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September 6, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1654-P – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2017; Proposed Rule
81 Fed. Reg. 46162 (July 15, 2016)

Dear Acting Administrator Slavitt:

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) 2017 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 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 CPT and HCPCS G-codes to the list of telehealth services: ESRD-related services (CPT codes 90967 through 90970); Advance care planning (CPT codes 99497 and 99498); and Telehealth Consultations for a Patient Requiring Critical Care Services (GTTT1 and GTTT2).

ACS CAN supports CMS' proposed expansion of Medicare's coverage of telehealth services. Approximately one-fourth of all Medicare beneficiaries live in isolated or rural areas and many confront formidable barriers to quality cancer care.¹ Individuals with cancer – particularly those in rural or frontier areas – often have challenges accessing specialists or oncology services due to geographic limitations. Telehealth services can help cancer patients overcome geographic limitations to accessing specialist care and allow patients the opportunity to receive services without having to incur additional

¹ 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>.

travel costs. Beyond geographic and cost barriers, the process of accessing specialty care for cancer patients is further complicated by their health status. Pain from symptoms, discomfort caused by treatment, and the emotional toll associated with having cancer make it particularly challenging, both mentally and physically, to travel long distances to access treatment. Research has shown that being able to readily access quality specialty care can significantly influence outcomes for people living with cancer and providers, and health care systems are testing models specifically targeted to cancer patients especially for delivering palliative care, pain management and patient navigation services.^{2,3,4,5}

As health information technology advances and access to broadband services expands, more health care services may be ripe for inclusion within the Medicare telehealth program. In future years as CMS redesigns the telehealth program, we urge the Agency to examine the feasibility of incorporating patient navigation services into the telehealth program. Patient navigation is individualized assistance offered to patients, their families and caregivers that help them overcome barriers and facilitate timely access to medical care. Research has demonstrated that patients who utilize patient navigation services experience better health outcomes and improved patient satisfaction.^{6,7}

E. Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

2. Non-Face-to-Face Prolonged Evaluation & Management (E/M) Services

CMS proposes, beginning in CY 2017, to recognize two Evaluation & Management (E/M) Services CPT codes: 99358 and 99359. CMS notes that the time could not be counted more than once towards the provision of CPT codes 99358 or 99359 or any other Physician Fee Schedule service. CMS proposes to require the services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code.

ACS CAN supports CMS' proposal to provide reimbursement for non-face-to-face prolonged evaluation and management services because it would benefit cancer patients who need palliative care services. Palliative care services prevent and relieve suffering and support the best possible quality of life for patients and their families, regardless of the stage of the disease or the need for other therapies. It focuses on relief of the pain, symptoms, and stress of serious illness and on improving communication with patients and families. Palliative care services often require care coordination among many providers outside the presence of the beneficiary.

² Doolittle GC, Spaulding AO. Providing Access to Oncology Care for Rural Patients via Telemedicine. *J Oncol Pract.* Sep 2006; 2(5): 228-230.

³ Doorenbos, A.Z., Demiris, G., Towle, C. et al. Developing the Native People for Cancer Control Telehealth Network. *Telemed J E Health.* 2011; 17: 30–34.

⁴ Hennemann-Krause L1, Lopes AJ1, Araújo JA2, Petersen EM2, Nunes RA1. The assessment of telemedicine to support outpatient palliative care in advanced cancer. *Palliat Support Care.* 2014 Aug 27:1-6.

⁵ Holland DE1, Vanderboom CE, Ingram CJ, Dose AM, Borkenhagen LS, Skadahl P, Pacyna JE, Austin CM, Bowles KH. The feasibility of using technology to enhance the transition of palliative care for rural patients. *Comput Inform Nurs.* 2014 Jun;32(6):257-66.

⁶ Impact of Patient Navigation on Timely Cancer Care: The Patient Navigation Research Program. *JNCI Journal of the National Cancer Institute.* 2014;106(6):dju115. doi:10.1093/jnci/dju115.

⁷ Pruthi S., Stange K.J., Malagrino Jr. G.D., Chawla K.S., LaRusso N.F., Kaur J.S. Successful implementation of a telemedicine-based counseling program for high-risk patients with breast cancer *Mayo Clinic Proceedings*, 88 (1) , pp. 68-73. Freund KM, Battaglia TA, Calhoun E, et al.

4. *Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM Services)*

In light of stakeholder feedback, CMS is proposing several changes in the payment rules for chronic care management (CCM) services. CMS is proposing to more appropriately recognize and pay for CPT codes 99487 and 99489. CMS proposes to allow CPT codes 99487, 99489, and 99490 to only be used once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period.

ACS CAN is generally supportive of CMS' proposed changes which seek to provide administrative simplicity to the rule regarding chronic care management services. However, we are concerned with the proposal to replace the required 24/7 access to the beneficiary's care plan with a requirement that the care plan be shared in a "timely" manner. We are concerned that the term "timely" is undefined in this context and could result in a delay in the sharing of this important document, which represents the beneficiary's intent regarding her care.

5. *Assessment and Care Planning for Patients With Cognitive Impairment*

CMS is proposing a G-code that would provide separate payment to recognize the work of a physician or other appropriate billing practitioner in assessing and creating a care plan for beneficiaries with cognitive impairment, GPPP6. CMS also proposes the add-on code must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same day as other enumerated E/M services.

ACS CAN supports CMS' proposal to provide an add-on payment for the development of a care plan for beneficiaries with cognitive impairments. These plans often take additional time and resources in order to develop.

We also are pleased that CMS' proposal includes palliative care services as a required service element. Currently the required service element includes "Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference." Research has demonstrated that palliative care services are appropriate at the point of diagnosis⁸ and should not only be limited to end of life care. Thus, we urge CMS to separate these policies into two separate elements.

III. OTHER PROVISIONS OF THE PROPOSED RULE

J. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

In 2012, the Center for Medicare & Medicaid Innovation (CMMI) awarded a Health Care Innovation Award to the Young Men's Christian Association (YMCA) to test whether National Diabetes Prevention Program (DPP) services could be successfully furnished by non-physician, community-based organizations to Medicare beneficiaries diagnosed with prediabetes and therefore at a high risk for development of Type 2 diabetes. CMS' Office of the Actuary determined that the DPP is likely to reduce

⁸ Smith, TJ, Temin S, Alesi ER, Abernathy AP, Balboni TA, Basch EM, Ferrell BR, Loscalzo M, Meier DE, Paice JA, Peppercorn JM, Somerfield M, Stovall E, Von Roenn JH. American Society of Clinical Oncology Provisional Clinical Opinion: The Integration of Palliative Care Into Standard Oncology Care. *J Clinical Oncol* 2012; 30: 880-887.

Medicare expenditures.⁹ Based on the success of the DPP, CMS proposes to expand the program to become the Medicare Diabetes Prevention Program, a new additional preventive service in Medicare.

ACS CAN applauds CMS for expanding the DPP to become a new Medicare preventive service. Many of the interventions included in the DPP will also help beneficiaries lower their risk of developing cancer. For most Americans who do not use tobacco products, weight management, good nutrition, and physical activity are the greatest modifiable determinations of cancer risk.¹⁰ Approximately one fifth of cancer cases are due to excess weight, poor nutrition, and physical inactivity.¹¹ Individuals who are overweight or obese have an increased risk of developing cancer or a recurrence of cancer as well as a decreased risk of survival of cancer.¹² We recommend that as part of the ongoing evaluation of the DPP, the impact on incidence and mortality from weight-related cancers also be considered.

Overall, we support the goals of the Medicare DPP of small but significant amounts of weight loss followed by maintenance of that weight loss. We are pleased that individuals who achieve the minimum 5 percent average weight loss are eligible for additional monthly maintenance sessions as long as the weight loss is maintained. Research shows that the majority of people who lose weight regain it,¹³ and support is needed to prevent weight regain among DPP participants following weight loss. We recommend that the expansion of the DPP be done as consistently as possible with CDC's evidence-based Diabetes Prevention Recognition Program, to help to ensure the same public health and cost savings benefits will be realized in the Medicare population as in the clinical trial. As a new Medicare preventive service, the DPP should be available to eligible participants without cost sharing.

We believe that successful implementation of the Medicare DPP could provide an opportunity for Medicare coverage of other evidence-based community-based chronic disease prevention programs. To that end, the proposed rule notes "MDPP services . . . have been recommended by the Community Preventive Services Task Force, which is similar to the USPSTF, and therefore a USPSTF recommendation is not necessary" for coverage as a Medicare preventive service. Other evidence-based interventions for cancer prevention and its risk factors of excess weight and obesity, physical inactivity, and tobacco use have been recommended by the Community Preventive Services Task Force.¹⁴ CMS should consider providing or expanding Medicare coverage for these other evidence-based cancer prevention services as part of a future rulemaking.

⁹ CMS Office of the Actuary, Certification of Medicare Diabetes Prevention Program, Mar. 14, 2016, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf>.

¹⁰ Kushi LH, Doyle C, McCullough M, et al. and the American Cancer Society 2010 Nutrition and Physical Activity Guidelines Advisory Committee. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention. *CA Cancer J Clin* 2012;62:30-67.

¹¹ American Cancer Society, Cancer Facts & Figures 2016, available at <http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf>.

¹² Kushi, et al.

¹³ Wing RR and Phelan S. Long-term weight loss maintenance. *Am J Clin Nutr* 2005; 82(1): 2225-2255.

¹⁴ Community Preventive Services Task Force. The Guide to Community Preventive Services. Available at <http://www.thecommunityguide.org/>. Accessed August 18, 2016.

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 2016, an estimated 595,690 Americans are expected to die from cancer – about 1,630 people per day.¹⁵ 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.¹⁶ In the Medicare population, colorectal cancer is the second leading cause of cancer related deaths.¹⁷ Colorectal cancer accounted for nearly 11 percent of Medicare fee-for-service cancer payments in 2011.¹⁸ 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.¹⁹ Most of these polyps can be identified and removed during a colonoscopy; thus, in many cases, colorectal cancer is preventable through timely screening.²⁰

Due to the importance of this public health issue, over 300 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. In 2010, one in three people over age 65 were not up to date with their recommended colorectal cancer screenings.²¹

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

¹⁵ American Cancer Society, Cancer Facts & Figures 2016.

¹⁶ *Id.*

¹⁷ National cancer for Health Statistics, Prepared by the Surveillance and Health Services Research Program of the American Cancer Society, 2012.

¹⁸ Medicare five percent sample LDS SAF files, 2011. Analysis by Direct Research, LLC.

¹⁹ Winawer SJ. Natural history of colorectal cancer. *Am J Med* 1999;106:3S-6S; discussion 50S-1S.

²⁰ 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.

²¹ American Cancer Society, Cancer Prevention and Early Detection Facts and Figures, 2013, available at <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-037535.pdf>.

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.

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 a discrepancy with respect to how CMS defines the screening continuum. 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. We urge CMS 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
Senior Policy Director
American Cancer Society Cancer Action Network

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.