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September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1676-P – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program Proposed Rule
82 Fed. Reg. 33950 (July 21, 2017)

Dear Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule implementing changes to the calendar year (CY) 2018 Medicare Physician Fee Schedule and other revisions to the Part B program. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society and supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN offers the following comments on the proposed rule:

II. PROVISIONS OF THE PROPOSED RULE

C. Medicare Telehealth Services

The Centers for Medicare and Medicaid Services (CMS) proposes to add the following HCPCS code to the list of telehealth services: HCPCS code G0296: Counseling visit to discuss the need for lung cancer screening using low dose computed tomography (LDCT).

ACS CAN supports CMS' proposed expansion of Medicare's coverage of telehealth services. In the United States, lung cancer is the second most commonly diagnosed cancer in both men and women.[1] Lung cancer is also the leading cause of cancer death in men and women, accounting for 1 out of every 4 cancer deaths. We believe that adding the lung cancer screening counseling session to the list of approved telehealth codes will help to ensure that more beneficiaries are able to access this much-needed service.

[1] American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society; 2017.

Approximately one-fourth of all Medicare beneficiaries live in isolated or rural areas and many confront formidable barriers to quality cancer care.[2] Telehealth services can help patients overcome geographic limitations to accessing care and allow patients the opportunity to receive services without having to incur additional travel costs.

III. OTHER PROVISIONS OF THE PROPOSED RULE

A. New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

3. Proposed Care Management Requirements and Payment for RHCs and FQHCs

CMS propose a new G code for use by RHCs and FQHCs. G code GCCC1 would be a General Care Management code for RHCs and FQHCs, with the payment rate set at the average of the national non-facility PFS payment rates for the chronic care management (CCM) and general behavioral health initiative (BHI) codes: CPT code 99490, CPT code 99487, and HCPCS code G0507. RHCs and FQHCs would be permitted to bill under the new General Care Management code when the requirement for any of these three codes are met.

ACS CAN supports CMS' proposal to add the new General Care Management code for use by RHCs and FQHCs. Community health centers – including FQHCs and RHCs – provide essential community-oriented primary care in areas that are underserved or lack other health care services.

Medicare beneficiaries with cancer often require a range of services – including oncology care, specialty care and primary care – and must navigate between multiple providers in different care settings through the course of their treatment. Research has shown that effective care coordination at each phase along the continuum of cancer care is vitally important for patients.[3] Care coordination allows for deliberate organizing of patient care, ensuring that the patients' needs are communicated at the appropriate time and to the appropriate person which in turn allows for safer and more effective care.[4] Conversely, a lack of care coordination for cancer patients has been shown to result in lower quality of care for cancer patients.[5]

However, we are concerned with the proposal to allow the code to be used only once per month for a beneficiary. While we recognize the need to ensure that this code is not over utilized, we nevertheless urge CMS to reconsider its position that the code can only be used once per beneficiary per month and may not be combined with other care management codes. Rather than restricting the use of these codes due to concerns of possible overuse, CMS should consider removing the once-per-month

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[2] Medicare Payment Advisory Commission, Health Care Spending and the Medicare Program, June 2016, ch. 2, available at http://www.medpac.gov/documents/data-book/june-2016-data-book-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0.

[3] Hewitt M, Greenfield S, Stovall, eds. Committee on Cancer Survivorship: Improving Care and Quality of Life, Institute of Medicine, National Research Council. *From Cancer Patient to Cancer Survivor: Lost in Translation.* Washington, DC: National Academies Press; 2006.

[4] Care Coordination. May 2015. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html.

[5] Bowles EJA, Tuzzio L, Wiese CJ, et al. Understanding High-Quality Cancer Care: A Summary of Expert Perspectives. *Cancer*, 2008; 112(4): 934-942.

restriction and actively monitor the use of these codes to determine whether overuse occurs. We fear that the by restricting the use of the codes, providers may choose not to perform these vital functions.

III. OTHER PROVISIONS OF THE PROPOSED RULE

D. Payment for Biosimilar Biological Products Under Section 1847A of the Act

In the CY 2016 Medicare Physician Fee Schedule final rule CMS made clear that the payment amount for a biosimilar biologic product is based on the average sales price (ASP) of all biosimilar products within the same billing and payment code. Citing concerns that the current policy may discourage development of new biosimilar drugs, CMS requests comments on the current Medicare Part B biosimilar product policy.

ACS CAN appreciate CMS' interest in ensuring a viable biosimilar market. We believe biosimilar products approved by the Food and Drug Administration (FDA) offer potential for increasing accessibility to, and affordability of, effective cancer therapies. We note that to date there have been few FDA-approved biosimilar products, none of which have been deemed interchangeable. Interchangeability provides the greatest promise of competition and reduced prices. The intent behind creating the biosimilar approval pathway was to lower the barrier to entry for biologic drugs that could compete with older innovator biologics.

As CMS revisits its current policy we note that under the FDA process, biosimilar manufacturers are not required to obtain all the same indications that are applicable for the branded reference product. For example, a reference product could have ten indications, but biosimilar manufacturer "A" could seek and obtain FDA approval for only four of the indications, while biosimilar manufacturer "B" could seek and obtain all ten along with interchangeable status. Under the current CMS policy, both the biosimilar products are assigned the same reimbursement code and rate. This policy does not allow differentiation from a reimbursement standpoint between drugs with different FDA-approved indications. We urge CMS to ensure that its policies recognize differences in products and promote the development of high-quality, well-characterized biosimilars. Further, we do not want any policy to unintentionally result in prescribing practices inconsistent with the approval status of a biosimilar.

K. Proposed Changes to Medicare Diabetes Prevention Program (MDPP) Expanded Model

In the CY2017 Medicare Physician Fee Schedule final rule CMS implemented an expanded Medicare Diabetes Prevention Program (MDPP). In the current proposed rule, CMS now proposes some modifications to this benefit.

ACS CAN strongly supports Medicare coverage of the MDPP, an evidence-based program to prevent diabetes in people at risk for the disease. Many of the interventions included in the MDPP will likely also help beneficiaries lower their risk of developing cancer. Research suggests that at least thirteen cancers are linked to obesity[6] and one in five cancer cases are caused by physical inactivity, poor diet, and excess weight.[7]

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[6] Lauby-Secretan B. Scoccianti C, Loomis D, et al. Body Fatness and Cancer – Viewpoint of the IARC Working Group. N Engl J Med 2016; 375:794-798.

[7] American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society; 2017.

We encourage CMS to consider coverage of similar evidence-based programs in future rulemaking including a pilot program to examine the impact of the MDPP on other health outcomes, including cancer incidence and mortality.

We recommend CMS consider developing a risk adjustment strategy or pilot for low-income participants to ensure these beneficiaries have sufficient access to the program. Research shows African Americans and low income people are not likely to lose as much weight as non-Hispanic whites and individuals with higher incomes.[8, 9] In addition, it can be difficult to engage beneficiaries with lower income for a three-year period. By not adjusting for socio-economic status, there is a concern that providers could be incentivized to cherry pick beneficiaries and/or certain service locations in order to limit enrollment to participants who are more likely to be able to lose the required amount of weight and maintain the weight loss for the three-year program period. We are concerned that this would reduce access to the program for low income people and other at-risk populations.

c. Proposed Changes Related to Beneficiary Eligibility

iii. Once-Per-Lifetime Set of Services

CMS proposes to clarify that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions, is available only once per lifetime per MDPP beneficiary. CMS also proposes to limit the ongoing services period to three years.

ACS CAN is concerned that the once-per-lifetime benefit may be insufficient to prevent the onset of diabetes and other chronic diseases in the long term. We urge CMS to remove this limitation in order to ensure that more individuals are able to take advantage of this benefit.

Individuals often need help in establishing healthy behaviors to develop or maintain a healthy weight in order to ensure they do not go on to develop Type 2 diabetes or other costly diseases in the future. The three-year time frame is not sufficient to ensure that individuals retain their healthy behaviors for a lifetime. Moreover, we note on average Americans are now living longer and thus a beneficiary who completes the MDPP at age 65 would not be eligible to participate in the program in future years, despite the fact that the beneficiary's ability to maintain a healthy lifestyle may change ten to twenty years later. Factors that cause such a change include retiring from full-time work, moving to a new housing situation, or suffering a mobility-limiting injury or chronic disability. All of these life changes are likely to affect a beneficiary's ability to exercise or eat well, and all of these life changes are very common among the Medicare population. An enrollee may learn one set of strategies at age 65 that would no longer be helpful or effective once she has a disability, for example. In addition, other similar preventive services, such as obesity counseling or tobacco cessation treatment, do not have a similar restriction.

If CMS decides to retain the once-per-lifetime limitation, we urge CMS at a minimum to include an exception to the once-per-lifetime benefit limit for participants who experience a major life event that precludes them from completing the program or changes their life-situation to an extent where the

[8] Ackermann RT, Liss DT, Finch EA, et al. A Randomized Comparative Effectiveness Trial for Preventing Type 2 Diabetes. Am J Public Health 2015; 105(11): 2328-2334.
[9] Embree GGR, Samuel-Hodge CD, Johnston LF, et al. Successful long-term weight loss among participants with diabetes receiving an intervention promoting an adapted Mediterranean-style dietary pattern: the Heart Healthy Lenoir Project. *BMJ Open Diabetes Res Care* 2017; 5(1): e000339.

program is necessary again. A beneficiary should not be denied access to the service if her inability to complete the program was due to factors beyond her control (e.g., an intervening cancer diagnosis), or if the strategies she learned during previous enrollment are no longer relevant due to a life event (like cancer treatment that has left her disabled).

iv. Eligibility Throughout the MDPP Services Period

CMS continues to maintain that in order to be eligible to participate in the MDPP monthly maintenance sessions a beneficiary must attend monthly maintenance sessions and maintain at least a five percent weight loss.

ACS CAN is concerned that these requirements fail to support long-term behavior change and reduce disease risk. Mandatory participation in monthly maintenance sessions and the requirement that a participant maintain a minimum weight loss could be overly punitive. For example, an individual may miss a monthly meeting due to life events, and should not be permanently disqualified from the program (particularly given that under the proposed policy an individual receives a once-per-lifetime benefit limit). In addition, part of the intent of the program is to teach individuals how to maintain weight loss. Penalizing individuals whose weight fluctuates above a certain point (even if that weight fluctuation is temporary) denies the individual the support needed to return to their weight goal.

Colorectal Cancer Screening Clarity Needed

We are also pleased with CMS' expansion of preventive services, and encourage CMS to do more to prevent cancer and cancer re-occurrence in Medicare beneficiaries. In 2017, an estimated 600,920 Americans are expected to die from cancer – about 1,650 people per day.[10] Yet up to half of all cancers can be prevented.

We urge CMS to clarify that beneficiaries are not subject to co-insurance for screening colonoscopies that include polyp removal or biopsy. Colorectal cancer is the third most common cancer in men and women.[11] In the Medicare population, colorectal cancer is the second leading cause of cancer related deaths.[12] Colorectal cancer accounted for nearly 11 percent of Medicare fee-for-service cancer payments in 2011.[13] Fortunately incident rates have been declining in recent years, in large part due to the increase in colorectal cancer screening rates.

Most colorectal cancers result from abnormal growths ("adenomatous polyps") in the lining of the colon that become cancerous over time.[14] Most of these polyps can be identified and removed during a colonoscopy; thus, in many cases, colorectal cancer is preventable through timely screening.[15]

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[10] American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta, GA: American Cancer Society; 2017.
[11] Id.
[12] National cancer for Health Statistics, Prepared by the Surveillance and Health Services Research Program of the American Cancer Society, 2012.
[13] Medicare five percent sample LDS SAF files, 2011. Analysis by Direct Research, LLC.
[14] Winawer SJ. Natural history of colorectal cancer. Am J Med 1999;106:3S-6S; discussion 50S-1S.
[15] Zauber AG, Winawer SJ, O'Brien MJ, et al. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. N Eng J Med 2012;366:687-96.

Due to the importance of this public health issue, over 1,000 health-related organizations have committed to increase the nation's colorectal cancer screening rate to 80 percent by the year 2018. In order to achieve this goal, obstacles that prevent Americans from getting tested must be removed. Despite Medicare's coverage of screening colonoscopy, the number of beneficiaries who are up to date on recommended colorectal cancer screening falls short of the goal of 80 percent screened. Colonoscopy with the removal of polyps reduces mortality from colorectal cancer by 53 percent.[16] Approximately 90 percent of those diagnosed with early stage cancer live five or more years so that a colonoscopy can literally save a person's life when a polyp is found and removed.[17] Of those people who will be newly diagnosed with colorectal cancer, nearly two-thirds are Medicare beneficiaries.[18] Yet in 2015, about one in three people over age 65 were not up to date with their recommended colorectal cancer screenings.[19]

Treatment costs for colorectal cancer can be very high, especially for advanced forms. Annual treatment costs can exceed $300,000 a year.[20] Estimates suggest that about $14 billion is spent annually on colorectal cancer treatments in the U.S. with Medicare bearing one half of the cost ($7-$8 billion).[21] Preventing colorectal cancer through polyp removal or catching cancer at an earlier stage saves lives and can reduce costs for public payers and private insurance.

Under current Medicare policy, beneficiaries are still required to pay coinsurance when the preventive action of removing a polyp, abnormal growth, or suspicious-looking tissue occurs during a screening colonoscopy. Medicare's current cost-sharing policy is confusing to beneficiaries, and the threat of out-of-pocket costs can serve as a deterrent to screening. Many beneficiaries are surprised to learn they owe coinsurance for a screening colonoscopy with polyp removal. While the Administration purports colorectal cancer screening to be a "free" preventive service, for nearly half of beneficiaries who choose colonoscopy as their method of colorectal cancer screening, coinsurance will apply. Recent analysis has indicated that nearly half of all patients who undergo screening colonoscopy have a polyp or other tissue removed.[22,23] CMS' current policy is not only unfair, but disproportionately affects lower income beneficiaries because they are most likely to lack supplemental insurance coverage to defray the expense of these unexpected out-of-pocket costs. This is also the population which has the lowest current participation in colon screening services. A recent study estimated that 58 percent of all

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[16] Zauber et al. Colonoscopic Polypectomy and Long-Term Prevention of Colorectal-Cancer Deaths *N Engl J Med* 2012; 366:687-696.
[17] Howlader N, Noone AM, Krapcho M, et al, eds. SEER cancer statistics review, 1975–2010, Bethesda, MD: National Cancer Institute. Available at http://seer.cancer.gov/csr/1975_2010/. [accessed June 3, 2016]
[18] American College of Gastroenterology. Press Releases April 28, 2015. http://gi.org/wp-content/uploads/2015/04/SCREEN-Act-ACG-Press-Release-FINAL-04282015.pdf. [accessed June 3, 2016].
[19] American Cancer Society, *Cancer Prevention and Early Detection Facts and Figures*. Atlanta, GA: American Cancer Society; 2017.
[20] Schrag D. The price tag on progress—chemotherapy for colorectal cancer. *N Engl J Med.* 2004; 351(4): 317-9.
[21] Id.
[22] Wolf HJ, Masias A. Cumulative Evaluation Report for the Colorado Colorectal Screening Program, June 1, 2006 – June 14, 2010. Project Deliverable for the Colorado Colorectal Screening Program Funded by the Cancer, Cardiovascular and Pulmonary Disease Grant program. Denver: Colorado Department of Public Health and Environment. 2010.
[23] GI Quality Improvement Consortium Ltd. GIQuIC data registry: A joint initiative of the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE); 2012.

colorectal cancer deaths in 2020 will be due to "non-screening" – this means that thousands of colorectal cancer deaths could be prevented if people are screened per recommendations.[24]

Cost sharing for polyp removal during a screening colonoscopy may discourage patients from getting their screening altogether leading to higher costs for Medicare in the long-term. Yet, the costs associated with advanced treatment and premature death due to colorectal cancer are largely avoidable with appropriate screening.

In addition, we note that colorectal cancer screenings can be conducted through a fecal occult blood test (FOBT), flexible sigmoidoscopy, double contrast barium enema, colonoscopy, or CT colonography. It appears there is an additional discrepancy with respect to coverage of colorectal cancer screening by Medicare. In some cases, beneficiaries who receive a colonoscopy following a positive FOBT test may be charged cost-sharing for the colonoscopy, which could be coded as diagnostic. The distinction between screening colonoscopy and screening follow up colonoscopy in the Medicare program creates a financial incentive for Medicare beneficiaries to select the more costly and more intrusive colorectal cancer screening exam, or forego recommended screening altogether. Through regulatory interpretation, CMS should consider a policy that does not discourage Medicare beneficiaries from accessing colonoscopy following a positive FOBT. We urge CMS to clarify that all approved colon cancer screening tests (including multiple types of test, where medically appropriate) be covered without cost-sharing obligations to the beneficiary.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Kirsten Sloan
Vice President, Public Policy
American Cancer Society Cancer Action Network

[24] Meester RGS, Doubeni CA, Lansdorp-Vogelaar I, et al. Colorectal Cancer Deaths Attributable to Nonuse of Screening in the United States. Annals of epidemiology. 2015;25(3):208-213.e1. doi:10.1016/j.annepidem.2014.11.011.