The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201 The Honorable Julie Su Acting Secretary U.S Department of Labor 200 Constitution Avenue NW Washington, DC 20210

The Honorable Janet Yellen Secretary U.S. Department of the Treasury 1500 Pennsylvania Ave NW Washington, DC 20220

Dear Secretary Becerra, Acting Secretary Su, and Secretary Yellen:

We are writing to request that you issue guidance related to colorectal cancer screening that will expand access to care and save lives.

Specifically, we support coverage for the surveillance colonoscopy that patients need after having precancerous polyps or lesions removed during an initial colorectal cancer screening test. Ensuring coverage of the surveillance colonoscopy at no cost-sharing to the patient is critical to a complete screening to detect, treat or possibly prevent colorectal cancer. We believe this is consistent with Medicare coverage¹ policy and the United States Preventive Services Task Force (USPSTF) guidelines on colorectal cancer screening.

To ensure that private plans are compliant with the statute, we urge you to provide written guidance to clarify that surveillance colonoscopy after a colonoscopy that required polyp removal is part of the screening continuum and that patients should not face out-of-pocket costs for the surveillance procedure.

Colorectal Cancer Screening Continuum

The U.S. Multi-Society Task Force (USMSTF) on Colorectal Cancer recommends that after the initial screening, asymptomatic individuals receive repeat colonoscopy exams to look for new polyps. The repeat, or surveillance, colonoscopy will be performed 1-10 years after the initial exam, depending on how many and what type of polyps were removed initially. While the intervals of repeat exams differ, the principle is the same: to detect and remove polyps in asymptomatic individuals.² Hence, this falls in

¹ Sections 1861(s)(2)(R) and 1861(pp) of the Social Security Act (the Act)

² Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer:

https://journals.lww.com/ajg/Fulltext/2020/03000/Recommendations for Follow Up After Colonoscopy.19.asp

the category of a screening—but at a different interval.³ It is important to note that these patients started out as average-risk patients and now are part of the screening continuum of care, which is consistent with the language in the USPSTF recommendations.

According to the USMSTF guidelines, undergoing one or two surveillance examinations reduces the risk of colorectal cancer by 43–48%.⁴ And for patients with advanced adenoma, one surveillance colonoscopy reduces their colorectal cancer risk to that of the general population; for advanced adenoma patients who do *not* receive at least one surveillance colonoscopy, their colorectal cancer risk is four times higher.⁵

Policy Clarifications are Necessary

We urge the Administration to continue the fight against colorectal cancer and update the ACA's FAQ guidance, stipulating that the surveillance colonoscopy should be treated as a "screening" and part of the ACA "preventive services" benefit. The patient is otherwise asymptomatic or has no symptoms, but they require an interval surveillance examination. This is the standard of care and is also the current policy under Medicare. We believe that this policy should be consistent among all insurers. Currently, commercial insurers regulated by the ACA treat a surveillance exam as a "diagnostic" service despite the patient having no signs or symptoms, thus triggering patient cost-sharing for a preventive service. Not only is this counter to the clinical standard of care, but it is also inconsistent with CMS' medical coding guidance.⁶

USPSTF Recommendations – Colorectal Cancer Screening Continuum

The Administration announced in a February 2022 FAQ guidance that insurers must cover, at no cost to the patient, the necessary colonoscopy subsequent to another colorectal cancer screening test.⁷ This is critically important, as patients who did not have a colonoscopy after a non-invasive colorectal cancer-screening test have a 103% higher risk of death from colorectal cancer, compared with those who had a colonoscopy.⁸ The FAQs cite language in the USPSTF's "Practice Considerations" section as rationale for this change.⁹

³ Of note: The guidelines clearly exclude individuals with symptoms, undergoing colonoscopy for an indication deemed necessary for diagnosis and management of a medical condition. ⁴ USMST Guidelines:

https://journals.lww.com/ajg/Fulltext/2020/03000/Recommendations for Follow Up After Colonoscopy.19.asp X

⁵ Cottet V, Jooste V, Fournel I, et al. Long-term risk of colorectal cancer after adenoma removal: a populationbased cohort study. Gut 2012;61:1180–1186

⁶ According to <u>CMS' ICD-10-CM Official Guidelines for Coding and Reporting FY 2023</u>, a screening is "the testing for disease or disease precursors in seemingly well individuals so that early detection and treatment can be provided for those who test positive for the disease." However, the "testing of a person to rule out or confirm a *suspected diagnosis* because the patient has some sign or symptom" is a diagnostic examination.

⁷ When must plans and issuers begin providing coverage without cost sharing for a follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization test based on the new USPSTF recommendation?: <u>https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf</u>

⁸ Zorzi M, et al. Gut 2022;71:561–567. doi:10.1136/gutjnl-2020-322192

⁹ "In its 'Practice Considerations' section detailing screening strategies, the Final

The USPSTF specifically emphasizes the importance of adhering to the colorectal cancer screening continuum, intervals, and treatment process.¹⁰ Cost-sharing is a demonstrated barrier to access to care and colorectal cancer screening.¹¹ These patients have a personal history of polyps and are now subject to cost-sharing simply because they must have another screening within 10 years.

For the surveillance colonoscopy in asymptomatic patients, we note that in the implementation section of USPSTF's recommendations, the Task Force underscores the need for, and importance of, following the colorectal cancer screening continuum, including the "intervals, follow-up [surveillance] colonoscopy and treatment."¹² This is especially important to help achieve health equity in screening across all patient populations. In the "Advising Black Adults" section, the Task Force "encourages the development of systems of care to ensure adults receive high-quality care across the continuum of screening and treatment with special attention to Black communities, which historically experience worse colorectal cancer health outcomes." ¹³ Thus, we believe that USPSTF guidance applies to asymptomatic patients who need to be screened at earlier intervals.

We also note that the ACA does not limit or restrict other clinical guidelines in addition to the USPSTF for preventive services coverage determinations.¹⁴

Why This is Important

As part of the Cancer Moonshot initiative, the Biden Administration set bold goals to "end cancer as we know it" including cutting the death rate from cancer by at least 50% over the next 25 years.¹⁵ As the second leading cause of cancer death for men and women combined, colorectal cancer must be part of

Recommendation Statement provides: 'When stool-based tests reveal abnormal results, follow up with colonoscopy is needed for further evaluation.... Positive results on stool-based screening

tests require follow-up with colonoscopy for the screening benefits to be achieved.' Additionally, the Final Recommendation Statement provides with respect to direct visualization tests: Abnormal findings identified by flexible sigmoidoscopy or CT colonography screening require follow-up colonoscopy for screening benefits to be achieved.'" https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf

¹⁰ U.S. Preventive Services Task Force: Recommendation on Colorectal Cancer Screening.

 ¹¹ Muthukrishnan, M. Patients' self-reported barriers to colon cancer screening in federally qualified health center settings. Preventive Medicine Reports. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6531912/
¹² USPSTF Colorectal Cancer Screening Recommendations (May 2021): "Maintaining comparable benefits and harms of screening with the various strategies requires that patients, clinicians, and health care organizations adhere to currently recommended protocols for screening intervals, follow-up colonoscopy, and treatment."

¹³ USPSTF Colorectal Cancer Screening Recommendations (May 2021): "The USPSTF recognizes the higher colorectal cancer incidence and mortality in Black adults and strongly encourages clinicians to ensure their Black patients receive recommended colorectal cancer screening, follow-up, and treatment. The USPSTF encourages the development of systems of care to ensure adults receive high-quality care across the continuum of screening and treatment, with special attention to Black communities, which historically experience worse colorectal cancer health outcomes."

¹⁴ ACA: "Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force."

that effort. Colorectal cancer is unique in that when detected early, it is highly treatable and sometimes even preventable. The American Cancer Society estimates that when detected and treated early, the 5-year survival rate for colorectal cancer is 90%. Unfortunately, early detection occurs in less than 40% of colorectal cancer cases.¹⁶

There have been great strides in lowering colorectal cancer incidence rates in the Medicare population. However, with the 2022 USPSTF screening guidelines that recommend screening start at age 45, we must increase screening rates in this new cohort and ensure private insurers do not create barriers to screening. The stakes are high: colorectal cancer is expected to be the leading cause of cancer-related deaths by 2030 for those ages 20 to 49.¹⁷ According to a recent study, approximately 43% of colorectal cancer diagnoses in those under the age of 50 are in people aged 45-49.¹⁸ We are at an inflection point in this crisis, as incidence and death rates among younger Americans rise. We need to remove barriers to appropriate surveillance intervals for young patients.

Inequities in colorectal cancer screening

According to the American Cancer Society, Black Americans have a 20% higher incidence rate and are 40% more likely to die from colorectal cancer compared to other racial and ethnic groups.¹⁹ The rate of colorectal cancer is 40% more in the lowest socioeconomic status when compared to those in the highest socioeconomic status.²⁰ Increasing screening to 80% from current levels could reduce the number of people diagnosed with colorectal cancer by 22%, and could reduce deaths from colorectal cancer by 33%.²¹ In providing written guidelines to insurers, it will eliminate a significant barrier to screening and directly improve access to care in minority populations.

Conclusion

We urge the Administration to provide written guidance to private insurers to clarify that surveillance colonoscopy should be treated as a preventive service since it is part of the screening continuum and therefore patients should not be subject to cost-sharing. Colorectal cancer remains the second leading cause of cancer deaths in the U.S. among men and women combined and the trends for younger Americans are quite alarming as well. Screening and adherence to surveillance exams are powerful tools in the fight against colorectal cancer, yet patient cost-sharing is a demonstrated barrier to screening.²² ²³

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2778204

²³ Cancer screenings like colonoscopies are supposed to be free. Hers cost \$2,185:

¹⁶ American Cancer Society: 2021 Facts & Figures; Colorectal Cancer Facts & Figures 2020-2022.

https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf

¹⁷ Estimated Projection of US Cancer Incidence and Death to 2040:

https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21772#:~:text=Approximately%2043%25%20of%20d iagnoses%20before,%25)%20younger%20than%2050%20years.

¹⁹ American Cancer Society: 2021 Facts & Figures

²⁰ American Cancer Society: Colorectal Cancer 2020-2022 Facts & Figures

²¹ U.S. Centers for Diseases Control and Prevention. Cost-Effectiveness of Colorectal Cancer Interventions: https://www.cdc.gov/chronicdisease/programs-impact/pop/colorectal-cancer.htm

²² Patients' self-reported barriers to colon cancer screening in federally qualified health center settings: <u>Patients'</u> <u>self-reported barriers to colon cancer screening in federally qualified health center settings - PMC (nih.gov)</u>

https://www.npr.org/sections/health-shots/2022/05/31/1101861735/colonoscopy-cost-cancer-screening

It is imperative that we have in place policies that foster the continuum of screening and reduce barriers to preventive care. We urge your agencies' immediate attention to resolving this problem and look forward to collaborating with you in combatting this preventable disease.

Sincerely,

American College of Gastroenterology American Gastroenterological Association American Society for Gastrointestinal Endoscopy Fight Colorectal Cancer

- Academy of Medicine of Cleveland & Northern Ohio
- Alabama Gastroenterological Society
- Alaska State Medical Association
- Ambulatory Surgery Center Association
- American Association of Physicians of Indian Origin Oklahoma
- American Cancer Society Cancer Action Network
- American Society of Anesthesiologists
- Arizona Ambulatory Surgery Center Association
- Arizona Medical Association
- Arkansas Medical Society
- Association of Pakistani-Descent Gastroenterologists of North America
- California Ambulatory Surgery Association
- California Colorectal Cancer Coalition
- California Medical Association
- Capital Area Medical Society
- Collaborative Group of the Americas on Inherited Gastrointestinal Cancer (CGA-IGC)
- Colon Cancer Coalition
- **Colorectal Cancer Alliance**
- **Colorectal Cancer Equity Foundation**
- **Community Liver Alliance**
- **Dallas County Medical Society**
- Delaware Medical Society
- **Digestive Disease National Coalition**
- Florida Gastroenterologic Society
- FORCE: Facing Our Risk of Cancer Empowered
- Georgia Center for Oncology Research and Education
- Georgia Gastroenterologic and Endoscopic Society
- **GH** Foundation
- **Global Liver Institute**
- Greater Louisville Medical Society
- Hawaii Medical Association
- Hitting Cancer Below the Belt
- Illinois Ambulatory Surgery Center Association

- Illinois State Medical Society
- Indiana Federation of Ambulatory Surgical Centers
- Indiana State Medical Association
- International Foundation for Gastrointestinal Disorders
- Kansas Association of Ambulatory Surgery Centers
- Kentucky Medical Association
- Maine GI Society
- Massachusetts Association of Ambulatory Surgery Centers
- Massachusetts Gastroenterology Association
- MedChi, The Maryland State Medical Society
- Medical Association of the State of Alabama
- Medical Society of New Jersey
- Michigan Ambulatory Surgery Association
- Michigan Gastrointestinal Society
- Minnesota Medical Association
- Mississippi Medical and Surgical Association
- Mississippi State Medical Association
- Missouri Ambulatory Surgery Center Association
- Missouri GI Society
- Moffitt Cancer Center Foundation
- Montana Medical Association
- National Coalition for Cancer Survivorship
- National LGBT Cancer Network
- Nebraska Cancer Coalition
- Nebraska Medical Association
- Nevada Cancer Coalition
- Nevada State Medical Association
- New Mexico Medical Society
- North Dakota Medical Association
- North Texas Indian Physician Charity Foundation
- Northern California Society for Clinical Gastroenterology
- Northern California Society of Gastroenterology Nurses and Associates
- Ohio Association of Ambulatory Surgery Centers
- Ohio State Medical Association
- Oklahoma County Medical Society
- Oklahoma State Medical Association
- **Oley Foundation**
- ONE CANCER PLACE
- **Oregon Medical Association**
- Pacific Northwest Gastroenterology Society
- Pennsylvania Ambulatory Surgery Association
- Pennsylvania Medical Society
- Pennsylvania Society of Gastroenterology
- Phoenix Society of Gastroenterology

South Carolina Gastroenterology Association Southern California Society of Gastroenterology Texas Indo-American Physicians Society-NE Chapter Texas Medical Association Texas Society for Gastroenterology and Endoscopy The HPV Alliance The Kentucky Society of Gastrointestinal Endoscopy (KSGE) The Ohio Gastroenterology Society United Ostomy Associations of America, Inc. Utah Medical Association Virginia Gastroenterological Society Wisconsin Medical Society Wyoming Medical Society