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ELIMINATE COLORECTAL CANCER ACT OF 2001

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Mr. KENNEDY, from the Committee on Health, Education, Labor,
and Pensions, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany S. 710]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 710) to require coverage for colorectal cancer screenings, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY OF BILL

As reported by the Committee on Health, Education, Labor, and Pensions, S. 710 increases access to colorectal screening tests for insured Americans. This legislation requires issuers of group health plans and individual health plans to cover screening tests

for colorectal cancer. In doing so, the committee is acting to increase public access to screening services for colorectal cancer in order to prevent premature deaths from this disease.

II. BACKGROUND AND NEED FOR LEGISLATION

The value of effective screening for colorectal cancer

As the second leading cause of cancer deaths, colorectal cancer takes a tremendous toll on the American public with about 148,300 new cases diagnosed annually. This year alone, approximately 56,600 Americans will die from this disease. An overwhelming body of medical evidence shows the value of screening in detecting—and thus providing the opportunity to treat—colorectal cancer at an early stage. When colorectal cancer is diagnosed early, more than 90 percent of patients survive for five years or more. Once the disease has metastasized, only 8 percent of patients survive for that period. As Secretary of Health and Human Services, Tommy Thompson, has so rightly stated, “Colorectal cancer is the second leading cancer killer in the United States and screening can save lives. If Americans age 50 or older had regular screening tests, our nation would see a substantial reduction in colorectal cancer deaths.”

The value of early screening for colorectal cancer is also recognized by numerous scientific and professional societies with expertise in cancer. For example, the American Gastroenterology Association, the American Cancer Society, the American Medical Association, the American Academy of Family Physicians, the American College of Obstetricians & Gynecologists and an interdisciplinary task force originally convened by the U.S. Agency for Health Care Policy and Research in 1997 have all adopted similar guidelines recommending regular colorectal cancer screening for individuals over 50 and for younger persons at high risk for colorectal cancer. Specifically, these organizations recommend a range of screening options—fecal occult blood test (FOBT), flexible sigmoidoscopy, colonoscopy, and double contrast barium enema (DCBE)—because it is important that patients and physicians choose the most medically appropriate test.

In its most recent report updating its 1996 colorectal cancer screening guidelines, the United States Preventive Service Task Force (USPSTF) also strongly recommends regular colorectal cancer screening as an effective way to reduce the mortality and morbidity associated with this disease. According to the report, “The USPSTF strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer.” The Task Force deems this a Grade A recommendation which, under the Task Force’s grading scheme, means that the Task Force “found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.” A Grade A recommendation also indicates that the Task Force “strongly recommends that clinicians routinely provide [the service] to eligible patients.” There is no doubt that colorectal cancer screening is effective and is critical to reducing colorectal cancer mortality in this country.

In addition to upgrading the overall recommendation for colorectal cancer screening, the Task Force also recommended the

same full range of screening tests—FOBT, flexible sigmoidoscopy, colonoscopy, and DCBE—as the scientific and professional organizations mentioned above. The Task Force did not recommend one test for all individuals. Rather, it outlined the range of options and advised that patients should discuss each option with their physician before selecting the test that is best for them. As the Task Force noted, “Each option has advantages and disadvantages that may vary for individual patients and practice settings. The choice of specific screening strategy should be based on patient preferences, medical contraindications, patient adherence, and available resources for testing and follow up. Clinicians should talk to patients about the benefits and potential harm associated with each option before selecting a screening strategy.” Thus, the recommendations of the Task Force and the intent of the legislation approved by the committee are consistent; both recognize the value of colorectal cancer screening while allowing patients and physicians to choose the most appropriate screening methodology.

The effectiveness of different colorectal cancer screening tests

Much research has been conducted recently on the relative sensitivity of various colorectal cancer screening tests. A substantial and increasing body of evidence shows that colonoscopy is by far the most sensitive of the tests, since only colonoscopy can clearly visualize lesions in the proximal colon. By contrast, flexible sigmoidoscopy provides physicians with a view only of the distal colon, which consists of about one-third to one-half of the colon. FOBT detects the presence of blood in the stool, but is highly subject to false readings and has a low patient compliance rate. DCBE provides an image of the entire colon, as does colonoscopy, but its level of resolution is far lower than that of colonoscopy. During the committee’s executive session on the legislation, it was noted that colonoscopy has been the test of choice for many committee members and that President Bush also recently had a colonoscopy. As Dr. Richard Tubb, the President’s physician, stated, “The beauty of the colonoscopy is that it is able to examine an entire colon from start to finish. There are other colorectal screening procedures, but colonoscopy is the one and only that can look in detail at the entire colon . . . this is preventive medicine at it finest.”

Several large scale studies reported in leading medical journals have demonstrated the value of colonoscopy. A study by Lieberman and colleagues in the *New England Journal of Medicine* in 2000 found that colonoscopy detected neoplasms in the proximal colon which would have gone undetected by less sensitive techniques. The study found that 52 percent of patients with advanced proximal neoplasms had no distal neoplasms. Thus, their colorectal cancer would have gone undiagnosed with flexible sigmoidoscopy. A study by Imperiale and colleagues in the same issue of the *Journal* found similar results. In that study, 46 percent of patients with advanced proximal neoplasms had no distal polyps. Again, the presence of polyps in these patients was revealed only through colonoscopy.

Because colonoscopy allows both for visualization and removal of cancerous polyps, it allows for detection and prevention of colorectal cancer in the same procedure. For this reason, colonoscopy can markedly reduce the incidence of colorectal cancer.

After conducting a six year study involving 1,418 patients, Winawer and colleagues reported in the *New England Journal of Medicine* in 1993 that there was a 76 to 90 percent decrease in the incidence of colorectal cancer among patients who had previously had a polyp removed during colonoscopy.

The safety of colonoscopy has also been well-studied. While there is a risk associated with colonoscopy, primarily due to bleeding or perforation of the colon, the risk is very low. In an extensive study of colonoscopy performed at Veterans' Affairs hospitals, Nelson and colleagues found that approximately 3 persons out of every 1000 examined by colonoscopy experienced complications requiring medical intervention. Pignone and colleagues found that complication rates for colonoscopy ranged from 0.03 to 0.62 percent. Tran and colleagues, reporting in the September 2001 edition of *American Surgery*, found that perforation occurred in 21 out of 26,162 colonoscopies analyzed. Only one death occurred among the 16,948 screening colonoscopies analyzed. Analyses of colonoscopy performed in Germany and in Sweden have reported similar low frequencies of complication.

Clinical trials using randomly assigned controls prospectively are often used to prove the effectiveness of new treatments or technologies, but these types of studies are not feasible or necessary to show the effectiveness of colonoscopy in reducing cancer mortality. Prospectively controlled trials rely on randomly assigning a population to either an experimental or control group. In a hypothetical randomized prospectively controlled trial of the effectiveness of colonoscopy, one group would receive a colonoscopy and the other would receive some other form of colorectal cancer screening or no screening at all. A trial structured in this manner would require some patients to give up their opportunity to have a colonoscopy and instead settle for a test that is commonly known to be less accurate. Furthermore, such a trial would require experimenters not to intervene medically as patients in the control population developed colorectal cancer so as not to bias the outcome of the study. Needless to say, an experiment of this type would likely fail to recruit participants and would violate basic ethical requirements for the protection of research subjects.

Extensive studies to examine the effectiveness of colonoscopy in reducing mortality have been performed that used age- and sex-matched controls as well as clinically matched controls from retrospective analysis of medical records. A study of exactly this design was reported by Winawer and colleagues in the *New England Journal of Medicine* (NEJM 329: 1977–1981). Patients were randomly assigned to one of two study cohorts in which they received different protocols of colorectal screening using colonoscopy followed by polyp removal. The cancer incidence and death rates of each cohort were followed and compared to three reference groups. The first reference group was derived from the general population and was age- and sex-matched to the experimental population. The second and third reference groups were controls who had similar clinical histories to the experimental group, but did not receive colonoscopy. Rather than subjecting a control population to an ethically unacceptable elevated risk of cancer, the experimenters derived these two control populations from a retrospective analysis of medical records. In this well-controlled clinical trial, the experi-

menters found that patients undergoing colonoscopy had mortality rates that were significantly lower than either of the three control populations. Evidence from this and similarly well-controlled clinical trials was persuasive for a wide range of expert medical organizations as well as the USPSTF to include colonoscopy in their current screening guidelines.

Barriers to widespread screening

Although screening can save lives, screening rates are low. In fact, a mere 44% of adults over 50 have had any type of recent screening test for colorectal cancer. As a result, only about 37% of colorectal cancers are actually diagnosed at an early stage, when the cancer is most treatable. The remaining 63% of colorectal cancer patients—more than 90,000 Americans every year—do not receive treatment for colorectal cancer when it is most effective because the disease is not detected in its early stages. Early detection would thus spare thousands of Americans from needless suffering and premature death from this deadly form of cancer.

An important element in raising screening rates are campaigns to inform the public about colorectal cancer, such as the “Screening for Life” campaign conducted by the Department of Health and Human Services (HHS) and the “Polyp Man” campaign designed by the American Cancer Society and the Ad Council. Yet such campaigns will have little value if patients cannot obtain coverage for colorectal cancer screening through their health insurance plans.

Recognizing that colorectal cancer screening rates among Medicare beneficiaries were extremely low, Congress took action to make the benefits of regular colorectal cancer screening available through Medicare. In 1997, Congress enacted the Balanced Budget Act, which provided coverage of FOBT and flexible sigmoidoscopy to Medicare beneficiaries 50 or older at average risk for the disease. Colonoscopy was also covered, but only for high-risk individuals. In regulatory guidance adopted in 1997 prior to the coverage effective date, the Department of Health and Human Services also provided coverage under Medicare for DCBE. In 2000, Congress enhanced this basic coverage by expanding colonoscopy coverage to average risk individuals. Thus, every Medicare beneficiary now has access to the full range of scientifically accepted tests that provide screening for colorectal cancer: colonoscopy, FOBT, flexible sigmoidoscopy and DCBE. However, Medicare coverage of colonoscopy generally becomes available to individuals at age 65, which is 15 years after the age at which screening is first recommended.

Americans below the age of 65 face a far more uncertain terrain when trying to obtain health insurance coverage for colorectal cancer screening. While many insurers indicate that they provide coverage for some types of colorectal cancer screening, few provide comprehensive coverage that includes colonoscopy, the most sensitive colorectal cancer screening test. Commercial health plan coverage data is generally held proprietary by the health plans. However, a recent study by the Lewin Group, a respected health care consulting firm, analyzed the range of colorectal screening tests that were included in the plan brochures of insurance plans participating in the Federal Employee Health Benefit Plan (FEHBP), which posts its plan brochures publicly. While plans may at their

own option provide services not specifically enumerated in the plan brochure, the plan is required to cover only those specific services spelled out in the brochure or contract of coverage. Thus, a beneficiary has no certainty of receiving coverage for any service unless it is specified in the brochure.

The study found that fewer than 5 percent of these plan brochures stated that they cover colonoscopies as a method to screen for colorectal cancer, although all provided coverage for flexible sigmoidoscopy and/or FOBT. In a letter submitted for the record during committee consideration of this legislation, the Office of Personnel Management (OPM) agreed that FEHBP plans are currently providing coverage for colonoscopy for *diagnosis*. However, OM's most recent guidance encourages plans to expand their current limited coverage to include *screening* colonoscopy.

The fact that plans are covering FOBT and flexible sigmoidoscopy but not colonoscopy is significant from a fiscal perspective. A cost analysis, also prepared by The Lewin Group, showed that colonoscopy was no more expensive than the FOBT/flexible sigmoidoscopy combination in terms of per member per month (PMPM) costs. The analysis found that for plans already covering FOBT and flexible sigmoidoscopy, adding coverage for colonoscopy could actually reduce PMPM costs by 11 cents. Therefore, if insurers already cover FOBT combined with flexible sigmoidoscopy, there is no financial reason not to cover colonoscopy as well. Colonoscopy can be covered for little or no additional costs, and the savings in human terms are immeasurable.

A survey conducted by the American Association of Health Plans (AAHP) claims that most plans cover the full range of screening tools, including colonoscopy. However, the AAHP study methodology made available to the committee does not define "screening coverage." This term often means plans allow patients to get a colonoscopy once they have exhibited symptoms or as a follow up to another test. Because colorectal cancer is highly metastatic, waiting until other signs or symptoms indicate its presence before performing a colonoscopy unnecessarily raises the morbidity and mortality associated with this disease. Thus, the finding that many plans cover colonoscopy after initial tests indicate the likelihood of cancer does not reduce the need for the legislation. The intent of this legislation is to assure that patients receive the benefits of colorectal cancer screening before they develop the disease, rather than as a method to confirm diagnosis.

Several lines of evidence, however, contradict the assertion that insurance companies routinely cover the costs of the full range of medically recommended screening tests. First, a report prepared for the Health Insurance Association of America (HIAA) on new medical technologies acknowledges that health plans are currently not providing coverage for the full range of screening tests, noting that "most private insurers will only cover colonoscopies for high risk populations" ("The Impact of Medical Technology on Future Health Care Costs", a report prepared for HIAA and Blue Cross/Blue Shield in February of 2001).

Second, information provided directly from health insurance companies indicates that coverage for colorectal screening is incomplete. Legislation to require coverage of colorectal cancer screening has been enacted in sixteen states and considered in several others.

Two bills have been introduced in the Pennsylvania legislature dealing with coverage for colorectal cancer screening; one dealt solely with colorectal cancer screening, while the other encompassed both colorectal cancer screening and prostate cancer screening. In its analysis of the latter, the Pennsylvania Health Care Cost Containment Council examined the degree to which insurance companies in Pennsylvania provided coverage for colorectal cancer screening. To that end, the Council requested data from leading insurers on their coverage of colorectal cancer screening tests. In its submission to the Council, Blue Cross of Northeastern Pennsylvania stated that “under traditional coverage * * * for the asymptomatic patient, there would be no coverage for periodic screening examinations.” Another leading insurer, Highmark, notified the Council that “under Highmark’s traditional group and individual coverage and preferred provider organization (PPOs) benefit plans, routine ‘screening’ tests are not considered eligible for reimbursement” (Pennsylvania Health Care Cost Containment Council; Review of Senate Bill 39).

Finally, documents from the widely respected HHS “Screen for Life” campaign support the conclusion that insurance coverage for the full range of medically recommended colorectal cancer tests is sporadic. According to the HHS fact sheet on screening options used in this campaign, “coverage is variable when colonoscopy is used for screening. If it’s needed for a follow-up test or diagnosing a problem, most plans cover” (“Colorectal Cancer: Facts on Screening,”; CDC publication #099-6486; CMS publication #11012).

Thus, evidence from national surveys of insurance plans, data from individual insurance companies and HHS’ own flagship screening program for colorectal cancer all support the conclusion that while most insurance companies do provide coverage for colorectal cancer detection procedures as a diagnostic test for colorectal cancer, coverage of the full range of medically recommended tests for screening purposes is sporadic.

However, even if one were to accept the argument advanced by opponents of the legislation that the vast majority of insurance companies already provide adequate coverage for screening, the need for the legislation would be undiminished. If indeed the bulk of insurance companies are already providing the coverage required by the legislation, then complying with the requirements of the bill would have no impact on the vast majority of insurance plans. It is hard to reconcile opponents’ arguments that insurance companies are already providing coverage for colorectal screening with their simultaneous assertion that the legislation is an undue burden on insurance issuers.

A second inconsistency is found in opponents’ arguments that providing insurance coverage for colorectal cancer screening will have little impact on utilization rates. This argument is based in part on a GAO report analyzing rates of colorectal cancer screening among Medicare beneficiaries. This report was issued in March of 2000 and examined utilization rates in 1999, only two years after enactment of the initial legislation establishing coverage for colorectal cancer screening. GAO found that screening rates among beneficiaries were low—an unsurprising finding, given the short interval between enactment of the authorizing legislation and the time the data were collected. However, some opponents of the legis-

lation have used this report to argue that requiring insurance companies to cover colorectal cancer screening will have little effect on screening rates. Yet at the same time, they assert that enacting S. 710 will drive up the costs of insurance. Both of these assertions cannot simultaneously be valid. If the legislation will have little effect on utilization rates, it will similarly have little effect on costs. Whereas if the legislation does affect costs, it will do so through increasing the utilization rate for the covered service and thus saving lives.

Screening requirements save lives

The benefits of screening requirements such as that provided by S. 710 are shown by the experience of States that have enacted requirements for insurance plans to provide coverage for breast cancer screening. The first state law requiring coverage for breast cancer screening was enacted in 1981, and now 49 States have enacted such requirements. The increase in breast cancer screening during the period since 1981 has been dramatic. Fifteen years ago, fewer than a third of women between the ages of 50 and 64 received mammograms. Now almost three quarters of women in this age bracket receive these needed tests. Increased screening has resulted in reduced death rates from breast cancer. Breast cancer rates have dropped by 2 percent a year since 1990 and are dropping almost 4 percent a year now. It is the committee's belief that the legislation approved by the committee could result in similar dramatic increases in the rate of screening for colorectal cancer and concomitant decreases in the death rate from this painful disease.

Some have argued that enacting requirements for insurance companies to cover colorectal cancer screening is best left to the states. Indeed, 16 states and the District of Columbia have already enacted laws assuring coverage of colorectal cancer coverage screening. However, Federal legislation can assure that the benefits of colorectal cancer screening are realized in all states, not simply the few that have already taken action.

Even in states that have enacted requirements for insurance companies to cover colorectal cancer screening tests, state law does not have jurisdiction over ERISA plans. Thus, residents of those states who receive health insurance through ERISA plans are not assured coverage of the full range of colorectal cancer screening tests despite state laws to the contrary. Only Federal legislation can ensure that all plans cover these lifesaving screening tests.

III. LEGISLATIVE HISTORY AND COMMITTEE ACTION

S. 710 was introduced on April 5, 2001 by Senator Kennedy for himself and Senator Helms was cosponsored by Senators Brownback, Cantwell, Cochran, Daschle, Jeffords, Johnson, Kerry, Landrieu, Miller, Murray, Reid, Roberts and Snowe. S. 710 was referred to the Committee on Health, Education, Labor, and Pensions. On July 10, 2002, the Senate Committee on Health, Education, Labor, and Pensions held an executive session to consider S. 710. The committee approved by voice vote an amendment offered by Senator Kennedy and Senator Roberts to make technical improvements in the legislation.

The committee rejected by roll call vote 11 to 10 an amendment proposed by Senator Gregg that it was the Sense of the Senate that

there be established an expert Standing Commission that shall be required to study and make recommendations to Congress regarding the costs and benefits of mandated health insurance benefits. Voting in the negative were Senators Kennedy, Dodd, Harkin, Jeffords, Mikulski, Bingaman, Wellstone, Murray, Reed, Edwards, and Clinton. Voting in the affirmative were Senators Gregg, Frist, Enzi, Hutchinson, Warner, Bond, Roberts, Collins, Sessions and DeWine.

The committee rejected by roll call vote 15 to 6 an amendment offered by Senator Frist to strike all provisions of the bill after the enacting clause and replace them with (1) a survey to be conducted by the Comptroller General and (2) a study by the Institute of Medicine. The survey by the Comptroller General would examine the extent to which health insurance issuers and group health plans provide coverage for colorectal cancer screening, including colonoscopy. The study by the Institute of Medicine would analyze the available medical evidence regarding the safety and effectiveness and cost of various colorectal cancer screening methods. The study would also identify factors that may affect patient access to, and use of, colorectal cancer screening and the extent to which each of these factors contributes to screening frequency among patients. Voting in the negative were Senators Kennedy, Dodd, Harkin, Jeffords, Mikulski, Bingaman, Wellstone, Murray, Reed, Edwards, Clinton, Warner, Roberts, Collins and DeWine. Voting in the affirmative were Senators Gregg, Frist, Enzi, Hutchinson, Bond and Sessions.

The committee accepted by voice vote an amendment proposed by Senator Enzi to assure that the provisions of the Act apply to insurance plans that are the subject of collective bargaining agreements with the same effective date (January 1, 2003) applicable to other plans.

S. 710 was ordered reported, as amended, favorably by a roll call vote in which Senators Bingaman, Clinton, Collins, DeWine, Dodd, Edwards, Harkin, Hutchinson, Jeffords, Kennedy, Mikulski, Murray, Reed, Roberts, Warner, and Wellstone voted in the affirmative and Senators Bond, Enzi, Frist, Gregg, and Sessions voted in the negative.

IV. COMMITTEE VIEWS

The Committee recognizes the need for access to colorectal cancer screening as part of a comprehensive strategy in the war against cancer. Congress has played a crucial role in the nation's war against cancer. The committee intends for this legislation to build on this Congressional effort and to increase access to and use of colorectal cancer screening.

In adopting the Kennedy-Roberts substitute amendment, the committee intended to clarify the provisions of the legislation in several areas.

First, the amendment clarifies the scope of tests that insurance plans are required to cover under the terms of the legislation. The amendment specifies that insurance providers and plans must cover tests that are (1) deemed appropriate by a physician treating the participant or beneficiary, in consultation with the participant or beneficiary and (2) one of the four tests covered under Medicare (FOBT, flexible sigmoidoscopy, colonoscopy or double contrast barium enema) or are otherwise specified by the Secretary of HHS

“based upon the recommendations of appropriate organizations with special expertise in the field of colorectal cancer.”

Through this provision, the committee intends to ensure that the decision regarding whether or not a patient receives a colorectal cancer screen and the choice of the screening method used remains a decision made by the patient and treating physician—rather than being determined by the coverage policies of an insurance plan. The choice of screening method used is customarily based upon the preferences and health status of the patient as well as the accessibility of health professionals with the training and expertise to provide accurate and safe endoscopic tests. This policy is consistent with the recommendations and guidelines of leading medical and scientific organizations.

In adopting the provision allowing the Secretary of HHS to update the range of tests required to be covered, it was the committee’s intent to allow the requirements of the legislation to be flexible enough to respond to evolving scientific and medical knowledge. For example, the efficacy of “virtual colonoscopy” in providing reliable screening for colorectal cancer has not yet been definitively established. However, ongoing research in this area may in the future show that virtual colonoscopy is an effective means to provide for early detection of precancerous polyps. If the efficacy of virtual colonoscopy is indeed established and recognized by the medical expert community, it is the committee’s intent to allow the Secretary of HHS to add this procedure or other effective screening methods to the range of tests required to be covered by insurance plans under the legislation.

Second, the amendment clarifies the frequency of screening required to be covered under the legislation. Under Medicare, no coverage is provided for tests conducted at intervals more frequent than those specified under Section 1834(d) of the Social Security Act. In adopting the Kennedy-Roberts amendment, it was the intent of the committee to mirror this provision of Medicare, but also to allow the Secretary of HHS the flexibility to modify the required coverage frequencies where such modifications are “based upon new scientific knowledge and consistent with the recommendations of appropriate organizations with special expertise in the field of colorectal cancer.”

It is the committee’s intent to allow such modifications to the required frequencies of coverage only if new scientific findings clearly indicate that such modifications are warranted and only if such modifications receive the approval of the scientific and medical communities with expertise in this field. Finally, any modified frequency must be no less effective in providing colorectal cancer screening than the frequency of coverage provided under Medicare as of the date of enactment of this Act.

Third, the Kennedy-Roberts amendment also specifies the characteristics of patients for whom insurance plans must provide coverage. Specifically, the legislation requires coverage for (1) any participant or beneficiary age 50 or over and (2) any participant or beneficiary under the age of 50 who is at a high risk for colorectal cancer. The amendment incorporates the definition of “high-risk” from the requirements of Medicare (as specified in section 1861(pp)(2) of the Social Security Act), under which a high risk individual is defined as “an individual who, because of family history,

prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer."

Fourth, the Kennedy-Roberts amendment clarifies that the health care provider who recommends that patient receive a colorectal cancer screening must be a physician under the meaning of that term as defined in the Social Security Act (42 U.S.C. 1395x(r)). It is the committee's intent to ensure that patients receive a recommendation to receive a colorectal cancer screening test from a physician familiar with their medical condition.

V. COST ESTIMATE

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

S. 710—Eliminate Colorectal Cancer Act of 2002

Summary: S. 710 would require group health plans and health insurance issuers to cover colorectal cancer screening at regular intervals for all plan enrollees over the age of 50 and for certain enrollees under the age of 50 who are at high risk of developing colorectal cancer. The bill would require insurers to adopt guidelines used in the Medicare program that specify the types and frequency of screening procedures that must be covered. The bill would not preempt state laws that require plans to provide more comprehensive benefits for colorectal cancer screening than the requirements of the bill.

Enacting S. 710 would affect the federal budget because it would result in higher premiums for employer-sponsored health benefits. Higher premiums, in turn, would result in more of an employee's compensation being received in the form of nontaxable employer-paid premiums, and less in the form of taxable wages. As a result of this shift, federal income and payroll tax revenues would decline. CBO estimates that enacting the bill would reduce federal tax revenues by \$10 million in 2003, by \$125 million over the 2003–2007 period, and by \$375 million over the 2003–2012 period. Because the bill would affect revenues, pay-as-you-go procedures would apply.

Enacting S. 710 would not affect spending in the Federal Employees' Health Benefits program because participating health plans already meet the requirements of the bill under current law.

The bill's requirements for colorectal cancer screening would apply to health plans operated by state, local, and tribal governments for the benefit of their employees. It also would preempt some state laws that establish requirements for colorectal cancer screening. These provisions of the bill would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA), but the costs would not exceed the threshold established in UMRA (\$58 million in 2002, adjusted annually for inflation).

The bill would impose a private-sector mandate, as defined in UMRA, on group health plans and health insurance issuers by requiring them to provide coverage of colorectal cancer screening for certain plan enrollees. CBO estimates that the direct cost of this mandate would equal about \$110 million in 2003, about \$240 million in 2004, and more in later years. Those amounts would not ex-

ceed the annual threshold established in UMRA (\$115 million in 2002, adjusted annually for inflation) in the first year that the mandate would be effective, but would exceed the annual threshold in each of the subsequent four years.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 710 is shown in the following table.

	By fiscal year, in millions of dollars—					
	2002	2003	2004	2005	2006	2007
CHANGES IN REVENUES						
Income and HI Payroll Taxes (on-budget)	0	-5	-10	-20	-20	-30
Social Security Payroll Taxes (off-budget)	0	-5	-5	-10	-10	-10
Total changes	0	-10	-15	-30	-30	-40

Note.—HI = Hospital Insurance.

Basis of estimate: The bill would require group health plans and health insurance issuers to provide coverage for colorectal cancer screening to all plan enrollees aged 50 and over, and to provide that coverage to certain high-risk enrollees under age 50. Plans would be required to cover the screening procedures specified in Medicare guidelines, including fecal-occult blood test, flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema. The frequency with which those procedures would be covered would also have to be consistent with Medicare's guidelines. For example, plans would be required to cover one screening colonoscopy every 10 years for individuals who are not at high risk of colorectal cancer, and one colonoscopy every two years for individuals who are at high risk of colorectal cancer. High-risk enrollees would be defined using rules established for the Medicare program and would include those individuals with a family history of colorectal cancer, a prior diagnosis of colorectal cancer or precursor neoplastic polyps, a history of chronic digestive disease, or genetic markers for colorectal cancer.

The bill's requirements would apply to both self-insured and fully insured group health plans as well as plans sold in the individual market. In states with laws that require coverage of more comprehensive benefits for colorectal cancer screening, fully insured plans would be required to comply with the state law, while self-insured plans would be required to comply with the provisions of S. 710.

CBO's estimate of the cost of this bill is based on data about the use of colorectal cancer screening procedures among the privately insured population, the extent of current coverage of colorectal cancer screening in private health insurance plans, and the cost of performing each procedure that the bill would cover. CBO assumed that under the bill, utilization of colorectal cancer screening procedures among enrollees in plans that do not currently cover those procedures would grow to match the utilization rates of those procedures among enrollees in plans that do cover them. CBO estimates that among enrollees between the ages of 50 and 64, about 210,000 additional insured colonoscopies and 67,000 additional insured flexible sigmoidoscopies would be performed in 2003. Among enrollees at high risk of colorectal cancer, about 4,600 additional insured colonoscopies would be performed in 2003. The numbers of

additional procedures performed as a result of the bill's enactment would grow in subsequent years.

CBO's estimate also takes into account the costs of follow-up care for individuals who receive newly covered screening procedures. Those costs include the cost of removing polyps identified by the screening, the cost of treating perforations of the colon (a side effect of both the screening procedure and polyp removal), and the cost of more frequent colonoscopies for individuals who were identified as being at high risk through a screening procedure.

Because some individuals who would have developed colorectal cancer will be identified through screening and have polyps removed prior to their becoming cancerous, our estimate includes the savings from treating those averted cancer cases.

CBO estimates that enacting S. 710 would increase premiums for private health insurance by an average of less than 0.1 percent, before accounting for the responses of health plans, employers, and workers to the higher premiums. Those responses would include reductions in the number of employers offering insurance to their employees and in the number of employees enrolling in employer-sponsored insurance, changes in the types of health plans that are offered, and reductions in the scope or generosity of health insurance benefits, such as increased deductibles or higher copayments. CBO assumes that these behavioral responses would offset 60 percent of the potential impact of the bill on total health plan costs.

The remaining 40 percent of the potential increase in costs, or about 0.03 percent of group health insurance premiums, would occur in the form of increased outlays for health insurance. Those costs would be passed through to workers, reducing both their taxable compensation and other fringe benefit. For employees of private firms, CBO assumes that all of that increase would ultimately be passed through to workers. We assume that state, local, and tribal governments would absorb 75 percent of the increase and would reduce their workers' taxable income and other fringe benefits to offset the remaining one-quarter of the increase. CBO estimates that the resulting reduction in taxable income would grow from \$21 million in calendar year 2003 to \$185 million in 2012.

Those reductions in workers' taxable compensation would lead to lower federal tax revenues. The estimate assumes an average marginal rate of about 20 percent for income taxes and the current-law rates for the Hospital Insurance and Social Security payroll taxes (2.9 percent and 12.4 percent, respectively). CBO further assumes that 15 percent of the change in taxable compensation would not be subject to the Social Security payroll tax. As a result, we estimate that federal tax revenues would fall by \$10 million in 2003 and by a total of \$375 million over the 2003–2012 period if S. 710 were enacted. Social Security payroll taxes, which are off-budget, account for about 30 percent of those totals.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in governmental receipts that are subject to pay-as-you-go procedures are shown in the following table. Changes in Social Security receipts are not subject to pay-as-you-go procedures. (Hence, the following table shows only the estimated changes in Income and Hos-

pital Insurance Payroll taxes.) For the purposes of enforcing pay-as-you-go procedures, only the effects through 2006 are counted.

	By fiscal year, in millions of dollars—										
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Changes in receipts	0	-5	-10	-20	-20	-30	-30	-30	-30	-40	-40
Changes in outlays	Not applicable										

Estimated impact on state, local, and tribal government: The requirements in S. 710 would apply to health plans that state, local, and tribal governments operate for the benefit of their employees, specifically those that self-insure their benefit programs. Those requirements would be intergovernmental mandates as defined in UMRA. State, local, and tribal governments that do not self-insure their benefit programs, but rather contract with private health insurers, also would face increased premium costs, but the requirements (and hence the mandates) included in the bill would fall on the private plans. However, significant costs would be passed on to the state and local governments that purchase the health care coverage.

CBO estimates that state and local governments that self-insure would be directly responsible for providing regular screenings for colorectal cancer and would face increased costs as a result of the mandate of between \$40 million in 2003 and \$50 million in 2007. In no year would those costs exceed the threshold for intergovernmental mandates established in UMRA (\$58 million in 2002, adjusted annual for inflation).

The bill also would preempt state laws that do not provide greater protection for colorectal cancer screening than the bill. This preemption would be an intergovernmental mandate as defined in UMRA because it would limit the application of state law. It would not, however, impose additional costs on state, local, or tribal governments.

Estimated impact on the private sector: The bill would impose a mandate on private-sector group health plans and health insurance issuers by requiring them to provide coverage of colorectal cancer screening for certain plan enrollees. CBO estimates that premiums for private health insurance would increase by less than 0.1 percent if the bill were enacted. The direct cost of the mandate in the bill would equal about \$110 million in 2003, rising to about \$450 million in 2007. That amount would not exceed the annual threshold established by UMRA (\$115 million in 2002, adjusted annually for inflation) in the first year that the mandate would be effective, but would exceed the annual threshold in each of the subsequent four years.

Estimate prepared by: Federal Receipts: Alexis Ahlstrom; Federal Outlays: Chuck Betley; Impact on State, Local, and Tribal Governments: Leo Lex; and Impact on the Private Sector: Jennifer Bowman and Judy Wagner.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

The Eliminate Colorectal Cancer Act amends the Public Health Services Act and the Employee Retirement Income Security Act to

ensure health insurance coverage of colorectal cancer screening tests and, as such, has no application to the legislative branch.

VII. REGULATORY IMPACT STATEMENT

The committee has determined that there will be no increases in the regulatory burden of paperwork as a result of this bill.

VIII. SECTION-BY-SECTION ANALYSIS

Section 1. Short title; findings

Section 1 provides that this Act may be cited as the “Eliminate Colorectal Cancer Act of 2001”. Section 1 provides information that attests to the importance and need for screening for colorectal cancer. The findings are facts about the frequency of colorectal cancer and the importance of public access to screening in decreasing the number of deaths due to colorectal cancer each year.

Section 2. Coverage for colorectal cancer screening

Section 2 requires group health plans referred to in the PHSA and ERISA to cover colorectal cancer screening for colorectal cancer. This section also requires individual health insurance issuers to provide coverage for screening tests for colorectal cancer. These programs are meant to provide access to a full-range of screening tests for colorectal cancer for Americans who are individuals age 50 or over or at high risk and covered by private insurance plans.

IX. MINORITY VIEWS OF SENATORS GREGG, FRIST, ENZI, BOND, AND SESSIONS

Colorectal cancer is the second leading cause of cancer-related deaths in the United States for men and women combined. As a public health matter, colorectal cancer is a serious concern. The good news is that screening can detect colorectal cancer early, when treatment can be very effective. There is no dispute about the value of colorectal cancer screening, and the Minority is committed to finding meaningful ways to increase awareness and screening rates, and ultimately finding a cure for the disease.

The legislation mandates that all private health plans cover the full range of screening methods recommended by the American Cancer Society and covered under the Medicare program. However, there is not sufficient evidence to support the Majority's claim that S. 710 would improve colorectal cancer screening rates. Instead, it is an attempt to mandate that all private-sector health plans cover a particular screening test, colonoscopy, as a first screen for all asymptomatic persons, even those at low risk. At no time in the debate on this bill was there discussion of any other form of colorectal cancer screening, nor was there any claim made that private insurers are not covering these other forms of screening. The debate and this bill are aimed at colonoscopy. Advocates for this legislation believe that colonoscopy is a superior form of screening, that there is a significant lack of coverage in the private market, and therefore an insurance mandate is justified.

While there is no debate about the value of screening, the scientific evidence currently available simply does not support the superiority of any one method. Moreover, there is no credible evidence that private health plans routinely deny coverage for scientifically proven screening methods. Given the degree of scientific uncertainty in this area and the lack of evidence to support claims that private insurance coverage is lacking, the Minority believes that, while well-intentioned, this legislation misses the mark with respect to reducing colorectal cancer mortality. Moreover, the Minority is concerned that this legislation potentially puts patients in harm's way by ignoring the scientific evidence on colorectal cancer screening.

Scientific evidence

The United States Preventive Services Task Force (Task Force) is the official advisory group to the U.S. Government on the current status of scientific evidence related to preventive services, including screening tests. It consists of a panel of independent, multidisciplinary experts who have no professional, personal, or financial interest attached to their recommendations. On July 16, 2002, just 6 days after the committee approved S. 710, the Task Force released its new guidelines for colorectal cancer screening.

Based on its comprehensive analysis, the Task Force found that “the quality of evidence, magnitude of benefit, and potential harms vary with each method,” and that “there is insufficient evidence to determine which strategy is best in terms of the balance of benefits and potential harms or cost-effectiveness.” S. 710, however, makes just such a determination by mandating coverage of all screening methods, regardless of their potential risks, and in spite of lack of proof of efficacy, as a first screen for asymptomatic persons. The entire Task Force report can be found on the website of the Department of Health and Human Services, under the Agency for Health Care Policy and Research (AHRQ), U.S. Preventive Services Task Force (www.ahrq.gov/clinic/3rduspstf/colorectal/colorr.htm).

The Majority references to particular studies regarding the advantages of colonoscopy over other procedures are a misleading attempt to justify a government mandate of a specific medical procedure. For instance, the Majority fails to highlight the Task Force warning that studies regarding effectiveness of colonoscopy “should be interpreted with caution, because they are based on historical controls.” The public should bear in mind that the Task Force considered all the studies and evidence regarding the different types of colorectal cancer screening and sensitivity of tests and still it “did not find direct evidence that screen colonoscopy is effective in reducing colorectal cancer mortality.” The bottom line on colonoscopy is that there has not been one single randomized clinical trial to date that demonstrates that colonoscopy reduces colorectal cancer mortality.¹

This is not to say that colonoscopy may not turn out to be a superior screening methodology after further scientific review. Many health professionals believe that colonoscopy is superior. Rather, it is to say that Congress should not mandate coverage of specific screening methods, particularly when the scientific evidence is lacking.

The Majority also fails to provide all the relevant findings on the safety of colonoscopy. While it is true that the risks of colonoscopy are fairly low, the Task Force notes that “screening colonoscopy poses higher risks than fecal occult blood tests (FOBT) or sigmoidoscopy, both because it is a more invasive procedure and because generally it is used with conscious sedation, which may lead to complications.” Even low rates of complications are a significant public health concern when a test is being advocated for universal use and when most of those receiving it are asymptomatic, well people. It is precisely to such populations that a higher standard of safety in screening tests is typically applied. Regarding safety, the Task Force concludes that “it is unclear whether the increased accuracy of colonoscopy compared with alternative screening methods offsets the procedure’s additional complications, inconvenience, and costs.”

State of insurance coverage

In addition to being inconsistent with the scientific evidence, the legislation appears to be based on a misunderstanding about the

¹ Notice that the evidence on using colonoscopy as a diagnostic tool is stronger than using it as a screening tool. However, the legislation only deals with a screening mandate.

state of insurance coverage. According to data presented at the committee markup of S. 710, health plans provide comprehensive coverage of colorectal cancer screening. On its website, the Centers for Disease Control notes that “many insurance plans, including Medicare, help pay for colorectal cancer screening” (CDC’s Screen For Life Program; *www.cdc.gov*). The American Association of Health plan’s (AAHP) 2001 Annual Industry Survey revealed that many health plans rely on the Task Force recommendations as the authoritative guide to clinical preventive services. The survey revealed that 93 percent of all health plans cover colonoscopy for colorectal cancer screening.²

Not only are health plans covering screening, but many plans actively promote colorectal cancer screening services. For instance, GIGNA HealthCare sends out annual birthday reminder cards to their enrollees that recommends colorectal cancer screening, including screening colonoscopy, for all enrollees beginning at age 50. Physicians also report that they have no problems getting insurance companies to cover colonoscopy.

The Majority assertion that insurance coverage is a barrier to screening, and therefore “a major factor contributing to this unacceptable number of preventable deaths from colon cancer,” is baseless. The Majority references an unpublished Lewin study of the Federal Employees Health Benefits Program (FEHBP) that was based on a review of a public website. However, the Majority has refused to provide the actual study to the Minority or submit it for the record. Moreover, the Office of Personnel Management, the agency that administers FEHBP, dismisses the Lewin conclusions as inaccurate and uninformed. The truth is the Majority failed to provide a single shred of evidence at the markup or since that time that supports their erroneous claim about insurance coverage.

Given these data, it is unlikely that an insurance mandate would improve colon cancer screening rates. This is supported by Medicare’s experience. Several years after mandating colorectal cancer screening for Medicare beneficiaries, the U.S. General Accounting Office found that screening rates remain very low for that population. Specifically, GAO found that:

various factors contribute to the low use of screening and diagnostic services, some of which are beginning to be addressed by public health agencies and private organizations. Key among these is poor patient awareness of recommendations and coverage for screening, physician reluctance to perform the procedures because of the time and complexity involved, and lack of monitoring systems to encourage greater use. (Medicare: Few Beneficiaries Use Colorectal Cancer Screening and Diagnostic Services; GAO/T–HEHS–00–68)

The Majority also erroneously asserts, based on a Lewin study, that insurance coverage of colonoscopy will reduce costs for plans that cover other screening procedures. However, screening tests do not reduce costs. If they are effective, they save lives at a cost of

²The 2001 AAHP Annual Industry Survey represents a profile of the industry and provides information on 64.3 million covered lives, or approximately 68 percent of total U.S. managed care enrollment.

\$20,000–\$30,000 per year of life saved. The true costs of colonoscopy will depend, in part, on the frequency of complications that will require medical treatment. The true frequency of these complications is unknown since colonoscopy has not been studied in community-based studies, in conditions that will exist if it is a universally used, first-line, screening test.

Understanding screening rates

There are many reasons unrelated to insurance coverage for low rates of colorectal cancer screening, including lack of awareness about the prevalence of colon cancer and the importance screening, as well as the distasteful nature of the screening methods. Instead of creating a costly and ineffective insurance mandate, the Minority believes the committee should focus its efforts on finding and addressing real reasons behind low screening rates.

For instance, many members of this committee supported a Senate commitment to finding lifesaving cures for all cancers by doubling the National Institutes of Health research funding over 5 years. In addition, the committee has supported CDC's Chronic Disease Prevention and Health Promotion Program, which houses CDC's "Screen for Life" Campaign. That Campaign is a multi-year, multimedia, national campaign to inform men and women age 50 years and older about the importance of having regular colorectal cancer screening tests. Many are familiar with the CDC's public service announcements on television featuring the "Polyp Man."

Appropriate government role

Even if this bill were based on a reasonable degree of scientific certainty, the Minority would find it difficult to support a precedential new Federal mandate of this nature, particularly during this time of skyrocketing insurance premiums and large numbers of uninsured. Congress rarely passes insurance mandates (states are the traditional regulators of insurance), and has never passed legislation that mandates a particular screening benefit for private health insurance. This is due, in part, to the fact that private employers and health insurers have actually led the market in offering and promoting preventive health benefits. In contrast, government programs, such as Medicare, provide less generous benefits than private insurance and are totally reliant on Congress to add new benefits like prescription drugs and preventive screening.

The Majority correctly states that S. 710 allows physicians, in consultation with their patients, to make the ultimate decision regarding which screening method to use. However, it is well documented that insurance coverage drives physician utilization patterns, and it is logical that a government mandate of coverage would augment that effect. Moreover, an insurance mandate that is out of sync with the scientific evidence will send a conflicting and confusing message to physicians and patients.

The Majority asks the rhetorical question why not go ahead and mandate insurance coverage if most plans are already providing these benefits? This is the wrong question to ask. The better question in this context is whether the Federal Government should dictate insurance coverage, and, therefore, medical practice in the area of colorectal cancer screening? In general, the Minority is con-

cerned that piecemeal mandates will, overtime, translate into higher health insurance costs, and lock in outdated medical practice. This is particularly true when there is scientific uncertainty and a lack of solid information on private health coverage.

Sometimes the practice of medicine, when pushed by advocacy rather than science, has had to reverse its course. For example, during the 1980s, endometrial biopsy at menopause was recommended for all high risk women. Likewise, during the early 1990s, autologous bone marrow transplant and high dose chemotherapy were considered the cutting edge treatment for certain types of breast cancer. Breast cancer advocates intensely pursued insurance coverage of this treatment and were successful in getting many states to mandate such coverage. Most private health plans decided to implement coverage, in part, to avoid a public backlash, even though they were concerned about the lack of scientific evidence. When the research on these treatments was finally concluded, it showed that, not only is the treatment ineffective, but it is actually harmful to some women. Even now, the breast cancer community is embroiled in recently-released questions about the relative benefits and risks of mammography among asymptomatic women.

Based on this experience, the Minority strongly believes that it is not the appropriate role for the Federal Government to micro-manage medical practice and insurance coverage in the private market. Imagine if, given the recent recommendations by NIH, Congress had enacted Federal insurance mandate to cover Hormone Replacement Therapy? The current state of confusion and fear brought on by recent events concerning HRT would only be exacerbated if the government had mandated coverage of such therapy.

There are numerous screening tests, including colorectal cancer screening, pap smear, mammography, prostate screening, amniocentesis and other maternity screenings, that are offered by insurers without a Congressional mandate. There has been no evidence offered that the private sector insurance market is not keeping up with scientific evidence. If S. 710 were enacted, there would likely be a great deal of increasing pressure for Congress to add similar mandates for a wide range of screening techniques and other medical procedures. Over time, this would result in Congressional micro-management of private health insurance, which would probably mean fewer benefits and more expensive health insurance for everyone.

State experience

Finally, State experience with insurance mandates, including colorectal cancer screening, does not offer convincing evidence that the Federal Government should get involved in this area. Only eleven States have passed a colorectal cancer screening mandate to date. After years of over-regulation, most States are now seeking ways to reduce insurance costs and improve access, rather than add new mandates. Twenty-five States have enacted some sort of process or commission for evaluating the benefits and costs of a particular mandate before they decide to enact it. Pennsylvania specifically examined a colorectal cancer screening proposal, similar

to S. 710, and concluded that “while there is a general consensus about the medical efficacy of screening for colorectal cancer, there is disagreement about the need to mandate coverage and whether mandated coverage would bring a desired increase in screening utilization.” (“Mandated Benefits Review by the Pennsylvania Health Care Cost Containment Council,” S. 636, Colorectal Cancer Screening Mandate, May 2002).

At present, there is insufficient and sometimes conflicting information about the state of insurance coverage for colorectal cancer screening using specific screening methods. There is also a lack of scientific consensus about the relative efficacy of different screening methods. Finally, the Minority has very serious concerns regarding the appropriate role of the Federal Government in mandating coverage of specific medical procedures. These are the types of issues typically clarified during hearings, but unfortunately, the committee never held a hearing on this legislation or even on the issue of colorectal cancer. In conclusion, the Minority believes that there are simply too many unknown factors and unanswered questions about this legislation to warrant support of S. 710. If and when the legislation is considered by the full Senate, the Minority intends to pursue full debate and bring light to these important issues while simultaneously focusing on meaningful solutions to promote screening and reduce the incidence and burden of colon cancer.

JUDD GREGG.
BILL FRIST.
MICHAEL B. ENZI.
CHRISTOPHER S. BOND.
JEFF SESSIONS.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

**TITLE XXIX—MISCELLANEOUS HEALTH
COVERAGE**

SEC. 2901. COVERAGE FOR COLORECTAL CANCER SCREENING.

(a) *COVERAGE FOR COLORECTAL CANCER SCREENING.*—

(1) *IN GENERAL.*—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide coverage for colorectal cancer screening at regular intervals to—

(A) any participant or beneficiary age 50 or over; and

(B) any participant or beneficiary under the age of 50 who is at a high risk for colorectal cancer.

(2) *DEFINITION OF HIGH RISK.*—For purposes of subsection (a)(1)(B), the term “high risk for colorectal cancer” has the meaning given such term in section 1861(pp)(2) of the Social Security Act (42 U.S.C. 1395x(pp)(2)).

(3) *REQUIREMENT FOR SCREENING.*—The group health plan or health insurance issuer shall cover methods of colorectal cancer screening that—

(A) are deemed appropriate by a physician (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))) treating the participant or beneficiary, in consultation with the participant or beneficiary;

(B) are—

(i) described in section 1861(pp)(1) of the Social Security Act (42 U.S.C. 1395x(pp)(1)) or section 410.37 of title 42, Code of Federal Regulations; or

(ii) specified by the Secretary, based upon the recommendations of appropriate organizations with special expertise in the field of colorectal cancer; and

(C) are performed at a frequency not greater than that—

(i) described for such method in section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) or section 410.37 of title 42, Code of Federal Regulations; or

(ii) specified by the Secretary for such method, if the Secretary finds, based upon new scientific knowledge and consistent with the recommendations of appropriate organizations with special expertise in the field of colorectal cancer, that a different frequency would not adversely affect the effectiveness of such screening.

(b) NOTICE.—A group health plan under this section shall comply with the notice requirement under section 714(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

(c) NON-PREEMPTION OF MORE PROTECTIVE STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—This section shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage that provides greater protections to participants and beneficiaries than the protection provided under this section.

(d) DEFINITIONS AND ENFORCEMENT.—The definitions and enforcement provisions of title XXVII shall apply for purposes of this section.

* * * * *

TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—GROUP MARKET REFORMS

Subpart 1—* * *

* * * * *

PART B—INDIVIDUAL MARKET RULES

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2741. GUARANTEED AVAILABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE TO CERTAIN INDIVIDUALS WITH PRIOR GROUP COVERAGE.

(a) GUARANTEED AVAILABILITY.—* * *

* * * * *

SEC. 2752. [300gg-52] REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.

The provisions of section 2706 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

SEC. 2753. COVERAGE FOR COLORECTAL CANCER SCREENING.

(a) IN GENERAL.—The provisions of section 2901(a) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health

insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.

* * * * *

SEC. 2762. PREEMPTION.

(a) IN GENERAL.—Subject to subsection (b), nothing in this part (or part C insofar as it applies to this part) shall be construed to prevent a State from establishing, implementing, or continuing in effect standards and requirements unless such standards and requirements prevent the application of a requirement of this part.

(b) RULES OF CONSTRUCTION.—(1) Nothing in this part (or part C insofar as it applies to this part) shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144).

(2) Nothing in this part (other than [section 2751] sections 2751 and 2753 shall be construed as requiring health insurance coverage offered in the individual market to provide specific benefits under the terms of such coverage.

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EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

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Sec. 714. Coverage for colorectal cancer screening.

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TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

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SEC. 714. COVERAGE FOR COLORECTAL CANCER SCREENING.

(a) COVERAGE FOR COLORECTAL CANCER SCREENING.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide coverage for colorectal cancer screening at regular intervals to—

- (A) any participant or beneficiary age 50 or over; and
 - (B) any participant or beneficiary under the age of 50 who is at a high risk for colorectal cancer.
- (2) DEFINITION OF HIGH RISK.—For purposes of subsection (a)(1)(B), the term “high risk for colorectal cancer has the meaning given such term in section 1861(pp)(2) of the Social Security Act (42 U.S.C. 1395x(pp)(2)).

(3) REQUIREMENT FOR SCREENING.—The group health plan or health insurance issuer shall cover methods of colorectal cancer screening that—

- (A) are deemed appropriate by a physician (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))) treating the participant or beneficiary, in consultation with the participant or beneficiary;
- (B) are—

- (i) described in section 1861(pp)(1) of the Social Security Act (42 U.S.C. 1395(pp)(1)) or section 410.37 of title 42, Code of Federal Regulations; or
- (ii) specified by the Secretary, based upon the recommendations of appropriate organizations with special expertise in the field of colorectal cancer; and

- (C) are performed at a frequency not greater than that—
- (i) described for such method in section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) or section 410.37 of title 42, Code of Federal Regulations; or

- (ii) specified by the Secretary for such method, if the Secretary finds, based upon new scientific knowledge and consistent with the recommendations of appropriate organizations with special expertise in the field of colorectal cancer, that a different frequency would not adversely affect the effectiveness of such screening.

(b) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirements of this section shall be treated as a material modification in the terms of the plan described in section 102(a), for purposes of assuring notice of such requirements under the plan; except that the summary description required to be provided under the third to last sentence of section 104(b)(1) with respect to such modification shall be provided by not later than 60 days after the first day of the first plan year in which such requirements apply.

* * * * *

Subpart C—General Provisions

SEC. 731. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) * * *

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(c) RULES OF CONSTRUCTION.—Except as provided in section [711] sections 711 and 714, nothing in this part shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

* * * * *

SEC. 732. SPECIAL RULES RELATING TO GROUP HEALTH PLANS.

(a) GENERAL EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of this part (other than **[section 711]** *sections 711 and 714*) shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

* * * * *

