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August 11, 2008

Dr. Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: *NCA for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)*

Dear Dr. Phurrough:

On behalf of the American College of Gastroenterology, I want to thank you, Dr. Rich and your colleagues for meeting with representatives of the College on August 5, 2008. We very much appreciated the opportunity to share the College's views on the agency's pending national coverage analysis (NCA) of computed tomographic colonography (CTC) for the expanded indication of an approved screening test for colorectal cancer. We remain committed to our recommendation that this coverage not be expanded at this time.

Current coverage for CTC exists by 47 CMS local carrier decisions that allow this testing for high risk patients or those with suspected obstruction. Therefore, the current NCA is not about any issue of patients who may need CTC getting the access to do so. The issue facing CMS is whether it is reasonable and necessary to expand coverage via a national policy decision to include screening.

As we discussed in our meeting and as indicated by our official comment letter, the College is absolutely committed to supporting coverage and payment decisions for Medicare that follow the science and evidence. Presently, however, we believe that national coverage for screening CTC would be premature and may be potentially harmful to our patients. Indeed, we think that the current system whereby local coverage decisions are employed for determining the appropriate use of CTC has been working well. Further, we believe that such coverage would add considerable additional costs to the healthcare system and would not necessarily increase screening rates nor improve outcomes. We would like to highlight several specific areas that were discussed.

1.Capacity to support screening colonoscopy

No reliable and validated evidence supports that there is a shortage in the capacity to provide access to screening colonoscopy. This has been previously addressed in a comprehensive analysis by Drs Lieberman and Rex (*Gastroinest Endosc* 2001;54:662-7) The potential annual demand for screening colonoscopy in the United States can be calculated by dividing the number of adults age 50 to 70 years by the interval recommended for screening (currently 10 years). Demographic data suggest there are about 77 million Americans in this age group, with 4 million more added annually.

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Assuming that 10% of this group would undergo screening colonoscopy in any given year, the maximum number of expected examinations per year is 7.7 million. The actual number of colonoscopies performed in the United States in 1999 was 4.4 million. Thus, the potential demand exceeds the number of colonoscopies currently performed.

For several reasons, actual demand would be substantially less than that suggested by simple calculation. First, compliance with any screening test is never 100%. Compliance with fecal occult blood test (FOBT) and sigmoidoscopy screening is no better than 25% to 30%. Compliance could reach 60%, a level similar to that for mammography in women over age 50 years, but is unlikely that compliance with colonoscopy would exceed that for mammography. Second, some patients will have had a prior colonoscopy to evaluate GI symptoms. In the Veterans Administration screening colonoscopy study, nearly one-half of prospective "screenees" had a colon examination within 10 years. Because many underwent sigmoidoscopy or barium enema, some of these individuals would still benefit from screening colonoscopy. A telephone survey of middle income persons in the Pittsburgh area found that 19% of average-risk and 33% of high-risk persons had undergone a full colon examination within 5 years. Based on these data, perhaps one-fourth of patients over age 50 years will have had a complete colon examination. Third, some patients with serious medical problems, particularly those approaching age 70 years, would not be candidates for further screening. Data on recruitment for the Veteran's Administration study suggest this would be about 5% to 10% of subjects (N Engl J Med 2000;343:162-8.) Calculations based on the above assumptions suggest that implementation of colonoscopy screening would create an annual demand for about 2.6 million colonoscopies are as follows:

Estimation of demand for screening colonoscopy	
Eligible Americans	Potential demand (millions)
Too ill (5%)	
All eligible Americans	77
Minus those too ill (5%)	73.2
Minus 40% noncompliant	43.9
Minus 25% already screened	25.6/10y or 2.56/y

The actual demand would be less than 2.6 million because of additional limiting factors. For example, the demand for screening colonoscopy is controlled by reimbursement. As you know, reimbursement for screening colonoscopy every 10 years has been legislated for Medicare beneficiaries, but this does not mean that private insurers will follow suit and only 24 states have any mandate for CRC screening and less than 25% of these states allow colonoscopy as the preferred strategy. Some patients and physicians will choose screening tests other than colonoscopy; these will continue to be available and may be preferred by some patients as well as physicians trained in these methods. Thus, the actual demand for screening colonoscopy is likely to be significantly less than 2.6 million procedures per year.

The demand for screening colonoscopy will be much less than simple population-based calculations would suggest. However, the demand will be substantial and hopefully will increase with better public awareness and improvements in colonoscopy. The availability of colonoscopy to meet this demand can likely be met by implementation of several measures: (1) reduced use of colonoscopy for post-polypectomy and post-cancer resection surveillance; (2) replacement by screening colonoscopy of some flexible sigmoidoscopy by gastroenterologists and colonoscopy for low-yield indications; (3) open access for screening colonoscopy; and (4) training of current colonoscopists in measures that improve efficiency.

Effective implementation of these measures would require a significant effort to ensure compliance of practicing colonoscopists with recommended intervals for screening and surveillance. Importantly, improved efficiency in delivery of screening colonoscopy will require an investment in endoscopic facilities and resources to allow individual endoscopists to become efficient. Full exploitation of these measures is likely to produce sufficient availability of colonoscopy to meet the rising demand. These mechanisms, in our opinion, are more feasible than training additional colonoscopists. Further, the wisdom of training large numbers of colonoscopists is uncertain, given that accurate, cost-effective noninvasive testing for colorectal cancer will almost certainly eventually appear. This would position colonoscopy in only a therapeutic role, thereby reducing the need for colonoscopists. Thus, shifting endoscopic resources and improving the productivity of existing endoscopists are perhaps the most feasible and appropriate mechanisms for meeting the anticipated demand for screening colonoscopy, given that the duration of this demand is uncertain.

Currently, the AQA is reviewing and CMS is considering for inclusion in the PQRI measure set for 2009 a colonoscopy measure, "Surveillance Colonoscopy Interval for Patients with a History of Colonic Polyps- Avoidance of Inappropriate Use," designed to reduce the rate of persons at high risk who have repeat screenings before such screenings are generally medically indicated. Implementation of this measure would also serve to conserve current endoscopic capacity for more pressing screening needs.

Ultimately, the workload associated with colon cancer prevention and a screening colonoscopy program will depend on compliance. This is influenced by many factors, including public awareness of the problem of colon cancer and perceptions of discomfort or embarrassment associated with screening tests. With regard to the interaction between demand and availability for colonoscopy, the reality of imperfect compliance should be considered in discussions of the feasibility of screening colonoscopy. The success of screening will ultimately depend on the success of measures to improve compliance. For example, celebrity endorsements continue to improve patient awareness (*Arch Intern Med.* 2003;163:1601-1605) Recent studies have found that videos in physician offices enhance compliance with screening. (*Ann Intern Med* 2000;133:761-9.)

2. Adherence to CRC – the influence of patient choice – data that CTC will not increase adherence

Adherence to CRC screening – of whatever modality is essential to achieving cancer prevention- is the ultimate goal of screening. Scott et al evaluated this question and compared screening CT colonography and colonoscopy in an asymptomatic average-risk population, to

determine whether providing a choice of tests increased participation. (Am J Gastroenterol 2004;99:1145-5) One thousand and four hundred subjects from the general community were allocated one of three screening groups: colonoscopy, CT colonography, or a choice of these tests, and were sent an institutional letter of invitation. Those with symptoms, colorectal cancer in first-degree relatives, or colonoscopy within 5 years were ineligible. Participation in each screening group was not different. Both tests were accompanied by the same high levels of acceptability; most participants found colonoscopy (87%) and CT colonography (67%, $p < 0.001$) less unpleasant than expected. Colorectal neoplasia screening by colonoscopy or CT colonography was associated with modest participation, high levels of acceptability, and similar yield for advanced colorectal neoplasia. Providing a choice of test did not increase participation.

It is important for patients to understand that CTC does not at present represent a “painless” or risk free procedure, nor does it obviate the need for the colonic preparation (which is the factor that most concerns patients, if any issues do, with colonoscopy screening).

3. Impact on Colorectal Cancer (CRC) Screening Rates and Polypectomy

The other primary argument postulated for adding CTC to the list of Medicare covered screening options is that doing so will increase overall screening adherence rates. However, convincing evidence to support this theory is insufficient at best. If instead, CTC merely serves as a replacement for colonoscopy, polypectomy rates could fall and the incidence of colorectal cancer could actually increase because of CTC's lower specificity and the radiology community's stated position of not reporting diminutive polyps. (For a more detailed discussion of the issue of small polyps, please see the College's June official comment letter, a copy of which is attached for your convenience.)

To obtain a reduction in the incidence of colon cancer, introduction of CTC would need to lead to an increase in screening adherence rates. Furthermore, colorectal cancer prevention is directly tied to polypectomy. If the introduction of a new screening modality simply displaces patients who were already willing to undergo a colonoscopy, there will be no increased colon cancer prevention. (For more discussion of this issue, see: Rex, DK et al, "Considerations Regarding the Present and Future Roles of Colonoscopy in Colorectal Cancer Prevention. *Clin Gastroenterol Hepatol* 2008; 6:506-514.)

The American College of Radiology guidelines for CTC indicate that polyps below 6 mm need not be reported and those with one or two polyps between 6 and 9 mm could be offered a surveillance interval of three years. In a study that has been accepted for publication (see attached) in the *American Journal of Gastroenterology* by Rex et al, a study was done of the polyps removed from more than 10,000 patients who had undergone polypectomy at Indiana University. The study concludes that if CTC rather than colonoscopy were used in this population, and assuming 100% sensitivity of CTC for polyps > 6mm and ACR interpretation recommendations, then 29% of all patients and 33% of screening patients age > 50 years with high risk adenoma findings would be interpreted as normal, and an additional 18-23% of these groups, respectively, would have polypectomy delayed at least 3 years. The implications for this delay in terms of the exact number of additional colon cancers that would develop as a result of using CTC rather than colonoscopy is unclear, but worthy of more study.

In an analysis conducted by Hur, C et al (The management of small polyps found by virtual colonoscopy: results of a decision analysis. *Clin Gastroenterol Hepatol* 2007;5:237-244) small (6–9 mm) polyps identified by CTC were simulated to either undergo immediate colonoscopy for polypectomy (COLO), or wait 3 years for a repeat CTC examination (WAIT). A Markov model was constructed to analyze outcomes including the number of deaths and cancers after a 3-year follow-up period or time horizon. Values for the model parameters were derived from the published literature and from Surveillance Epidemiology and End Results data, and an extensive sensitivity analysis was performed. The COLO strategy resulted in 14 total deaths per 100,000 patients compared with 79 total deaths in the WAIT strategy, for a difference of 65 deaths. The COLO strategy resulted in 39 cancers per 100,000 patients vs 773 in the WAIT strategy, for a difference of 734 cancers. ***Accordingly, the availability of CTC as a screening test, introduces a contrarian result to the intention of increased screening and prevention of cancer.***

The problem of health disparities in utilization of CRC screening is well-documented. In 1998, screening rates for whites were approximately 13 percentage points higher than for Hispanic Americans and 7 percentage points higher than for African Americans and Asian Americans. In 2005, screening rates for whites were 21 percentage points higher than for Asian Americans, 20 percentage points higher than for Hispanic Americans, and 10 percentage points higher than for African Americans. However, evidence does *not* indicate that the availability of CTC would help to address this issue. In a 2007 study, New York University researchers found that compared with white patients, colonoscopy is better tolerated by minorities and is preferred over CTC for CRC screening. (Rajapaksa, RC et al “Racial/ethnic Differences in Patient Experiences with and Preferences for Computed Tomography Colonography and Optical Colonoscopy,” *Clin Gastroenterol Hepatol*, 2007 Nov., 5(11): 1306-12.)

4. Risk Assessment does not support CTC as an option for screening

An argument could be made that, notwithstanding the huge potential costs to the Medicare program, if a national coverage determination leads in favor of CTC leads to more overall screening it will be worthwhile if the associated risks are lower than colonoscopy. The fact is ***the risks of perforation during CTC are comparable to colonoscopy according to two extremely large studies.*** The data on perforation during colonoscopy includes all diagnostic and therapeutic procedures. In short, there are people with a variety of conditions and degrees of illness which must be put into perspective when comparing the procedures. The first study (Sosna, J et al. Colonic perforation at CT colonography: Assessment of risk in a multi-center large cohort. *Radiology* 2006 May;239:457-63) reviewed data from nearly 12,000 CTC studies performed at 11 centers in Israel during a two-year period. This represented some 95% of all CTC studies performed in the country during this interval. Seven perforations occurred, yielding a rate of 1 in 1700 or 0.06%. The second study (Burling, D et al. Potentially serious adverse events at CT colonography in symptomatic patients: national survey of the United Kingdom. *Radiology* 2006 May; 239:464-471) which involved interviews of lead gastrointestinal radiologists at 50 centers in the UK to determine the number of CTCs performed and the number of perforations. They reported 9 perforations in just over 11,000 cases. This works out to 1 in 1900 or 0.05%. These rates are much higher than those seen with barium enema and, for most

individual endoscopists, exceed the rate of diagnostic perforation during colonoscopy. (*N Engl J Med.* 2000;343:162-168).

Delaying polypectomy in 6- to 9-mm polyps for even 3 years resulted in a 20-fold greater rate of colorectal cancers and a 10-fold greater rate of colorectal cancer mortality compared with immediate polypectomy (Hur et al.). Thus, if a new imaging test is used primarily to displace patients from colonoscopy, the effect potentially could be to increase colorectal cancer compared with continued use of colonoscopy screening. Alternatively, if new imaging tests are used primarily to increase adherence to colorectal cancer screening, then the benefits would be clear. Increased adherence results in improved cost effectiveness and identification of medium- and large-sized polyps in previously non-adherent patients would increase polypectomy rates and reduce colorectal cancer detection. Unfortunately, there is no clear evidence that any of the tests actually will significantly improve adherence in their current forms. Investigation of the impact on adherence of these tests should be a top priority for colorectal cancer prevention investigators.

5. Radiation issues are a significant concern that argue against the intent of “screening” – which is to prevent cancer

The issue of radiation exposure risk are long-term and lifetime risks. The results of the impact of patients undergoing CT and other radiological exams for a variety of reasons will not be known for some time. We do, however, have the ability to estimate risks by looking to organ radiation dose exposure and applying the organ-specific cancer incidence or mortality data derived from the studies of the atomic bomb survivors and the radiation workers health data (Rad Research 2007; 168:1-64, Rad Research 2007; 167:396-416).

The earliest occupational groups exposed to ionizing radiation were radiologists and radiological technologists. H Ulrich, Incidence of leukemia in radiologists, *N Engl J Med* 234 (1946), pp. 742–743.)

Such workers, when employed before 1950 and when radiation exposures from fluoroscopy were high, had increased mortality from cancer. Since the development of the first commercial CT scanners in 1972, CT has become the major source of medical radiation. (CI Lee, AH Haims, EP Monico, JA Brink and HP Forman, Diagnostic CT scans, *Radiology* 231 (2004), pp. 393–398)

Possible biological influence of ionizing radiation depends on the energy absorbed per unit mass in a given tissue or organ. This quantity is called absorbed dose and is expressed in gray. In evaluating the radiation risk after partial exposures of the body, the radio sensitivity of the various organs has to be taken into consideration. When comparing risks of partial and whole body exposure, the quantity of effective dose is applied. The unit for this quantity is sievert (Sv). When assessing the total radiological exposure to a group of people, the term *collective effective dose* is used.

Conservative estimates are that more than 60 million CT examinations were done in 2002 in the USA, representing an estimated 70% of all medical X-ray exposure. (OW Linton and FA Mettler Jr, National conference on dose reduction in CT, with an emphasis on pediatric patients, *AJR Am J Roentgenol* 181 (2003), pp. 321–329) Although it is a challenge to define precise risk

estimates related to low doses of radiation exposure, the ionizing radiation exposure from a single abdominal or chest CT may be associated with elevated risk for DNA damage and cancer formation (M Loblrich, N Rief and M Kuhne *et al.*, In vivo formation and repair of DNA double-strand breaks after computed tomography examinations, *Proc Natl Acad Sci USA* **102** (2005), pp. 8984–8989.) The seventh National Academy of Science report on Biological Effects of Ionizing Radiation (BEIR) is the most recent update from a respected organization. (Committee to Assess the Health Risks from Exposure to Low Levels of Ionizing Radiation, BEIR VII: health risks from exposure to low levels of ionizing radiation (<http://www.nap.edu/reportbrief/11340/11340rb.pdf>) BEIR VII indicated that a single population dose of 10 mSv is associated with a lifetime attributable risk for developing a solid cancer or leukemia of 1 in 1000. The overall risk for developing a solid cancer or leukemia from all causes would be 42 in 100.

The radiosensitive tissues are predominantly within the field of view of common chest, abdominal, and pelvic CT scans: the typical abdominal examination dose is between 10 and 20 mSv. Unfortunately many patients are exposed to multiple examinations that increase cumulative dosing. A recent report focused on the effects of multiple exposures to ionizing radiation during CT. They found that a subset of patients with renal colic commonly had total exposure rates between 19.5 and 153.7 mSv (SI Katz, S Saluja, JA Brink and HP Forman, Radiation dose associated with unenhanced CT for suspected renal colic: impact of repetitive studies, *AJR Am J Roentgenol* 186 (2006), pp. 1120–1124)

Referring physicians in the emergency department are largely unaware that there are potential harmful effects from CT radiation exposure, with only 9% aware of increased cancer risk (CI Lee, AH Haims, EP Monico, JA Brink and HP Forman, Diagnostic CT scans, *Radiology* 231 (2004), pp. 393–398) Even more alarming is that radiologists doing CT examinations consider the radiation exposure of limited concern, with only 47% familiar with the increased risk of cancer, and many are unaware of the dose of radiation delivered to the patient during the examination. (Lee et al)

If, indeed, clinicians are not well versed in radiation risks associated with CT, it may not be surprising that these risks might not be explained clearly to patients before obtaining consent to an examination. By comparison, the estimated risk of serious complications and death from receiving iodinated intravenous CT contrast is around 1 in 400 000 (SK Morcos, Prevention of contrast media-induced nephrotoxicity after angiographic procedures, *J Vasc Interv Radiol* **16** (2005), pp. 13–23) which is lower than the lifetime attributable risk from a single 10 mSv dose. Yet, considerable attention is given to contrast risk during the consent process. This difference may be accounted for on the basis of a clear causal relation: contrast is injected and the patient immediately develops symptoms. Radiation effects may not manifest until 5–20 years after the scan, and causal relations are unapparent on an individual basis.

The US Food and Drug Administration has listed medical X-rays as a known carcinogen. It may be necessary for governments to place guidelines on acceptable maximum doses and indications for CT. For instance, questionable practices such as whole-body CT screening examinations that expose normal individuals to known risks with unknown benefits might need to be restricted.

Cross-sectional imaging has revolutionized diagnosis and medical practice in the past 30 years. Clinicians, as patients' advocates, are obliged to understand and explain the risks associated with CT radiation, and to provide state-of-the-art dose-reduction techniques,

X-rays used in medical diagnostic procedures is the largest man-made source of radiation exposure to the population, contributing some 14% of the total annual exposure from all sources. Ionizing radiation from diagnostic procedures has been postulated to cause several hundred cases of cancer per year in the UK (AB de Gonzales and S Darby, Risk of cancer from diagnostic x-rays: estimates for the UK and 14 other countries, *Lancet* 363 (2004), pp. 345–351) It is, however, reasonable to assume that many health professionals underestimate the potential hazard of ionizing radiation in common diagnostic procedures

Brenner and Hall (*N Engl J Med.* 2007;357:2277-2284.) estimated the lifetime risk of death from cancer that was attributable to a single "generic" CT scan of the head or abdomen. The risks varied depending on the age of patient at exposure and the organ-specific dose exposure. Extrapolating from the data provided, the risk of cancer-related death associated with one abdominal CT scan is 0.06% for a patient exposed at 25 years of age and 0.02% for a patient exposed at age 50. This risk is striking and apparent when looking at the lifetime radiation risk of two of the most common radiogenic cancers, namely lung and colon cancer. For exposure to as little as 10 mSv at 25 years of age, the risk of death from lung or colon cancer is .025% and 0.0125%, respectively. For a patient exposed at 50 years of age, these associated risks are 0.017% and 0.010% for lung or colon cancer, respectively.

With a proposed screening schedule of 5 years or less, depending upon findings of a CTC, the cancer risks from this test are significant. Between 1.5% and 2.0% of cancers are recognized as radiogenic. FDA classifies x-ray as a carcinogen. Indeed, the use of x-ray radiation for screening is prohibited by law in both Switzerland and Germany. CMS must consider whether encouraging greater exposure to radiation is the best way to stimulate colorectal cancer screening in light of other options.

6. CTC Cost-Effectiveness Evidence is Lacking

The cost-effectiveness of CT colonography has not been well studied. However, a 2007 study found that compared with no screening, CTC is cost-effective, but compared with optical colonoscopy, CTC is not cost-effective. (Vijan, S et al, "The Cost-Effectiveness of CT Colonography in Screening for Colorectal Neoplasia," *Am J Gastro* 2007; 102:380-390) Importantly, this study also notes that there is little or no data on the diagnostic accuracy or reliability of CTC using 3D outside academic settings where it is likely to be higher. Another study compared CTC to colonoscopy in patients with a positive FOBT test and found that CTC was overall, less effective, less accurate and more costly than colonoscopy, primarily owing to the better accuracy rate of colonoscopy. (Wallester S et al, "What is the Value of Computered Tomography Colonography in Patients Screening Positive for Fecal Occult Blood? A systematic review and economic evaluation. *Clin Gastroenterol Helpatol* 2007; 5: 1439-1446.)

Further, the lower specificity of CTC is likely to lead to follow-up colonoscopy. Even in the best performing study in the literature, the specificity of CTC dropped off to 80% for polyps 6

mm and larger in size. The specificity for polyps ≥ 5 mm has been as low as 63-78% in some of the largest studies (Hara, *Radiology* 2000;215:353-7; Fletcher, *Radiology* 2000;216:704-11; Kay, *Endoscopy* 2000;32:226-32; Yee, *Radiology* 2001;219:685-92; Johnson, *Gastroenterology* 2003;125:688-95). Thus, 30% or more of patients undergoing CTC in many centers might be sent for conventional colonoscopy for false positives. Using the specificity in the ACRIN data, would lead to colonoscopy 14% for each five-year screening cycle so that after 10 years (0,5,10 year screening), fully 42% of patients would have been referred to colonoscopy for false positive results (even if only the highest risk concern- polyp >9 mm is used as the threshold). Note: refer back to potential consequences if 6-9 mm polyps are not referred for colonoscopy (Hur, C et al (The management of small polyps found by virtual colonoscopy: results of a decision analysis. *Clin Gastroenterol Hepatol* 2007;5:237-244)

It is important to keep in mind that these results are from the top centers of excellence and the very best operators. It is reasonable to expect that false positives would be larger with less skilled physicians doing the examinations. Furthermore, the ACRIN trial was done under conditions where each CTC was followed by a complete colonoscopy. This removes the potential legal liability from the CTC exam due to missed lesions and/or cancers, also leading to a lower rate of unnecessary or questionable follow-up colonoscopy rates. In a real world setting beyond the centers of excellence and most highly trained radiologists, where a missed lesion or cancer as well as the possibility of waiting for a subsequent screening exam would expose the physician to legal liability, it is reasonable to believe physicians will always err on the side of sending the patient for the follow-up colonoscopy if there is any question at all about the CTC findings. It necessarily follows that this will also lead to a higher rate of false positive findings. There is also no data on how physicians and patients will behave when faced with a positive CTC report and a clean (negative) colonoscopy report. It would not be surprising to see patients return at shorter follow-up intervals, adding costs to the system without a concomitant improvement in outcomes. Finally, it is worth noting that the learning curve for image interpretation is an important quality and cost factor for CTC.

It is likely that both the effectiveness and cost-effectiveness of CTC depends on the population selected. To maximize both, it may make the most sense to screen in those populations with the least likelihood of neoplasia. An example of such a group would be nonsmoking women in their 50s – not typically a Medicare population and one likely at the highest risk of injury from radiation given its longer project lifespan.

A Washington State Health Care Authority analysis found that the cost of extra-colonic findings alone were \$2-34 per screening. (See http://www.hta.hca.wa.gov/documents/df021508_colonography_022908.pdf.) Indeed, extra-colonic findings are important to consider given that a meta analysis of 17 CTC studies found 40% of patients had extra-colonic findings and 14% underwent further investigation because of them. (Xion T et al Incidental Lesions Found on CT Colonography: Their Nature and Frequency, *Br. J. Radiol.* 2005; 78(925): 22-29.) Pursuit of the extra-colonic findings not only represent additive costs but also a potential additive risk to the patient for ancillary testing – e.g. radiation, biopsy, preparation. Any cost effectiveness analysis of CTC must take into account these extra-colonic findings.

Of note is the lack of coverage from private insurers who have issued recent coverage policy determinations against CTC for screening: such as Aetna, (http://www.aetna.com/cpb/medical/data/500_599/0535.html) United, Humana (http://aps.humana.com/tat/tad_new/retrunContent.asp?mime=application/pdf&id-6167&issue=747)etc) who all generally only cover CTC in extremely narrow circumstances where colonoscopy cannot be performed..

Clearly the Medicare costs to provide medical imaging is staggering and there are efforts to evaluate and control such cost expenditures to optimize necessary service but in the most cost efficient way to provide the necessary value. In light of the recent GAO report: Government Accountability Office (GAO) report June 08 -“Medicare Part B Imaging Services – Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices”, we feel the evidence and support is lacking to expand medical imaging for CTC to include screening.

7. Science Rather Than Business Imperatives Should Guide CMS

One of the driving forces behind asking CMS to consider whether a national coverage determination is warranted is the recent publication of the ACS/MSTF/ACR joint guidelines on colorectal cancer screening which, for the first time, included CTC as part of the menu of options. It is important to note that the guideline indicates that the prevention of cancer should be the primary goal of screening. Only colonoscopy, with its ability to remove polyps before they become cancerous, meets this objective. *Anything that trades off attempt for adherence needs to be evaluated against the risk of displacing patients from colonoscopic polypectomy which is the key element of cancer prevention.* (Furthermore, it is worth noting that the working group that negotiated the contents of the guideline agreed that any screening modality could be included provided it was at least 50% effective. This does not mean that it is necessarily appropriate or in the interest of public health for CMS to provide national coverage for colorectal screening for all of the tests.

Our members have been bombarded with information from companies involved in promoting expanding the use of CTC. You may be aware of the barrage of “informercials” that our members are receiving suggesting the concept of CTC as “the next big thing” and using it as a way to generate more revenue for a practice. We described some of these instances at our meeting. Regardless of any potential merits of these arguments, for purposes of screening it is in the interest of Medicare patients to have those tests that are shown to be most effective at detecting and preventing colorectal cancer available with as little risk as possible. *We would urge CMS to make no change to expand the current CTC indication to include screening.* The recent NCA on Computed Tomography for Coronary Angiography was a similar circumstance. In that case the decision was that coverage should be determined by local coverage decisions or case by case adjudication. We believe that innovation driven primarily by financial incentives is bad for patients (or certainly of unproven benefit). The implications can affect patient care (outcomes and safety), and furthermore, the cost impact in the case of CTC can be staggeringly high.

The American College of Gastroenterology uses a litmus test for endorsement of new technology or clinical care plans. When the science and patient need justify use of the technology, we will

support it. In this case, the aforementioned issues do not justify an endorsement for widespread application to the patients we serve. The data on CTC for expanded coverage raises a number of concerns- science, evidence for extrapolation beyond selected centers, risk profiles, patient outcomes and costs. In an era of emphasis on “value based purchasing”, we would ask how there might be justification for a decision to expand CTC use for screening beyond what is already present and the acceptable standard, and as stated above, we ***do not believe that screening indications of CTC currently meet the statutory requirement that they be reasonable and necessary.***

Again, we appreciate your willingness to meet with us to discuss this critically important coverage issue. Please don't hesitate to contact us if we can provide you with any additional information that would assist in your decision-making.

Sincerely,

A handwritten signature in black ink, appearing to read "Amy Foxx-Orenstein". The signature is fluid and cursive, with the first name "Amy" being particularly prominent.

Amy Foxx-Orenstein, D.O, FACP
President

A handwritten signature in black ink, appearing to read "David A. Johnson". The signature is cursive and somewhat stylized.

David A. Johnson, M.D., FACP
Immediate Past President

A handwritten signature in black ink, appearing to read "Bradley C. Stillman". The signature is cursive and somewhat stylized.

Bradley C. Stillman
Executive Director

Cc Kim S. Brown, CMS
Dr. Joseph Chin, CMS
Dr. Daniel Green, CMS
Beverly Lofton, CMS
Dr. Michael Rapp, CMS
Dr. Jeffrey Rich, CMS
Elizabeth Richter, CMS

Dr. Marcel Salive, CMS
Rochelle Scott, CMS
Thomas Scully, Alston & Bird
Dr. Kenneth Simon, , CMS
Todd Smith, CMS
Diane Stern, CMS
Dr. Tom Valuck, CMS