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April 06, 2022

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Submitted electronically: <u>Secretary@HHS.gov</u>

Dear Secretary Becerra:

The American College of Radiology (ACR) is writing you today to request that you exercise your statutorily mandated authority as Secretary of Health and Human Services under the Balanced Budget Act of 1997 (SEC. 4104 (a)(1)(D)) to deem CT Colonography (CTC), also known as virtual colonoscopy (VC), as a covered colorectal screening service under Medicare. CTC is a United States Preventive Services Taskforce (USPSTF) and American Cancer Society (ACS) approved screening test, is covered by a majority of major private insurers, with mandated private payer coverage in 37 states and the District of Columbia. In spite of the widespread acknowledgment of CTC as an effective screening tool for colon cancer, CTC remains the only USPSTF and ACS recommended test not covered by Medicare.

President Biden's relaunch of the Cancer Moonshot program has a goal of reducing the death rate from cancer by at least 50% over the next 25 years. This is only achievable if Medicare coverage supports prevention, early detection, and cancer screening. There are multiple effective options for colorectal cancer screening including CTC, a minimally invasive, cost-effective, and validated direct visualization test able to identify pre-cancerous polyps with high sensitivity. We strongly believe there is ample evidence to conclude that CTC is an appropriate colorectal cancer screening test for the Medicare population.

Since 2009, the ACR has requested the CMS Coverage and Analysis Group to include CTC as a covered exam for colorectal cancer screening in Medicare beneficiaries several times. A formal reconsideration request (attached)was recently submitted to present new supporting evidence and reflect our ongoing concerns.

The ACR recognizes that to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage. Section 4104 of the Balanced Budget Act of 1997 provides for coverage of screening colorectal cancer procedures under Medicare Part B. Medicare covers (1) annual fecal occult blood tests (FOBTs); (2) flexible sigmoidoscopy over 4 years; (3) screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years; (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy

¹ Sec. 4104. Coverage of colorectal screening. https://www.govinfo.gov/content/pkg/CRPT-105hrpt217/pdf/CRPT-105hrpt217/pdf/CRPT-105hrpt217.pdf

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for persons at high risk for colorectal cancer; and, (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.

Under this law, the Secretary of HHS has the authority to add CTC as a covered screening test for Medicare beneficiaries, and we strongly urge you to do so. Colorectal cancer continues to be one of the leading causes of cancer deaths in the United States. The March 2022 report from the Medicare Payment Advisory Commission report to Congress identified colorectal cancer as one of the most expensive conditions to treat per Medicare beneficiary. Offering another screening option that can prevent the development of colorectal cancer could lower these treatment costs. With the submission of this request, we are hopeful that HHS leadership will do the right thing and acknowledge the value of giving Medicare beneficiaries further freedom of choice with their colon cancer screening options and approve our coverage request. This ultimately will help save lives from this preventable malignancy in Medicare patients.

We appreciate this opportunity to comment on this important lifesaving preventive service for the Medicare population. We look forward to working with you to consider CTC as a covered colorectal screening service under Medicare. Please contact Cynthia R. Moran, ACR Executive Vice President of Government Relations & Economics, at (202) 223-1670 or cmoran@acr.org with questions or to let us know how we might be of assistance. Thank you for your consideration of our request.

Sincerely,

William T. Thorwarth, Jr., MD, FACR

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Chief Executive Officer

² Medicare Payment Advisory Commission. March 2022 Report to Congress. Retrieved from https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf