

September 17, 2010

Secretary Kathleen Sebelius
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act

Dear Secretary Sebelius:

Our undersigned organizations appreciate the opportunity to provide comments on the Department of Health and Human Service's (HHS) interim final rule OCIIO-9992-IFC, published on July 23, 2010 in the *Federal Register*, regarding the regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act (ACA) regarding preventive health services.

BACKGROUND

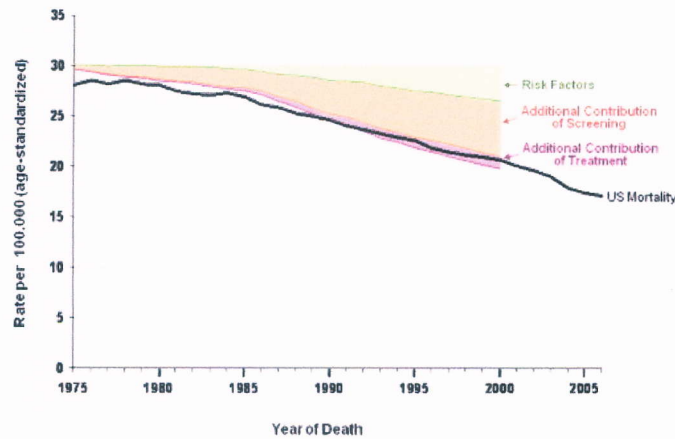
Colorectal cancer is the second leading cancer-related cause of death in the United States. According to the American Cancer Society, it is estimated that nearly 146,000 people were newly diagnosed with colorectal cancer in 2009, which resulted in nearly 50,000 deaths.

Unlike other types of cancer, colorectal cancer can be prevented by the detection and removal of adenomatous polyps. Virtually all colorectal cancer develops from these pre-cancerous polyps. When colorectal cancer is diagnosed early, while it is still localized, survival is significantly better. This is why colorectal cancer screening is highly effective and is why it is recommended for people age 50 and older, or earlier for those at increased risk.

The death rate from colorectal cancer has dropped in recent years as public and private payers have improved coverage for screening, yet low screening rates are troubling. As the interim final rule notes, almost 38 percent of U.S. adult residents over age 50 have never had a colorectal cancer screening. The drop in colorectal cancer death rates is evidence that screening really works and progress is possible if screening becomes more widespread. According to a report published in the journal *Cancer*, the overall observed decline in colorectal cancer mortality was 26 percent for 1975-2006.¹

The report highlights the use of microsimulation modeling to interpret past trends and predict future trends. Using the microsimulation modeling, it was predicted that changes in risk factors accounted for 9 percent of the drop in mortality, and that screening accounted for a 14 percent drop. Treatment added another 3 percent drop. If current trends in risk factor modifications, screening, and treatment continue, a 36 percent overall decline is predicted from 2000-2020. If the projected trends can be accelerated through increased screening, then an overall mortality reduction of 50 percent by 2020 is possible.

¹ Edwards, B, Ward, E, Kohler, B, et al. Annual Report to the Nation on the Status of Cancer, 1975-2006, Featuring Colorectal Cancer Trends and Impact of Interventions (Risk Factors, Screening, and Treatment) to Reduce Future Rates. *Cancer*. 2010; 116:544-573



Cancer 2010 (116:544-573)

PRESERVING PATIENT CHOICE

On Oct. 7, 2008, the U.S. Preventive Services Task Force (USPSTF) gave a grade “A” recommendation for colorectal cancer screening using fecal occult blood testing (FOBT), sigmoidoscopy, or colonoscopy, in adults beginning at age 50 and continuing until age 75. It is critical that patients understand that all three screening mechanisms – FOBT, sigmoidoscopy and colonoscopy – fall under the USPSTF “A” rating. Patients, in consultation with their physicians, must be allowed to choose the most appropriate screening tool based on clinical guidance and personal preference.

While our societies will continue to educate patients about screening options, there is also a significant and urgent need for HHS to educate physicians about adherence to evidence-based recommendations and guidelines for colorectal cancer screening. A Centers for Disease Control and Prevention study published in the April 2010 *Journal of General Internal Medicine* found that three-quarters of primary care physicians who recommend FOBT make use of in-office tests.² We want to underscore that FOBT is an important screening option; however, the study noted “in-office FOBT may be worse than no screening at all because it misses 95 percent of cases with advanced neoplasia, giving many patients a false sense of reassurance.” We believe that requiring health plans to cover colorectal cancer screening will help to save lives and will reduce costs to our health care system only if the benefit is properly administered.

We also encourage HHS to monitor implementation of this new requirement to ensure that health plans do not “steer” patients toward FOBT because it is less costly. We want to emphasize that the primary goal of colorectal cancer screening should be prevention. FOBT is not a test for detecting precancerous polyps; it is a test for detecting cancer. Conversely, colorectal cancer screening by colonoscopy is preventive in nature because when pre-cancerous polyps are detected during the procedure, they are removed at the same time, thus *preventing* colorectal cancer.

WAIVER OF COST SHARING WHEN A COLORECTAL CANCER SCREENING BECOMES THERAPEUTIC

Cost sharing creates financial barriers that discourage the use of recommended services. This is why our societies are pleased that certain cost barriers to colorectal cancer screening for many privately insured patients have been lifted through ACA. As noted in the interim final rule, according to 2005 data, only 48 percent of adults age 50 and older utilized a colorectal cancer screening. We hope that relieving patients of the financial responsibility of obtaining a colorectal cancer screening test will result in increased utilization. However, we are concerned that the interim final rule does not appear to fully eliminate the cost burden of colorectal cancer screening.

² Nadel, M, Berkowitz, Z, Klabunde, C, et al. Fecal Occult Blood Testing Beliefs and Practices of U.S. Primary Care Physicians: Serious Deviations from Evidence-Based Recommendations. *J Gen Intern Med.* 2010

The interim final rule states the following with respect to an item or service that has in effect an “A” or “B” rating from the USPTF:

§ 147.130 Coverage of preventive health services

(5) Services not described. Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

We ask that HHS provide clarification in the final rule on the waiver of patient cost sharing when a colorectal cancer screening becomes therapeutic. At a minimum, we believe that these regulations should be clarified so they are consistent with cost sharing requirements under Medicare. Sec. 4104 of the ACA requires that effective Jan. 1, 2011, the deductible for colorectal cancer screenings be waived for Medicare patients regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. We have conveyed to the Centers for Medicare and Medicaid Services our position that the co-payments should also be waived in instances that a colorectal cancer screening becomes therapeutic.

By not requiring cost sharing to be waived when a screening colonoscopy becomes therapeutic, patients will be subjected to a post-procedure “shock” of learning that they must pay out of pocket simply because they were responsible in getting screened and had a pre-cancerous polyp removed. This may also become a financial disincentive to screening, particularly among those with limited resources, that runs counter to the intention of health care reform.

As stated previously, colorectal cancer screening by colonoscopy, which has a grade “A” from the USPSTF, is a unique preventive service because when pre-cancerous polyps are detected they are removed at the same time, thus *preventing* colorectal cancer as opposed to detecting cancer at an early stage. **We believe that HHS should seek authority under Sec. 2713 of the ACA to require group health plans and health insurers to waive cost sharing for a colorectal cancer screening regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.**

As an alternative, HHS could require group health plans and health insurers to reduce the financial burden on patients by waiving the cost sharing requirements for the increment of the procedure that is screening in nature.

GUIDELINES FOR VALUE-BASED INSURANCE DESIGNS

As HHS develops guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance issuers with respect to preventive benefits, we ask that the following points be taken into consideration with respect to colorectal cancer screening:

- Colonoscopy every 10 years beginning at age 50 is the preferred colorectal cancer screening strategy and is consistent with evidence-based clinical guidelines. A colonoscopy is a preventative service because it allows pre-cancerous polyps to be identified and removed. This test is the most cost effective test for prevention of colon cancer. Patients should be incentivized to use colonoscopy as a


colorectal cancer screening mechanism by allowing the cost-sharing (co-pay and deductible) waiver for a screening colonoscopy to remain in place regardless of whether the screening becomes therapeutic.

- Physicians, including primary care physicians, should be measured on their adherence to evidence-based colorectal cancer screening guidelines and patients should be incentivized to seek care from those physicians who adhere to those guidelines.

We appreciate the opportunity to provide comments on this interim final rule.

Sincerely,

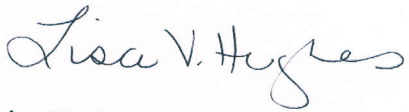

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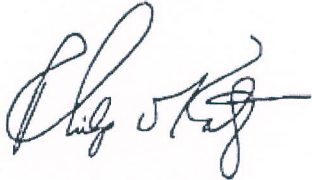

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