Officer for PTAC  
Physician-Focused Payment Model Technical Advisory Committee (PTAC)  
c/o Angela Tejada  
ASPE  
200 Independence Ave. SW  
Washington, DC 2020  
Via email to: PTAC@HHS.gov

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

Dear Ms. Page:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposal for a PFPM: Comprehensive Colonoscopy AAPM for Colorectal Cancer, Screening, Diagnosis, and Surveillance. The CAP is a national medical specialty society representing over 17,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals, and federal and state health facilities.

Our review of the model raised significant concerns related both to some of its premises on patient protection and care coordination, and also to its handling of pathology services. As a result, the CAP's comments express opposition to the PTAC recommending the implementation of the model. Reasons for the CAP's opposition are provided below, but are in essence that this proposal fundamentally fails to balance financial incentives with patient protections, or to provide for meaningful coordination of care.

## **Care Coordination**

The submission refers to team-based care for patients undergoing colorectal cancer screening, diagnosis, and surveillance using colonoscopy and indicates its comprehensive bundled payment model incorporates colonoscopy, anesthesia, moderate sedation, pathology, radiology, and evaluation and management services. It acknowledges that, unless physicians are already part of a multi-specialty group operating under a single tax identification number (TIN), there is no way to address care coordination across multiple providers and facilities with different TINs. The submission, however, provides neither guidance nor exposition on how care is to be coordinated or rendered in a team-based fashion as proposed. Instead, it blithely states that "a fixed price for the bundle will encourage physicians and other eligible professionals to deliver high-value health care." Without shared infrastructure, governance, or even a conceptual



description within the alternative payment model of how to provide care coordination, effective team-based care cannot simply be presumed to arise *sua sponte* because of a “fixed price for the bundle.”

Under the proposal, the endoscopist alone would establish a prospective payment. While somewhat unclear, it appears the reconciliation and distribution of any share of savings would also be performed by the endoscopist. This approach is significantly different from an integrated model with a structure that sets targets for performance improvement and payment levels, and calculates and distributes earned incentives.

### **Patient Protection**

The submission includes a brief section on patient safety, focused on the collection of rates of services from the initial physicians who indicated an interest in 2016 in the model, but lacks any tie to actual patient safety. In addition, patients are said to be “protected” against unintended consequences and less than optimal outcomes. It is actually these unintended but readily anticipated consequences which are of greatest concern.

The primary crux of the model is greatly reducing colonoscopy re-do rate over time. Strongly incentivizing reduction of the colonoscopy re-do rate does not itself translate into higher quality or patient protection. Reducing the colonoscopy re-do rate to (or below) the target to generate savings certainly does predispose to patients not getting a repeat procedure irrespective of medical indications. The submission acknowledges possible stinting of care and alludes to possible monitoring for this after implementation. No detail how this would be detected or monitored, however, is provided. The subsequent paragraph of the submission refers to “embedded monitoring” only as “under consideration.”

Similarly, the model’s other key focus, incentivizing movement of procedures to a lower cost setting, the ambulatory surgery center rather than the hospital, is also without either a conceptual model to guide implementation or a set of enunciated patient protections. In the absence of either, it fails to provide operational guidance to practitioners or safeguards to ensure that it is not detrimental to those patients for whom a hospital setting may be appropriate.

Finally in the area of patient protection and care improvement, several of the proposed quality metrics are not relevant for a model focused on colorectal screening, diagnosis, and surveillance. Some of the proposed measures are existing MIPS measures such as body mass index and tobacco use screening and cessation intervention, supporting the focus of the model being on cost reduction without an effective corresponding element of patient protection or care improvement.



### **Pathology Services**

Specifically concerning for pathologists is their apparently gratuitous inclusion in the proposal by “establish[ing] a cap on the number of pathology specimens” with no meaningful mechanism for participation or alignment with the model’s stated goals. As stated in the proposal, the overall anticipated impacts on Medicare spending is to limit repeat procedures, support performance of procedures in a lower cost setting, and cap the number of pathology specimens at the present average. Such a predetermined cap does not amount to “participation” in an alternative model of care by pathologists, but is rather a mere arrogation of additional services to the bundle. No quality or efficiency rationale is provided for the incorporation of this fixed cap nor is any opportunity provided for pathologists to effectively contribute.

As indicated above regarding patient protection, the model’s stated focus is on reduction in the colonoscopy re-do rate and increase in ambulatory surgery center utilization. Pathologists are not involved in either of these goals. It seems then that pathologists are therefore “included” not to help coordinate care and achieve objectives, but to generate savings for the model based on caps on services that lack clinical justification or evidence for care improvement. Savings as a result of such caps, it appears, would be disseminated to those who truly are participants rather than to pathologists as further explained below.

Under the proposal, although pathologists are among the physicians included in the model, they are the only physicians whose services are preset at a fixed rate with an express cap on the number of services without incentives to generate savings or improve quality. Coupled with the inability to affect the model’s primary objectives, reduction in the colonoscopy re-do rate and ambulatory surgery center utilization, this forces the CAP to question the legitimacy of the inclusion of pathology services at all.

“[P]ayment for pathology services are fixed” seems to affirm performance improvement incentives are inapplicable. The proposal establishes targets for the endoscopist colonoscopy re-do rate with savings distributed to the endoscopist and anesthesia professional. Similarly, an ambulatory surgery target applies to the endoscopist. Emergency department charges and claims for capsule and endoscopy and imaging procedures are paid and reconciled against the episode payment.

While payments for pathology services are not reconciled against the episode and the pathologist does not appear to be incentive-eligible, pathology services are capped at “2 bottles/procedure” and pathology special stains are “capped at 20% of procedures” where pathology specimens are obtained. Not only is this lacking in clinical justification, but the pathologist cannot practically fail to process and examine any specimens the endoscopist may submit, putting him or her in an untenable position with regard to “participating” in the proposed model.



## COLLEGE of AMERICAN PATHOLOGISTS

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The model's indication that "healthcare professionals are incented to provide high-quality, complete examination of the colon on the initial study" offers more confirmation of the lack of performance improvement incentive opportunity for pathologists. Regardless of the fixed payment and therefore lack of incentive for the pathologists, the submission's payment methodology section seems to apply downside risk to them under the following statement. "The penalties for failure are that all physicians and qualified health care 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, result in downside adjustment."

This inconsistency demonstrates not only the lack of meaningful pathologist participation and failure to align with the model's objectives, but also the need to remove pathologists from express inclusion in the model.

In closing, we again urge you not to recommend the model for adoption. We appreciate your consideration. Any questions or requests for additional information may be directed to Sharon West, JD, Director, Economic and Regulatory Affairs at 202-354-7112 or [swest@cap.org](mailto:swest@cap.org).





3300 Woodcreek Drive  
Downers Grove, Illinois 60515  
630-573-0600 / 630-963-8607 (fax)  
Email: [info@asge.org](mailto:info@asge.org)  
Web site: [www.asge.org](http://www.asge.org)

January 25, 2017

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Physician-Focused Payment Model Technical Advisory Committee  
c/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Re: Request for Public Comment on Comprehensive Colonoscopy Advanced  
Payment for CRC Screening, Diagnosis, and Surveillance

Dear Committee Members:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to provide comments regarding the proposal for a comprehensive Colonoscopy Advanced Payment Model for Colorectal Cancer Screening, Diagnosis, and Surveillance.

Since its founding in 1941, the ASGE has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 14,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

Tremendous strides have been made in improving colorectal cancer screening rates in the United States. According to the American Cancer Society, the significant decline (more than 30 percent) in colorectal cancer incidence rates over the past decade are largely attributable to the detection and removal of precancerous polyps as a result of increased colorectal cancer screening. Yet, colorectal cancer is still the fourth most common cancer and second leading cause of cancer-related deaths in the United States. Colonoscopy is a unique preventive service that allows for the detection of colorectal cancer and the removal of precancerous polyps during the screening procedure, thereby preventing cancer.

Advancing viable payment models that are well-suited for practicing gastroenterologists in all practice settings is critical, as currently there is not an alternative payment model (APM) pathway available for the vast majority of our members. Our members would benefit from a library of voluntary APM options from which to choose. ASGE looks forward to working with this Committee and other stakeholders in the development of APMs. We firmly believe all stakeholders — patients, physicians and the Centers for Medicare and Medicaid Services (CMS) — benefit when payment models are well-developed and their clinical data and quality metrics are well understood.

ASGE recognizes and appreciates the effort the Digestive Health Network (DHN) placed in the development and submission of what we believe constitutes an initial proposal for a colonoscopy APM. Colonoscopy is the highest volume procedure performed by gastroenterologists, and we support high-quality and cost-effective delivery of this service. The proposal appears to be oriented toward the goals defined by this Committee and CMS. However, the structure of a colonoscopy bundle, as well as a corresponding coding structure, remains under discussion by the major gastroenterology stakeholder organizations. Variations of this model have been recently implemented by several states and by commercial payers. The experiences and outcomes of these models, once available, should be relied upon when developing a colonoscopy bundle for adoption by the Medicare program. We support further consideration of a colonoscopy bundle by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and offer the following preliminary comments on the proposal for the Committee's consideration:

### **Bundle Components**

We recommend the initial bundle should be limited to screening of average risk individuals (including the patient who undergoes colonoscopy because of a positive fecal occult blood or DNA test) or polyp surveillance and exclude symptom-driven diagnostic and therapeutic indications. We suggest the bundle should be triggered by the procedure indication rather than the post-colonoscopy diagnosis. For example, if 211.3 benign neoplasm of colon is the indication for a procedure, this will not be a routine colonoscopy but rather a therapeutic colonoscopy with the intent of removing a polyp or surveillance of an existing polyp. Screening or surveillance situations or positive fecal tests as reasons for colonoscopy are ordinarily readily identified by ICD-10 codes for these circumstances and are distinguishable from other diagnostic or therapeutic circumstances.

The proposal states that "the cost and financial risk associated with the payment model are feasible for small practices." Without adequate pilot testing, it is unclear if this bundle will be acceptable or workable for practices that only have the gastroenterology professional component. To our knowledge, there is no example of services provided by independent pathologists, radiologists, and anesthesiologists which have been incorporated into a bundle, as structured in the DHN proposal, under which, they are held accountable for meeting goals for which they lack direct control. Furthermore, it is doubtful that a solo or small group gastroenterology practitioner could persuade and manage contracts involving the requisite range of specialists and facilities involved in the proposed bundle when involvement may involve price concessions, financial risk and quality measurement requirements.

### **Bundle Global Period**

A one-year payment model for colorectal cancer screening diagnosis, or surveillance would create a situation where unexpected events six to nine months after screening or surveillance colonoscopy would be handled inappropriately from a clinical perspective, because there would be the sense that no payment is forthcoming for the service. These events include but are not limited to GI hemorrhage, colitis, evaluation of new symptoms, and recurrent evaluation for anemia of unknown etiology.

We also see further complications arising with a one-year global period due to payment for large polyp management. Large polyp management often requires endoscopic mucosal resection (EMR, e.g. CPT code 45390). This procedure is often done by a different physician in or outside the group and perhaps in a different regional facility than by the physician who performed the initial colonoscopy. Under this proposal, if piecemeal mucosal resection was performed on the initial colonoscopy, there would be no payment for the necessary follow-up colonoscopy three to six months later.

To alleviate the above mentioned issues, we recommend a shorter global period be considered for a colonoscopy bundle that only includes screening and surveillance. A one-year global period for any service is unprecedented and requires pilot testing.

### **Site of Service**

The ambulatory surgery center (ASC) is a safe, cost-effective site for the provision of high quality care and endoscopic procedures. The HOPD and ASC share similar cost components, such as the human resources and equipment required for endoscopic procedures; however, legitimate differences in their cost structures must be recognized.

We believe that reimbursement, as well as patient cost sharing and cost transparency, can be used to leverage site-appropriate care, but cannot be applied in the form of a one-size-fits-all approach. Accordingly, we suggest an incremental and voluntary approach to a colonoscopy bundle. At a minimum, adequate risk adjustment will be necessary, as more high-risk, complex patients are cared for in the hospital outpatient department because of their stand-by capacity to immediately address complications.

### **Quality Performance Metrics**

ASGE is committed to achieving improved endoscopy-related health care outcomes in the most cost-effective manner. Costs of providing high-quality screening and surveillance colonoscopy reflect best practices, including complete examination in a well-prepared colon and avoidance of procedure-related complications. We support Merit-Based Incentive Payment System measures as outlined in the proposal, including the physician performance measures and beneficiary experience of care measurements. In addition to the metrics identified for the gastroenterologists, metrics should be identified for other stakeholders in the bundle for the purpose of sharing accountability.

Without a pilot study to determine that depression contributes to poor procedure preparation and post procedure complications, we would urge reconsideration of inclusion of the PHQ-2 screen in the initial bundle. Including the measure without further study would just contribute to the increased administrative burden of physicians. Similar considerations apply to quality measures that require preventive care, screening and counseling for tobacco use and alcohol abuse.

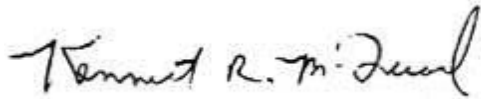
### **Conclusion**

Knowing that development and wide-spread adoption of APMs is a high-priority for CMS, it is critical that payment models that the PTAC recommend to HHS are accurate and incorporate multi-stakeholder support. This bundle is a step in the right direction and we welcome the opportunity to meet with developer and other stakeholders to reach consensus on a viable

voluntary payment model for colonoscopy that does not hold physicians accountable for components of the payment model which they cannot control and will offer broad appeal and adoption by GI physicians.

Thank you for the opportunity to provide comments. Should you need any additional information please contact Lakitia Mayo, Senior Director of Health Policy, Quality, and Practice Operation at (630) 570-5641 or lmayo@asge.org.

Sincerely,

A handwritten signature in black ink that reads "Kenneth R. McQuaid". The signature is written in a cursive style with a large, stylized initial 'K'.

Kenneth R. McQuaid, MD, FASGE  
President  
American Society for Gastrointestinal Endoscopy



## AMERICAN COLLEGE OF GASTROENTEROLOGY

6400 Goldsboro Road, Suite 200, Bethesda, Maryland 20817-5842; P: 301-263-9000;  
F: 301-263-9025

January 25, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)  
c/o Angela Tejada  
Office of the Assistant Secretary for Planning and Evaluation (ASPE)  
United States Department of Health and Human Services  
200 Independence Ave. SW  
Washington, D.C. 20201

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

The American College of Gastroenterology (ACG or College) appreciates the opportunity to provide comments on current proposals submitted to the PTAC. Specifically, the College urges PTAC to consider greater flexibility, should the agency decide to implement any alternative payment models involving gastroenterology.

Founded in 1932, the ACG is a physician organization that currently represents over 14,000 members providing gastroenterology specialty care. We focus on the issues confronting the gastrointestinal specialist in delivering high quality patient care. The primary activities of the ACG have been, and continue to be, promoting evidence-based medicine and optimizing the quality of patient care. The ACG is also committed to reducing administrative burdens among practicing gastroenterologists and other gastrointestinal clinicians.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) creates new ways for the Medicare program at the Centers for Medicare & Medicaid Services (CMS) to provide incentives for physicians to participate in Alternative Payment Models (APMs), including the development of physician-focused payment models (PFPMs). Section 101 (e)(1) of MACRA creates the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to make comments and recommendations to the Secretary of the Department of Health and Human Services (the Secretary, HHS) on proposals for PFPMs submitted by individuals and stakeholder entities.<sup>1</sup>

The PFPM criteria were outlined in the MACRA final rule with comment period that was made public on October 14, 2016 and published in the Federal Register on November 4, 2016.<sup>2</sup> These includes: Value

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<sup>1</sup> "Medicare Access and CHIP Reauthorization Act of 2015;" Public Law 114–10. 42 USC 1305.  
<https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>

<sup>2</sup> Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-FC).

over volume, flexibility, quality and cost, payment methodology, scope, ability to be evaluated, integration and care coordination, patient choice, patient safety, and health information technology.<sup>3</sup>

The College appreciates recent efforts to develop new payment and service delivery models. For example, the voluntary Bundled Payments for Care Improvement (BPCI) initiative includes bundled and episodes of care payments in specialties such as cardiology, orthopedic surgery, and gastroenterology.<sup>4</sup>

Some recently implemented initiatives, however, have required participation for certain physicians, depending on the specialty or area of the country in which they practice. This is a concern for our members, as mandatory participation is not likely to further CMS' goals of increasing flexibility and reducing reporting burdens as recently stated in the "Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models" final rule.<sup>5</sup> Instead, the ACG believes that one key to successful delivery reform is voluntary participation. Our members serve patients in a variety of settings, from large academic institutions to independent solo practices. Each setting poses unique practice-management and fiscal challenges, requiring members to participate in payment models that are most suitable for their respective practices and patients. A bundled payment for colonoscopy, for example, requires services performed by other specialists and may significantly impact the ability of small, independent practices to contract with other providers performing services inherent to endoscopy (e.g., anesthesia and pathology) as well as the facilities in which they contract to perform endoscopy. These issues were highlighted in the recent *CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report*:

BPCI participants indicated that they had entered into a variety of relationships with other organizations to prepare for and participate in BPCI. Most frequently, participants indicated that they had engaged external consultants to provide data analysis or information technology. According to site visit interviews, participants tried to collaborate with area providers, particularly PAC providers, in efforts to improve care coordination and gain efficiencies across the entire episode of care. There were few specific examples of successful collaborations and participants we spoke with indicated that it was challenging to establish relationships with other providers.<sup>6</sup>

The hospitals participating in BPCI gastrointestinal episodes were "larger than the typical hospital and were likelier to be teaching hospitals."<sup>7</sup> Many of our members do not practice in large academic centers and would face significant burdens and challenges if they were required to participate in such a bundle.

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<https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm>

<sup>3</sup> Physician-Focused Payment Model Technical Advisory Committee (PTAC) <https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee>

<sup>4</sup> <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-25.html>; and <https://innovation.cms.gov/initiatives/bundled-payments/>

<sup>5</sup> Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-FC). <https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm>

<sup>6</sup> The Lewin Group: "CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report." Report Prepared for CMS. August 2016.

<sup>7</sup> Ibid.

For example, while members may perform procedures at a facility, many may not control other facility-related costs associated with colonoscopy or be able to steer more of their patients to the ambulatory surgical center setting.

ACG and other stakeholders are also currently working with CMS on draft colonoscopy episodes of care under the Merit Based Payment System, and what clinical indications should be included and/or excluded from a colonoscopy episode. For example, there are times when a follow-up colonoscopy is in fact clinically indicated prior to the end of a one-year window. There is much more to this than just “gaming the system.” A one size fits all colonoscopy bundle gets more complicated when including diagnostic surveillance, surveillance of patients with inflammatory bowel disease, patients with Lynch syndrome, and partial polyp removal/resection of larger polyps. Further, it is unclear how a one year episode timeframe in this proposal can be incorporated in states such as Tennessee and Ohio that have already implemented colonoscopy episodes of care, but with different windows (30 days in Ohio for example). While the cost of bowel preparation products are included in the bundle payment, patient and provider choice is crucial in this area, too. Patient choice (both for the procedural setting and for certain bowel preparation products) is one key criterion the PTAC must consider when reviewing proposals. It is important that episodes of care and payment bundles be consistent under the MIPS and APMs options under MACRA, as well as at the state level. Otherwise, there is no ability to compare and contrast improved care and resource use (cost of providing).

Thus, the ACG urges PTAC to recognize the specific challenges facing independent practices that may be different from major health care institutions and/or larger health care practices when reviewing models impacting gastroenterology. When models can be implemented with flexibility, and provide choice, there is a greater the likelihood of long-term success and systemic reform. For example, the gastroenterology community is already significantly engaged in activities that advance the shared goal of improved patient outcomes.

### **GIQuIC- Voluntary Participation and Successful Implementation**

This proposal mentions the quality improvement efforts of the “The GI Quality Improvement Consortium, Ltd.” (GIQuIC). In 2009, ACG and the American Society for Gastrointestinal Endoscopy (ASGE) jointly established a quality improvement registry for gastroenterologists. These quality metrics include, but are not limited to, adenoma detection rate, appropriate colorectal cancer screening and surveillance intervals, completeness of high-quality, and safe examination. The registry now collects data on upper gastrointestinal endoscopy services as well. ACG welcomes the opportunity to introduce the PTAC to GIQuIC. It is also important to include GIQuIC in these discussions, as the proposal correctly cites the registry as a powerful tool in improving clinical care, but has not been included in this draft proposal or in any discussion in drafting this proposal.

To date, GIQuIC has collected data submitted by more than 4,000 providers at 500 facilities, for over 4 million colonoscopies. We now estimate that over 1/3 of all practicing gastroenterologists in the United States have *voluntarily* invested their own money and resources to incorporate GIQuIC registry into their practices.

The GIQuIC registry’s success demonstrates our members’ commitment to quality of patient care in our specialty as well as their willingness to undergo day-to-day practice management changes to measure individual performance based on accepted metrics in our specialty. This commitment underscores the

importance and value of physician “buy in” to achieve successful reform. However, choice and flexibility are key components to achieving successful payment reform. Thus, the ACG urges PTAC to not only oppose mandatory participation in any forthcoming recommendations to CMS, but also to carefully consider the intricacies and nuances of a colonoscopy bundle payment.

The ACG appreciates the opportunity to work with the PTAC on these important reforms. Please contact Brad Conway, Vice President of Public Policy, Coverage & Reimbursement, at 301.263.9000 or [bconway@gi.org](mailto:bconway@gi.org) for further discussion.





Physician-Focused Payment Model Technical Advisory Committee c/o Angela Tejada, ASPE  
 200 Independence Ave., SW  
 Washington, DC 20201  
[PTAC@hhs.gov](mailto:PTAC@hhs.gov)

**Re:** Public Comment—The Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance

Dear Committee Members,

Illinois Gastroenterology Group, LLC (IGG) submits this letter of support for the Physician-Focused Payment Model entitled Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance (Colonoscopy Advanced APM) submitted on December 29, 2016.

IGG is an independent gastroenterology member practice located in metropolitan Chicago with over 50 physicians and mid level providers, delivering high quality, cost-efficient and accessible care. Our physicians screen approximately 30,000 patients annually for colorectal cancer—the fourth most common cancer and second leading cause of cancer death in the United States.

IGG enthusiastically supports this proposal submitted by the Digestive Health Network. It addresses an issue in payment policy in a new, innovative and more inclusive manner that will expand opportunities for participation in APMs. The Colonoscopy Advanced APM is a comprehensive, prospective bundled payment with retrospective reconciliation that will encourage practitioners from multiple specialties to collaborate and coordinate care across settings to more effectively manage patients who require colonoscopy for colorectal cancer (CRC) screening, diagnosis, and surveillance, and for other diagnostic purposes. CRC screening is a critical tool in fighting colon cancer, Serious deficiencies in screening rates continue to exist in eligible U.S. adults age 50 to 75, and this Colonoscopy Advanced APM offers an opportunity to close the gaps in early detection and prevention of colon cancer. The Colonoscopy Advanced APM is designed to improve health care quality and CRC screening while providing cost savings to patients and the Medicare system, preserving patient choice and enhancing patient safety, which meets the criteria for PFPs as established by the Secretary of HHS in regulations at 42 CFR § 414.1465.

The Colonoscopy Advanced APM has been designed to affect practitioners' behavior to achieve higher value care using payment and other incentives, while incorporating development of a CPT code that overcomes the barriers of existing payment methodologies. The Colonoscopy Advanced APM is an important tool to assist in closing the gaps in CRC screening, improving detection of CRC at early stages, decreasing the rate of CRC, and improving survival for this disease. This is precisely the type of forward thinking Physician- Focused Payment Model that this Committee should embrace, and recommend that CMS implement this proposed payment model.

Sincerely,

Fred Rosenberg, M.D.  
 President  
 Illinois Gastroenterology Group

Larry Kosinski, M.D.  
 Board Member

Mitchell Bernsen, M.D.  
 Board Member

Doug Adler, M.D.  
 Board Member

Thomas Arndt, M.D.  
 Board Member

Kevin Liebovich, M.D.  
 Board Member

Jeff Victor, D.O.  
 Board Member

Northwest  
 Gastroenterologist  
 1415 S. Arlington Heights Rd  
 Arlington Heights, IL 60005  
 (847) 439-1005  
 Fax (847) 439-7555

Elgin Gastroenterology  
 745 Fletcher Dr. Ste 202  
 Elgin, IL 60123  
 (847) 888-1300  
 Fax (847) 888-1341

Lakeshore  
 Gastroenterology  
 20 Tower Court. Ste C  
 Gurnee, IL 60031  
 (847) 244-2960  
 Fax (847) 244-2986

Midwest Center for  
 Digestive Health  
 9921 Southwest  
 Highway  
 Oak Lawn, Illinois 60453  
 (708)-425-9456  
 Fax (708)-425-9468

Gastrointestinal Health Associates  
 25 N Winfield Road - Ste 410  
 Winfield, Illinois 60190  
 (630)-208-7388  
 FAX (630) 208-4818

North Shore Gastroenterology  
 2551 Compass Road  
 Suite 130  
 Glenview, IL 60025  
 (847) 677-1170  
 Fax: (847) 677-1233

January 25, 2017

Physician-Focused Payment Model Technical Advisory Committee  
c/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C.  
20201 [PTAC@hhs.gov](mailto:PTAC@hhs.gov)

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

To: The Physician Focused Payment Model Technical Advisory Committee

I am writing this letter in support of The Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance; a proposal currently under consideration by the PTAC. This proposal aims to broaden CMS' APM portfolio by addressing an issue in payment policy in a new manner by including APM entities whose opportunities to participate in APMs have been limited. Additionally, this project fills an existing need for a way to bundle payments for Colonoscopy. It promotes a value-based approach to Colorectal Cancer Screening and will ultimately lead to lower cost/procedure. The current coding structure does not allow for coordination of payments for Colonoscopy and leads to excess costs.

Sincerely,

Lawrence R. Kosinski, MD, MBA, AGAF, FACG  
Clinical Practice Councilor: American Gastroenterological Association  
Managing Partner: Illinois Gastroenterology Group  
745 Fletcher Drive  
Elgin, Illinois 60123  
(847)370-8878