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September 8, 2015

BY ELECTRONIC SUBMISSION

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on CMS-1631-P

Dear Acting Administrator Slavitt:

On behalf of the more than 1,200 gastroenterologists and other physician specialists whose medical practices are members of the Digestive Health Physicians Association (DHPA), we want to thank you for the opportunity to comment on the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for Calendar Year 2016 (CY 2016) Proposed Rule (CMS-1631-P), published in the July 15, 2015 Federal Register (the Proposed Rule).[1]

Our comments focus on an issue of immense importance to gastroenterologists and our Medicare patients—CMS's proposed cuts in the valuation of colonoscopy procedures and the impact that those cuts can be expected to have on the country's efforts to continue reducing the incidence of and mortality from colorectal cancer. We know that CMS has been engaged with and is receiving comprehensive comments from our sister societies in gastroenterology with respect to the methodological flaws in CMS's valuation of physician work and intensity of colonoscopy and other lower gastrointestinal endoscopy procedures. We are fully aligned with the American College of Gastroenterology ("ACG"), American Gastroenterological Association ("AGA"), and the American Society for Gastrointestinal Endoscopy ("ASGE") and do not repeat their analysis here. We focus, instead, on the ramifications that these proposed

[1] 80 Fed. Reg. 41686 (July 15, 2015).

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cuts can be expected to have on the country's efforts to fight colorectal cancer.

High quality and accessible colonoscopy procedures save lives and create enormous cost savings through the prevention and early detection of colorectal cancer. It is no coincidence that the 30% drop in the incidence of colorectal cancer in this country has paralleled robust public policy initiatives—by Congress, the Department of Health and Human Services, and CMS—aimed at increasing colorectal cancer screening, particularly in underserved minority populations and in rural communities. Yet, **we face the prospect of taking a dramatic step backwards in our battle against colorectal cancer by virtue of cuts in reimbursement that are not justified by any changes in the time, effort or resources employed by gastroenterologists who perform colonoscopy and other lower GI endoscopic procedures**.

No cuts are justified at this time. Unfortunately, CMS is poised to implement a dramatic payment change for colonoscopy procedures, even though the proposal directly conflicts with clear survey data that CMS received from our sister GI societies and is based on an unprecedented methodology that essentially equates different types of GI endoscopic procedures. CMS should preserve the current valuation for colonoscopy procedures until such time that CMS can engage in further study of the valuation process. Moreover, we join our sister GI societies in urging CMS not to finalize the proposed cuts without engaging in a study of the impact that such proposed cuts, if implemented, would have on colorectal cancer screening in the Medicare population as well as the attendant costs associated with higher incidence of and mortality from colorectal cancer that can be expected as a result of reduced access to a tool that has the capacity to screen for, prevent and treat colorectal cancer in a single procedure.

Digestive Health Physicians Association

DHPA formed in early 2014 to promote and protect the high quality, cost-effective and coordinated care furnished in independent gastroenterology practices. It is the only national medical association that exclusively represents the voices of those gastroenterologists who have chosen to care for patients in the independent practice setting. In its first 18 months of existence, DHPA has grown to include 54 member GI practices from 28 states in every region of the country. Our more than 1,200 physicians provide care to approximately 2.5 million patients annually in more than 3.5 million distinct patient encounters.

Most relevant for purposes of this comment letter, the physicians in DHPA's member practices are on the front lines of colorectal cancer screening, prevention and treatment. In 2014 alone, the physicians in DHPA's member practices performed well

over one million colonoscopies and diagnosed more than 25,000 new cases of colon cancer.

Colonoscopy is the Primary Method Used to Prevent, Detect and Treat Colorectal Cancer—A Leading Cause of Cancer Death in American Men and Women.

Colorectal cancer is the third most commonly diagnosed cancer and the third leading cause of cancer death in American men and women.[2] It is estimated that one in twenty Americans will be diagnosed with colon cancer in their lifetime. The American Cancer Society estimates that, in 2014 alone, there were more than 136,000 new cases diagnosed and over 50,000 deaths.[3] And, we know that there are significant disparities in the prevalence of and mortality rates associated with colorectal cancer, with African-Americans 25% more likely to develop colorectal cancer and 50% more likely to die from the disease.[4]

Strong evidence exists that increased use of colonoscopy has resulted in declining mortality rates from colon cancer. For example, a study published in the New England Journal of Medicine found that the **removal of precancerous polyps significantly reduced the risk of death from colorectal cancer**.[5] The study's authors concluded:

> "[W]e previously reported a lower-than-expected incidence of colorectal cancer in patients after the removal of adenomatous polyps, and this study shows that polypectomy results in reduced mortality from colorectal cancer. These combined findings indicate that adenomas identified and removed at colonoscopy include those that are clinically important, with the potential to progress to cancer and cause death."[6]

Fortunately, there has been "unprecedented progress" in reducing incidence and mortality rates over the last decade, **largely due to the prevention and early detection of colorectal cancer through screening—specifically, colonoscopy**.[7] (emphasis added).

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[2] American Cancer Society, *Colorectal Cancer Facts & Figures 2014-2016*, ("ACS Report") p. 1.
[3] *Id*.
[4] ACS Report, p. 5.
[5] Ann G. Zauber, Sidney J. Winawer, et al., Colonoscopic Polypectomy and Long-Term Prevention of Colorectal-Cancer Deaths, 366 New Eng. J. Med. 687 (February 23, 2012).
[66] *Id*.
[7] ACS Report, p. 5.

The improvement in the screening rate from 54% to 65% in less than a decade was driven primarily by increased use of colonoscopy.[8]

And, yet, there is still much work to be done. The Centers for Disease Control and Prevention ("CDC") recently found that about one-third of adults between 50 and 75 did not have an up-to-date colorectal cancer screening.[9] Even worse, 28% of adults between 50 and 75 – or about 23 million adults – have never been screened at all.[10] And, colorectal cancer screenings are also less common in rural areas where healthcare services are generally less accessible. Not surprisingly, with less access to colonoscopy, studies show that residents of rural areas are more likely to die of the disease.[11]

Colonoscopies are the predominant form of colon cancer screening for good reason. They are unique diagnostic tools because they allow physicians to screen for, biopsy, and even treat patients in a single procedure. As such, screening colonoscopies are a cost-effective procedure because they can detect and even prevent colon cancer through the biopsy and/or removal of polyps in the same clinical encounter. Colonoscopy is the most sensitive method for detection of colorectal cancer or adenomatous polyps, and provides the longest interval between screens – a single screening is generally required only once every ten years.[12] Most importantly, other forms of colorectal cancer screening still require a follow-up if abnormalities are found. This is precisely why the American Cancer Society, American College of Radiology, and leading gastroenterology societies issued joint guidelines calling for regular colonoscopy screenings.[13]

Colonoscopy has been recognized as an essential screening tool by CMS as well. The United States Preventive Services Task Force (USPSTF) gives an "A" grade to screening colonoscopies for adults ages 50 to 75, thus triggering CMS's obligation under Section 1833(a)(1) of the Social Security Act to cover the procedure in full.[14] This is the

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[8] Centers for Disease Control and Prevention, *Vital Signs: Colorectal Cancer Screening Test Use – United States*, 2012, 62(44) Morbidity and Mortality Weekly Report 881 (November 8, 2013).
[9] *Id*.
[10] *Id*. at 882.
[11] Allison M. Cole, J. Elizabeth Jackson, et al., *Urban–rural disparities in colorectal cancer screening: cross-sectional analysis of 1998–2005 data from the Centers for Disease Control's Behavioral Risk Factor Surveillance Study*, 1(4) Cancer Medicine 350 (December 2012).
[12] ACS Report, p. 13.
[13] Bernard Levin, David A. Lieberman, et al., *Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology*, 58 CA - A Cancer Journal for Clinicians 130 (2008).
[14] *Id.* at 40369; 42 U.S.C. § 1395*l*(a)(1).

highest level of recommendation issued by the USPSTF, and means that "***there is high certainty that the net benefit is substantial***."[15]

Increased Access to Colonoscopy Services Is a Stated Goal
of the Department of Health and Human Services.

CMS's proposed cuts are out of step with **multiple** screening goals and initiatives articulated within the Department of Health and Human Services ("HHS"). For example, CMS, the CDC, and the Agency for Healthcare Research and Quality ("AHRQ") are members of the National Colorectal Cancer Roundtable, which works to achieve 80% colorectal cancer screening rates by 2018.[16] The CDC separately runs the "Screen for Life" campaign, in place since 1999, which provides grant funding and program outreach to increase colorectal cancer screening rates.[17] The CDC also runs the Colorectal Cancer Control Program, which funds states and tribal organizations to increase screening rates through direct services and population-based activities.[18] Reduced colorectal cancer mortality rates and increased colorectal cancer screening rates are each current Healthy People 2020 population health goals.[19] HHS has therefore devoted substantial resources to encouraging patients, primary care providers, and specialists to seek out these lifesaving services.

Indeed, the Affordable Care Act ("ACA") reflects HHS's larger investment in access to colonoscopy. As part of the landmark health reform effort created by the ACA, all private plans are now required to eliminate cost sharing for screening colonoscopy services.[20] Although this reform does not directly change Medicare policies, it reinforces HHS's broader goal of increasing colorectal cancer screenings across the entire health care system.

Finally, access to colorectal cancer screening is a key measure of value-based care. Colorectal cancer screening rates are incorporated into the National Quality Forum

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[15] United States Preventive Services Task Force, Final Recommendation Statement: Colorectal Cancer Screening, October, 2008. Available at: http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/colorectal-cancer-screening.
[16] List of National Colorectal Cancer Roundtable member organizations, available at: http://nccrt.org/roundtable-members/member-organizations/. The CDC is a founding member organization, listed at: http://nccrt.org/roundtable-members/founding-organizations/.
[17] CDC Screen for Life Campaign, available at: http://www.cdc.gov/cancer/colorectal/sfl/index.htm.
[18] CDC Colorectal Cancer Control Program (CRCCP), available at http://www.cdc.gov/cancer/crccp/about.htm.
[19] Healthy People 2020 Goals C-9 and C-16, Department of Health and Human Services, available at: http://www.healthypeople.gov/2020/topics-objectives/topic/cancer/objectives
[20] Patient Protection and Affordable Care Act, P.L. 111-148, § 1001 (establishing § 2713 of the Public Health Service Act) (codified at 42 U.S.C. § 300gg-13). The patient may be charged a reasonable fee for removing polyps or a non-screening colonoscopy.

metrics, the CMS Physician Quality Reporting System metrics, the Healthcare Effectiveness Data and Information Set ("HEDIS") measures, and the CMS Accountable Care Organization quality metrics.[21] The inclusion of colorectal cancer screening in this range of quality measures reflects the fact that it is an essential part of quality, patient-centered care.

It is not surprising that multiple components of HHS have committed to encouraging the widespread use of colonoscopies. Colonoscopies are extraordinarily important tools because they present the unique possibility of **preventing cancer**. Even those cases that are not prevented by the removal of precancerous polyps benefit from early detection and treatment. Advanced colon cancer cases may require one or more courses of surgery, chemotherapy, or radiation therapy.[22] Every cancer prevented or treated early represents a far greater quality of life, avoided pain and suffering, and decreased risk of death for patients. Each cancer that is prevented or treated early also represents an enormous cost savings to the health care system. As such, far from cutting reimbursements for colonoscopy services, CMS should support other efforts within HHS to make colonoscopies even more widespread and accessible.

CMS's Proposed Cuts in Reimbursement Undervalue
the Extremely High Benefit of Colonoscopy Services for Patients.

In the Proposed Rule, CMS employed a flawed computation methodology to decrease the work relative value units ("wRVUs") of some of the most commonly utilized colonoscopy codes – specifically, 45378 (Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure)); 45380 (Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple); and 45385 (Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique).[23] CMS derived these values by calculating an "incremental difference" between the American Medical Association's Relative Value Scale Update Committee's ("RUC") recommended wRVUs for the "base"

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[21] See National Quality Forum metrics, "Colorectal Cancer Screening (COL)", available at: http://www.qualityforum.org/QPS/0034; CMS Physician Quality Reporting System Measures Codes, available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html; National Committee for Quality Assurance Healthcare Effectiveness Data and Information Set Measures, available at: http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx; and CMS Shared Savings Program Quality Measures and Performance Standards, available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality_Measures_Standards.html.
[22] National Cancer Institute, Colon Cancer Treatment Physician Data Query, available at: http://www.cancer.gov/types/colorectal/patient/colon-treatment-pdq#section/_162.
[23] *See* 80 Fed. Reg. at 41766 & Table 15.

colonoscopy code (45378) and the "base" esophagogastro-duodenoscopy code (43235), and adding this incremental difference to CMS's recommended wRVU for esophagogastroduodenoscopy to derive a new set of colonoscopy wRVUs.[24]

In other words, CMS has chosen to make substantial changes to its payment policy for vital cancer screening and prevention services based on an unsupported analogy to a completely different endoscopic procedure. In doing so, CMS stated that this is consistent with a methodology used by the RUC, whereby it "uses a base code or other comparable code and considers what the difference should be between that code and another code by comparing the differentials to those for other sets of similar codes."[25] CMS's simple subtraction of one base code's wRVU from another is intended to capture all of the unique complexities of performing this completely distinct service – including biopsy and removal of polyps. To our knowledge, this computational approach is without precedent.

Upper and lower GI endoscopy are clinically distinct. Endoscopy of the colon requires navigation of a much longer and more complex section of the digestive tract. The removal of polyps and other procedures in the colon are also more complex because of the higher risk of negative outcomes and complications. Notably, gastroenterologists have no voting seat at the RUC, and the RUC chose not to use survey data compiled by our sister GI societies in making its recommendation to CMS. This survey data demonstrated that neither the time nor intensity of colonoscopy procedures has decreased in a manner that would justify CMS's substantial reduction in wRVUs. Thus, Medicare patients face the risk of decreased access to critical colonoscopy services based on data that is fundamentally at odds with survey data presented by GI societies and based on a computation methodology that seeks to equate fundamentally different forms of endoscopic procedures.

Physicians in our member practices across the country perform thousands of colonoscopies each day – relying on this essential tool to prevent, diagnose and treat colorectal cancer. Given the sheer number of colonoscopies performed, reimbursement cuts to these services will have a profound impact on many gastroenterology practices. **Unfortunately, any limitation or closure of independent practices may also have a serious effect on patient access to care.** Independent specialty practices are, by their nature, often able to serve a far broader and more diverse set of communities than centralized, hospital-based practices. Reimbursement cuts are particularly likely to affect

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[24] *Id.*
[25] *Id.*

those practices with payor mixes more reliant on public payors like Medicare and Medicaid. In turn, this will have a disproportionate impact on communities that already lack access to colonoscopy screening and treatment. The cuts proposed by CMS therefore risk undermining the recent gains made in colorectal cancer screening and treatment, and pushing the important screening goals articulated by the CDC, AHRQ, and others further out of reach.

Conclusion

DHPA strenuously opposes CMS's proposed cuts in reimbursement to life-saving colonoscopy procedures. The physicians in our member practices are specialists who are devoted to high-quality digestive health and colonoscopies are an essential and integral part of their practices. Cuts to these services – in the face of contradictory data presented by our sister GI societies and based on a calculation methodology that collapses the clinical distinction between upper and lower endoscopic procedures—poses a significant risk to the continued viability of independent GI practices in our communities. And, with that risk, comes a serious threat to the accessibility of colonoscopy, especially in rural and minority communities where access to care is already limited, and health disparities already exist.

As a result, DHPA believes **no cuts** are justified for colonoscopy at this time. CMS should retain the colonoscopy rate paid under the existing MPFS for CY 2015. DHPA – with its more than 1,200 gastroenterologists who prevent, detect and treat colorectal cancer on a daily basis – looks forward to serving as a resource to CMS as it moves forward with its efforts to modify its proposals in advance of issuing the Final Rule for CY 2016. Please reach out with any questions to DHPA's Chair of Health Policy, Dr. Michael Weinstein (Michael.Weinstein@capitaldigestivecare.com, 202-296-3449,), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@kattenlaw.com, 202-625-3534).

Sincerely,

Scott Ketover, M.D.
President

Michael Weinstein, M.D.
Chair, Health Policy

cc: Howard Rubin, Esq., Katten Muchin Rosenman LLP