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# Study of Proposed Mandatory Health Insurance Coverage for Colorectal Cancer Screening

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A Report to the  
Governor  
and the  
Legislature of  
the State of  
Hawai'i

Report No. 10-02  
February 2010



**THE AUDITOR**  
STATE OF HAWAI'I

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## Office of the Auditor

The missions of the Office of the Auditor are assigned by the Hawai'i State Constitution (Article VII, Section 10). The primary mission is to conduct post audits of the transactions, accounts, programs, and performance of public agencies. A supplemental mission is to conduct such other investigations and prepare such additional reports as may be directed by the Legislature.

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STATE OF HAWAII

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# OVERVIEW

## *Study of Proposed Mandatory Health Insurance Coverage for Colorectal Cancer Screening*

Report No. 10-02, February 2010

### Summary

In House Concurrent Resolution No. 109, the 2009 Legislature asked the Auditor to assess the social and financial impacts of House Bill No. 823 (HB 823), which requires health insurers to provide coverage for colorectal cancer screening for asymptomatic adults aged 50 and above. This study assesses the impacts of mandating coverage for each of the colorectal screening procedures (colonoscopy, flexible sigmoidoscopy, computed tomographic colonography) and fecal tests (fecal occult blood test, fecal immunochemical test, and stool DNA) defined as the standard of care in HB 823, by applying the criteria set forth in Sections 23-51 and 23-52, Hawai'i Revised Statutes.

Colorectal cancer is a “disease in which cells in the colon or rectum become abnormal and divide without control, forming a mass called a tumor.” As of 2008, it is the third most common cancer among men and women and the second leading cause of death in the United States. Nationwide for 2009, the National Cancer Institute estimates 106,100 new cases of colon cancer, 40,870 new cases of rectal cancer, and 49,920 deaths due to colon and rectal cancer. From 2002 through 2006, the median age at colon cancer diagnosis was 71 years of age; the median age at death was 75 years of age.

By definition a screening looks for cancers *before* any symptoms are evident. Early stage colon and rectal cancers have very few symptoms, which make screenings more important in catching cancers early and making treatment easier. According to the U.S. Preventive Services Task Force (USPSTF), screening for colorectal cancer lags behind screening for other cancers. By one estimate, 18,800 lives could be saved each year if everyone over age 50 were regularly screened for colorectal cancer. Currently, 27 states and the District of Columbia have laws requiring health insurance screening coverage for colorectal cancer. The laws of 16 states and the District of Columbia follow the recommendations of the American Cancer Society (ACS), and two states follow the USPSTF 2008 guidelines.

Regular colorectal cancer screening for all average risk or asymptomatic adults aged 50 years or older is the standard of care based on the ACS 2008 guideline as well as that of the USPSTF—a leading independent panel of private sector prevention and primary care experts sponsored by the Agency for Healthcare Research and Quality (AHRQ) within the U.S. Department of Health and Human Services. According to the AHRQ, the USPSTF recommendations are considered the ‘gold standard’ for clinical preventive services. Differences in the standard of care are found in the procedures and tests used, and the intervals recommended by the ACS and USPSTF updated in the 2008 screening guidelines. For example, computed tomographic (CT) colonography and stool DNA (sDNA) are two newer procedures listed as acceptable screening options of the ACS, but are not recommended by the USPSTF because there is insufficient evidence with which



to assess their benefits and harms. For this reason, we could not assess the social impact of providing coverage to reduce the incidence of colorectal cancer or mortality because there is no consensus on the efficacy of these newer tests among preventive health care experts.

The USPSTF found convincing evidence that colorectal cancer screening is effective in reducing mortality in adults, beginning at age 50 and continuing until age 75, and recommends: annual FOBT; flexible sigmoidoscopy every five years combined with FOBT every three years; and colonoscopy at ten year intervals. Although double contrast barium enema is an acceptable option under the ACS 2008 guideline, its effectiveness is unknown, its use is in decline and it was not considered by the USPSTF in 2008. We conclude that HB 823 should amend the standard of care for colorectal screening to include only the procedures and tests recommended by the USPSTF in 2008 for adults at ages 50 to 75.

The purpose of HB 823 is to encourage all asymptomatic adults aged 50 and above to obtain a colorectal cancer screening using the full range of screening options, including colonoscopy every ten years, recommended in the ACS 2008 guideline. Although a colonoscopy is not the perfect screening test available, it is considered the reference standard against which the sensitivity of other tests is compared. We found that while there is some insurance coverage for colorectal cancer screening, colonoscopy is not a screening method covered by the second largest health insurer we surveyed, and until January 2010 had not been a covered benefit in the preferred provider plan of the largest health insurer in Hawai'i. For example, Kaiser Permanente Hawai'i provides routine colorectal screening using flexible sigmoidoscopy and two fecal tests—FOBT and FIT, but screening colonoscopy is not available to 77,368 asymptomatic adults age 50 and over. Moreover, because there is no consensus among prevention and primary care experts as to the effectiveness of extending life-years using CT colonography and sDNA, only one health insurer in Hawai'i provides coverage for all the screening options based on the ACS 2008 guideline. The other four health insurers surveyed follow the 2008 recommendations of the USPSTF to exclude screening coverage for CT colonography and sDNA.

House Bill No. 823 would be beneficial for a majority of Hawai'i's insured population of average risk or asymptomatic adults between the ages of 50 to 75 who are currently unable to select colonoscopy every ten years as a screening option. Insurance coverage can be expected to increase the use of screening colonoscopy but the cost of this increase should not bar the implementation of such coverage.

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## Recommendations and Response

We recommend the enactment of an amended House Bill No. 823 as appended to this report. The Departments of Health and Commerce and Consumer Affairs opted not to respond.

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# Study of Proposed Mandatory Health Insurance Coverage for Colorectal Cancer Screening

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Governor  
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Submitted by

**THE AUDITOR**  
STATE OF HAWAI'I

Report No. 10-02  
February 2010

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## Foreword

We assessed the social and financial impacts of mandating insurance coverage for colorectal cancer screening in Hawai‘i, as proposed by House Bill No. 823, pursuant to Sections 23-51 and 23-52, Hawai‘i Revised Statutes. The 2009 Legislature requested this assessment through House Concurrent Resolution No. 109.

We acknowledge and appreciate the cooperation of the Departments of Health and Commerce and Consumer Affairs and other organizations and individuals that we contacted during the course of this assessment.

Marion M. Higa  
State Auditor

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# Chapter 1

## Introduction

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In House Concurrent Resolution No. 109, the 2009 Legislature asked the Auditor to assess the social and financial impacts of House Bill No. 823, introduced during the Regular Session of 2009, which requires health insurers to provide screening coverage for colorectal cancer using colonoscopy and other screening tests. We conducted this study pursuant to Sections 23-51 and 23-52, Hawai‘i Revised Statutes (HRS). Section 23-51, HRS requires passage of a concurrent resolution requesting an impact assessment by the Auditor before any legislative measure mandating health insurance coverage for a specific health service, disease, or provider can be considered. The concurrent resolution must designate a specific legislative bill and include, at a minimum, the:

- Specific health service, disease, or provider that would be covered;
- Extent of the coverage;
- Target groups that would be covered;
- Limits on utilization, if any; and
- Standards of care.

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## Background

### ***House Bill No. 823 requires coverage for full range of colorectal screening options***

By definition a screening looks for cancers *before* any symptoms are evident. Early stage colon and rectal cancers have very few symptoms, which make screenings more important in catching cancers early and making treatment easier. The purpose of House Bill No. 823 (HB 823) is to encourage all average risk or asymptomatic adults aged 50 and above to obtain a colorectal cancer screening using any of the procedures or stool tests recommended in the 2008 joint screening guideline of the American Cancer Society (ACS) in *CA: A Cancer Journal for Clinicians*. By amending Chapters 431 and 432, HRS, HB 823 promotes an overriding goal of the ACS 2008 guideline to help physicians make patients aware of the full range of screening options. At a minimum, the ACS 2008 guideline recommends that:

[Physicians] should be prepared to offer patients a choice between a screening test that is effective at both early cancer detection and cancer prevention through the detection and removal of polyps and a screening test that primarily is effective at early cancer detection.

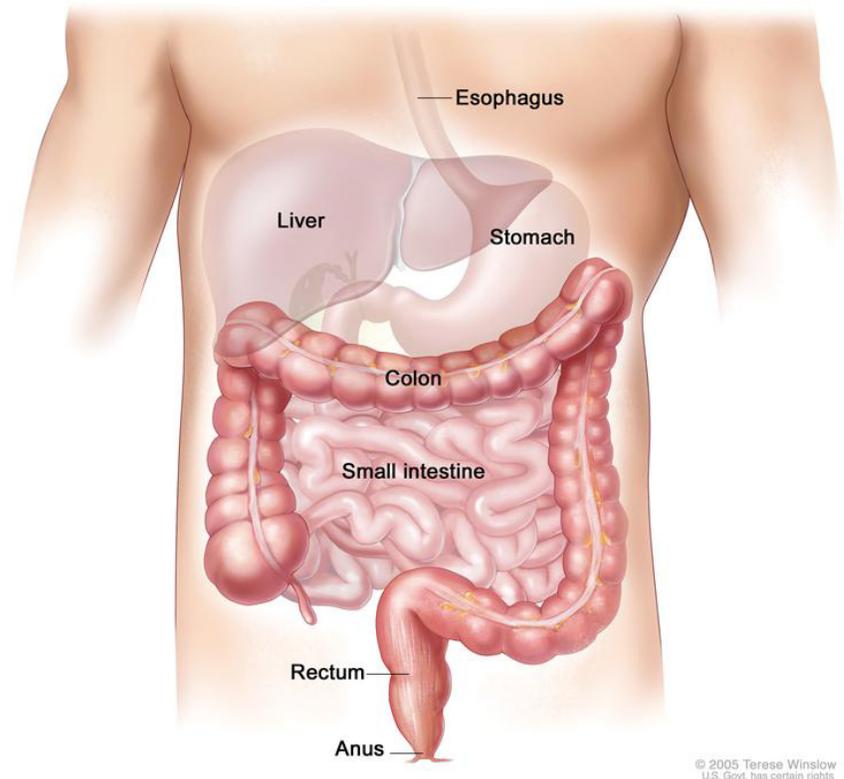
Beginning March 1, 2010, HB 823 would require health insurers to provide information about the risks associated with undiagnosed colorectal cancer and encourage insured patients to consult with a physician about available screening options. Chapter 432, HRS, would be amended by requiring all individual and group hospital and medical service contracts to provide coverage “by any of the methods specified by the revised 2008 screening guideline” to detect and prevent colorectal cancer in average risk adults beginning at age 50, including:

- Colonoscopy every ten years;
- Flexible sigmoidoscopy every five years;
- Computed tomographic (CT) colonography (or virtual colonoscopy) every five years;
- High-sensitivity fecal occult blood or fecal immunochemical testing every year;
- Double-contrast barium enema every five years; or
- Stool DNA at an unspecified interval.

***Colorectal cancer is the third most common cancer and second leading cause of death from cancer in the U.S.***

The National Cancer Institute (NCI) defines colorectal cancer as a “disease in which cells in the colon or rectum become abnormal and divide without control, forming a mass called a tumor.” Colorectal cancer cells may also invade and destroy the tissue around them. Cancer cells may also break away from a tumor and spread to form new tumors in other parts of the body. Symptoms of colorectal cancer include a change in bowel habits, such as diarrhea or constipation, gas pains or cramps; blood in the stool; weight loss; or vomiting. As shown in Exhibit 1.1, the colon and rectum are connected and part of the large intestine. As part of the body’s digestive system, the colon takes up nutrients from food and stores solid waste until it is passed out of the body.

### Exhibit 1.1 Anatomy of Colon and Rectum



Source: National Cancer Institute

#### Risk factors for colorectal cancer

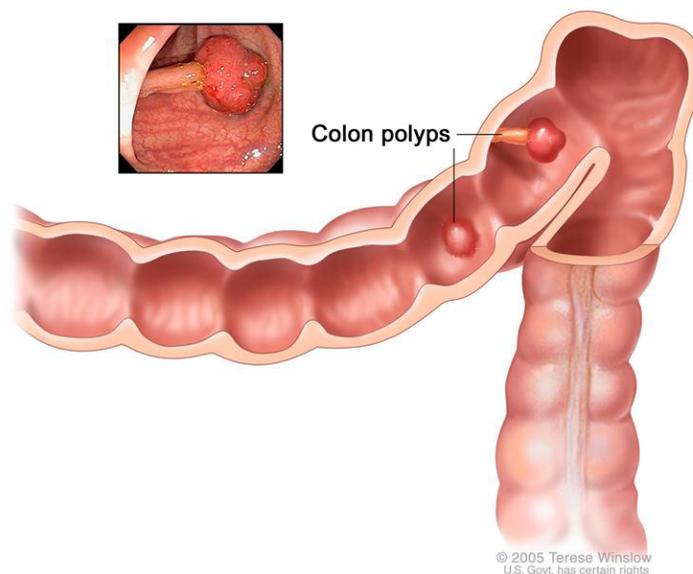
While the exact causes of colorectal cancer are unknown, studies show that certain factors may increase the chance of developing the disease. These risk factors include:

- **Age** – More than 90 percent of people with colorectal cancer are diagnosed after age 50. The average age at diagnosis is 72 years;
- **Polyps** – Abnormal growths, as shown in Exhibit 1.2 that protrude from the inner wall of the colon or rectum, are relatively common in people over 50. The most common and clinically important polyps are adenomatous polyps. Detecting and removing such growths may help prevent colorectal cancer;
- **Personal history** – People who previously had colorectal cancer may develop cancer again. Women who have had cancer of the

ovary, uterus, or breast are also at a higher risk of developing colorectal cancer;

- **Family history** – Close relatives (parents, siblings or children) of a person diagnosed with colorectal cancer are somewhat more likely to develop colorectal cancer;
- **Ulcerative colitis or Crohn colitis** – Inflammation and sores (ulcers) in the lining of the colon (ulcerative colitis) or chronic inflammation of the gastrointestinal tract, most often in the small intestine (Crohn colitis);
- **Diet** – Some evidence suggests that a high consumption of red or processed meats and low consumption of whole grains, fruits and vegetables, may be a risk factor; however, more research is needed;
- **Exercise** – Some evidence suggests a sedentary lifestyle may be associated with an increased risk of developing colorectal cancer. People who exercise regularly may have a decreased risk; and
- **Smoking** – Cigarette smoking may increase a person’s risk of developing polyps and colorectal cancer.

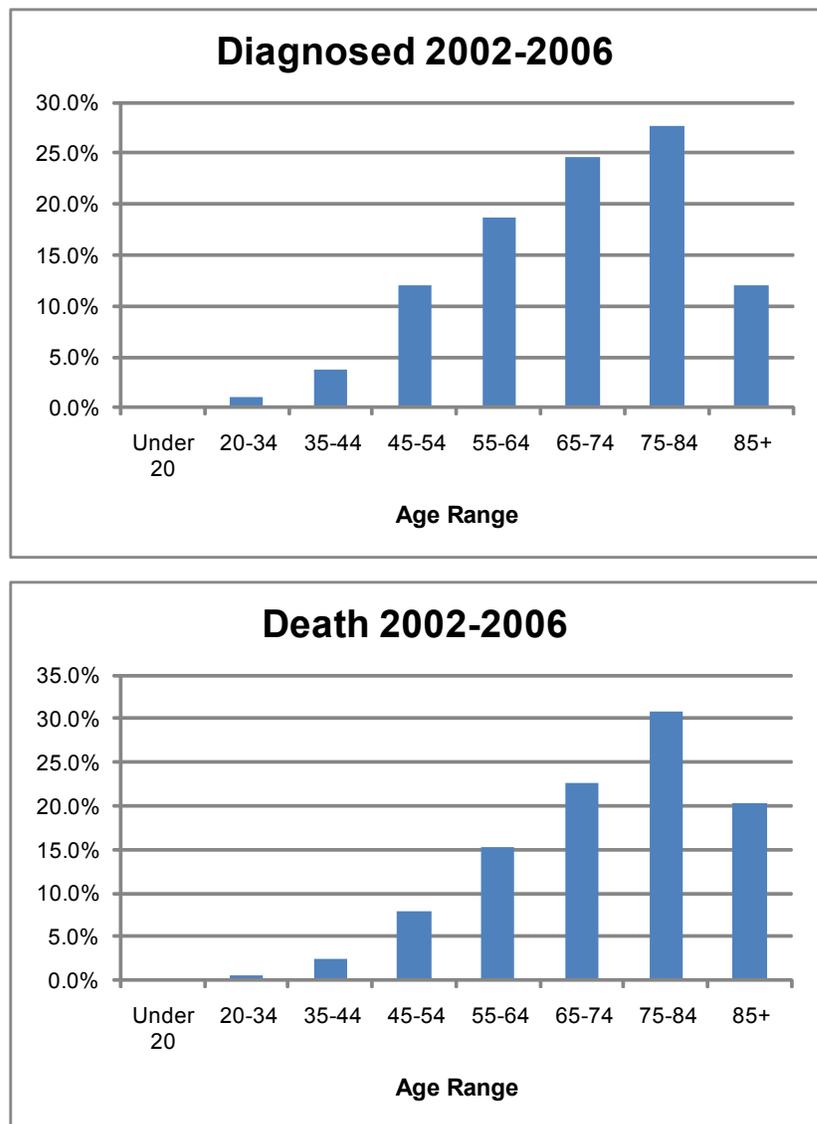
### Exhibit 1.2 Colon Polyps



Source: National Cancer Institute

Based on 2008 statistics, colorectal cancer is the third most common cancer diagnosed in both men and women and the second leading cause of death from cancer in the United States. The NCI estimates 106,100 new cases of colon cancer, 40,870 new cases of rectal cancer, and 49,920 deaths due to colon and rectal cancer nationwide for 2009. As shown in Exhibit 1.3, during the period 2002 through 2006, the median age at diagnosis for colorectal cancer was 71 years of age; the median age at death due to colorectal cancer was 75 years of age.

**Exhibit 1.3**  
**Median Age at Diagnosis and Death**



Source: Office of the Auditor, from data of the Surveillance Epidemiology and End Results (SEER) program, National Cancer Institute

***Periodic screening using some procedures and stool tests is effective in reducing mortality rates and incidence of colorectal cancer***

According to the U.S. Preventive Services Task Force (USPSTF), screening for colorectal cancer lags behind screening for other cancers. Based on a 2000 study by the Centers for Disease Control, if the cancer is caught in its early stages, people with colon cancer have a five year relative survival rate of 90 percent; furthermore, as many as 60 percent of deaths from colorectal cancer could be prevented if everyone age 50 and older were screened regularly.

The goal of cancer screening is to reduce mortality through the detection of early-stage cancer and the detection and removal of adenomatous polyps, which are common in adults over age 50. Adenomatous polyps represent approximately one-half to two-thirds of all colorectal polyps and are associated with a higher risk of colorectal cancer. While recent trends show a decline in colorectal cancer incidence and mortality rates, “even greater incidence and mortality reductions could be achieved if a greater proportion of adults receive[d] regular screening.” By one estimate, if everyone over age 50 were regularly screened for colorectal cancer, 18,800 lives could be saved per year.

**Colorectal cancer screening options**

The acceptable screening options under the ACS 2008 guideline fall into two categories: tests that look at the structure of the rectum and colon to find both colorectal polyps and cancer; and stool tests, which mainly look for signs of cancer. Structural tests include colonoscopy, flexible sigmoidoscopy, double contrast barium enema, and CT colonography. Stool tests include fecal occult blood test (FOBT), fecal immunochemical test (FIT), and stool DNA test.

**Colonoscopy**

Colonoscopy is a direct visualization technique, in which the rectum and entire colon are examined. This procedure offers substantial benefit over fecal tests. A thorough cleansing of the colon is necessary before this procedure, and most patients receive some form of sedation. A thin lighted tube, with a lens (colonoscope), is inserted through the anus and rectum into the colon to look for polyps, abnormal areas, cancer cells, and tumors. The colonoscope is also used to remove polyps (polypectomy) or tissue samples, which are subsequently checked under a microscope for signs of cancer.

Although a colonoscopy is not the perfect screening test available, or as the ACS guideline notes not “an infallible ‘gold standard’,” it is considered the reference standard against which the sensitivity of other screening tests is compared.

**Flexible sigmoidoscopy**

Flexible sigmoidoscopy is a visual inspection of the rectum and lower colon area only, as opposed to the entire colon. A thin tube-like instrument with a light and a lens for viewing, called a sigmoidoscope, is used to look inside the rectum and lower colon (sigmoid), for polyps, abnormal areas, or cancerous cells or tumors, and may have a tool to remove polyps or tissue samples. If the test shows abnormalities, a colonoscopy may be performed subsequently. A less extensive cleansing of the colon is needed for this procedure, but not sedation.

**Double contrast barium enema**

A double contrast barium enema, like a colonoscopy, evaluates the entire colon and can detect most cancers and the majority of significant polyps. It can serve as an alternative procedure where a colonoscopy has either failed or is contraindicated (meaning undesirable or improper). Also known as an air-contrast study, a double contrast barium enema involves a series of x-rays of the rectum and colon. The procedure has substantially lower sensitivity than other test strategies, and its use as a screening test for colorectal cancer is declining.

**CT colonography (or virtual colonoscopy)**

Computed tomographic colonography uses a series of x-rays to make pictures of the colon. The procedure is time-efficient, minimally invasive, requires no sedation, recovery time, or transportation chaperone after the procedure. A computer assembles the pictures to create a detailed image showing polyps and any other unusual formation on the inside surface of the colon. Images showing polyps of significant size require a therapeutic colonoscopy. Like a regular colonoscopy, a thorough cleansing of the colon and a restricted diet are also required prior to a therapeutic colonoscopy.

**Fecal occult blood test and fecal immunochemical test**

There are two types of fecal tests that look for blood in a person's stool, which may be a sign of polyps or cancer. In both tests, samples of three consecutive bowel movements are collected at home and sent to the doctor or laboratory for analysis. The first test, known as guaiac-based FOBT, or gFOBT, is the most common stool blood test used for colorectal cancer screening. Positive tests (blood in the stool) are associated with increased risk of colon cancer, and a colonoscopy is subsequently recommended. Tests which return negative results should be repeated annually. The second test, the fecal immunochemical test uses antibodies to detect human hemoglobin protein in stool samples. The FIT has several technological advantages over the gFOBT, including placing fewer demands on patients regarding diet and sampling procedures for some forms.

**Stool DNA test (sDNA)**

The stool DNA test (sDNA) is a newly developed test which checks for DNA in stool cells for genetic changes that may indicate colorectal cancer. The test is predicated on the concept of detecting molecular markers associated with advanced colorectal neoplasia. The sDNA test requires only a single stool collection and the sampling is non-invasive. The sDNA test is currently being studied in clinical trials.

***Mandated coverage in other states***

According to a survey conducted by the National Conference of State Legislatures (NCSL), and illustrated in Exhibit 1.4, 27 states and the District of Columbia have laws requiring health insurance screening coverage for colorectal cancer. Twenty-three states, including Hawai'i, do not mandate such coverage. Sixteen of the 27 states and the District of Columbia require screening coverage for some or all health insurance plans using colonoscopy in average risk adults aged 50 and over every ten years and other screening options recommended by the 2008 joint guideline prepared by the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer and the American College of Radiology. These states are Alabama, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, North Carolina, Oregon, Rhode Island, Tennessee, and Virginia. Another four states (Delaware, Nebraska, Texas, and West Virginia) require health insurance screening coverage using as an option colonoscopy every ten years for average risk adults beginning at age 50. Two states, New Mexico and Washington, follow the U.S. Preventive Services Task Force's recommendations to use high-sensitivity FOBT, sigmoidoscopy with interval FOBT, or colonoscopy for adults from age 50 and continuing only until age 75.



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## **Scope and Methodology**

Our study examined the social and financial impacts of mandating coverage of colorectal cancer screening in Hawai‘i as proposed in House Bill No. 823. We reviewed relevant literature relating to other states’ mandatory health insurance requirements and recent research literature and reports for colorectal cancer screening. We surveyed and obtained information from commercial insurers, mutual benefit societies, third party administrators, and health maintenance organizations. We obtained information from national organizations, including the National Conference of State Legislatures, the National Cancer Institute, the Henry J. Kaiser Foundation, the American Cancer Society, the U.S. Preventive Services Task Force, and the Centers for Disease Control and Prevention. To the extent that information was available, we reviewed and documented coverage for colorectal cancer screening adopted in other states.

To assess the potential social and financial effects of providing coverage for colorectal cancer screening, we used the following criteria set forth in Section 23-52, HRS, as applicable:

### ***Social impact***

1. Extent to which colorectal cancer screening is generally utilized by a significant portion of the population.
2. Extent to which insurance coverage for colorectal cancer screening is generally available.
3. If coverage is not generally available, the extent to which the lack of coverage prevents adults aged 50 or over from obtaining colorectal cancer screening.
4. If coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing colorectal cancer screening.
5. The level of public demand for colorectal cancer screening.
6. The level of public demand for individual or group insurance coverage for colorectal cancer screening.
7. The level of interest of collective bargaining organizations in negotiating privately for colorectal screening coverage in group contracts.

8. The impact of providing coverage for colorectal screening (such as morbidity, mortality, quality of care, change in practice patterns, provider competition or related items).
9. The impact of any other indirect costs upon the costs and benefits of coverage.

### ***Financial impact***

1. The extent to which proposed insurance coverage would increase or decrease the cost for colorectal cancer screening.
2. The extent to which the proposed coverage might increase the use of colorectal cancer screening.
3. The extent to which colorectal cancer screening might serve as an alternative for more expensive treatment for colon or rectal cancer.
4. The extent to which insurance coverage of colorectal cancer screening can be reasonably expected to increase or decrease insurance premiums and administrative expenses of policyholders.
5. The impact of such coverage on the total cost of health care in Hawai'i.

We conducted this study between August 2009 and November 2009 in accordance with the Office of the Auditor's *Manual of Guides* and generally accepted government auditing standards. Those standards require that we plan and perform the study to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our assessment objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives.

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# Chapter 2

## Assessment of Proposed Mandatory Health Insurance Coverage for Colorectal Cancer Screening

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### Introduction

This study assesses the social and financial impacts of mandating insurance coverage for each of the colorectal screening procedures or fecal tests defined as the standard of care in House Bill No. 823. According to the U.S. Preventive Services Task Force, there are substantial benefits to screening asymptomatic adults aged 50 to 75 for colorectal cancer. Periodic colorectal screening using some procedures and fecal tests, such as colonoscopy, flexible sigmoidoscopy, and fecal occult blood and fecal immunochemical tests, is effective in reducing the mortality rate and incidence of colon or rectal cancer.

There are differences between the American Cancer Society (ACS)'s and the U.S. Preventive Services Task Force (USPSTF)'s screening guidelines in the standard of care for the procedures, tests used, and recommended testing intervals. For example, computed tomographic colonography and stool DNA are two newer methods among the acceptable options of the ACS, but are not recommended by the USPSTF because there is insufficient evidence to assess the benefits and harms of those tests. For this reason, the social impact of providing coverage for these two tests to reduce the incidence of colorectal cancer or mortality could not be assessed. We found four of the five health insurers surveyed follow the USPSTF recommendations to exclude coverage for these procedures as screening methods in their health plans and only one health insurer in Hawai'i provides insurance coverage for all the acceptable screening options under the ACS guideline as proposed in House Bill No. 823 (HB 823). We found that despite the availability of some screening coverage for colorectal cancer, mandatory insurance coverage in Hawai'i would benefit a significant portion of Hawai'i's insured population whose health plans do not currently cover average risk adults between the ages of 50 to 75 for a colonoscopy every ten years. However, we believe that HB 823 would need to amend the proposed standard of care to include the procedures and tests recommended by the USPSTF 2008 guideline.

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### Summary of Findings

1. Periodic screening for colorectal cancer is not currently available to a significant portion of Hawai'i's insured population. Insurance coverage can be expected to increase the use of

screening colonoscopy, the reference standard among the various methodologies. The cost of this increase should not bar the implementation of such coverage.

2. Mandatory insurance coverage as proposed in House Bill No. 823 should be enacted, but the bill should be amended to include only the tests recommended by the U.S. Preventive Services Task Force.

## Social and Financial Impacts Data Argue for Mandatory Coverage

This study on the social and financial impacts of mandating insurance coverage for all colorectal cancer screening options is gleaned from survey responses and literature review. We obtained information from the American Cancer Society and surveyed six health insurance companies:

- Hawai‘i Medical Service Association (HMSA);
- Kaiser Permanente Hawai‘i (Kaiser);
- Hawai‘i Medical Assurance Association (HMAA);
- University Health Alliance (UHA);
- Summerlin Life and Health Insurance Company (Summerlin);
- and
- MDX Hawai‘i (MDX).

All of the above the health insurers responded to our survey except HMAA. Exhibit 2.1 shows the total membership and the number of members aged 50 and over for each respondent.

### Exhibit 2.1 Membership of Respondent Health Insurers

	Total Members	Members Aged 50 and Over
Hawai‘i Medical Service Association (HMSA)	677,293	203,116
Kaiser Permanente Hawai‘i (Kaiser)	222,594	77,368
University Health Alliance (UHA)	30,714	8,061
Summerlin Life and Health Insurance Company (Summerlin)	25,000	7,000
MDX Hawai‘i LLC (MDX)	25,000	6,000

Source: Office of the Auditor, based on responses by health insurance carriers

Overall, we found that while there is some insurance coverage provided by the health insurers surveyed, colonoscopy is not a screening method covered by the second largest health insurer in Hawai‘i and has not been a covered benefit in the preferred provider plan of the largest health insurer in Hawai‘i unless ordered by a doctor. Moreover, because there is no consensus among prevention and primary care experts as to the effectiveness of extending life-years using computed tomographic (CT) colonography and stool DNA (sDNA), the types of screening coverage based on the 2008 joint guideline prepared by American Cancer Society, U.S. Multi-Society Task Force on Colorectal Screening and the American College of Radiology is provided by only one health insurer in Hawai‘i. The other four health insurers surveyed follow the 2008 recommendations of the U.S. Preventive Services Task Force to exclude coverage for CT colonography and sDNA as screening methods in their health plans.

## ***Social impact***

### **1. Extent to which colorectal cancer screening is generally utilized by a significant portion of the population.**

While a national survey shows 60.1 percent of Hawai‘i’s population aged 50 and over have had a colonoscopy or sigmoidoscopy, based on data provided by respondents, usage of all colorectal screening options is low among members covered by HMSA, Kaiser, UHA, MDX and Summerlin.

According to a survey by the National Conference of State Legislatures, Hawai‘i ranks 20<sup>th</sup> among the 50 states and the District of Columbia, at 60.1 percent, of adults aged 50 and over who have ever had a colonoscopy or sigmoidoscopy. The national rate of screening is 61.8 percent. As of July 2008, an estimated 293,000 of Hawai‘i’s 487,000 adults aged 50 and over have had a colonoscopy or sigmoidoscopy. Data provided by respondents show the population of members aged 50 and over with each health care plan tested for colorectal cancer screening and diagnostic purposes is lower than the national rate for screening.

Exhibit 2.2 illustrates the percentage of use for all the colorectal cancer screening options by eligible members. It is important to note that Kaiser provides routine colorectal screening using flexible sigmoidoscopy and two fecal tests—FOBT and FIT. Kaiser does not endorse the use of screening colonoscopy for average risk adults. The 31.2 percent of Kaiser’s members who have had a colonoscopy have done so for diagnostic, not screening, purposes. The population of members aged 50 and over covered under HMSA and UHA reported to have been tested by colonoscopy or sigmoidoscopy for screening and diagnostic purposes is also less

than the national average. Summerlin, the only carrier that covers all the screening options, reports the highest usage among its eligible members—40 percent for colonoscopy, CT colonography, FOBT, and sDNA, and 20 percent for flexible sigmoidoscopy, barium enema, and FIT. HMSA, which has the highest population of members aged 50 and over, reports the lowest usage—less than 10 percent for colonoscopy, flexible sigmoidoscopy, and FIT.

**Exhibit 2.2  
Percentage of Use for Each Colorectal Screening Option**

Screening Option	HMSA	Kaiser	UHA	Summerlin	MDX
Colonoscopy	HMO=5.5% PPO=4.5%	31.2%	21.3%	40%	n/a
Flexible Sigmoidoscopy	HMO=0.2% PPO=0.2%	29.1%	1.8%	20%	n/a
Double Contrast Barium Enema	HMO & PPO=NA	3.5%	0.9%	20%	n/a
CT Colonography	HMO & PPO=NA	NA	NA	40%	n/a
Fecal Occult Blood Test (FOBT)	HMO=17.1% PPO=16%	35.7%*	13.7%	40%	n/a
Fecal Immunochemical Test (FIT)	HMO=.01% PPO=.08%		0.3%	20%	n/a
Stool DNA Test (sDNA)	HMO & PPO=NA	NA	NA	40%	n/a

\*Kaiser combined FOBT and FIT

HMO = health maintenance organization

PPO = preferred provider plan

NA = Not applicable because health insurance carrier does not provide insurance coverage for this screening option

n/a = Information not available from the health insurance carrier

Source: Office of the Auditor, based on responses by health insurance carriers

**2. The extent to which insurance coverage for colorectal cancer screening is generally available.**

Not all screening options for colorectal cancer recommended by the ACS 2008 guideline are generally available for average risk or asymptomatic adults beginning at age 50. For example, screening colonoscopies are not available under Kaiser’s preventive screenings options or under HMSA’s preferred provider plan (PPO).

House Bill No. 823 would make screening colonoscopies available for all average risk adults beginning at age 50 who are members of Kaiser's and HMSA's PPO plans.

Only one of our five respondents, Summerlin, provides coverage for all the colorectal cancer screening options for average risk adults at age 50 as recommended by the ACS 2008 guideline. Summerlin also provides coverage for all the colorectal screening options specified in HB 823 for adults at aged 50 and over, absent any high risk factors, such as family history. Except for Summerlin, no health insurers cover CT colonography or sDNA as screening options for colorectal cancer. Insurance coverage by HMSA, Kaiser, UHA, and MDX follow the guidelines of the U.S. Preventive Services Task Force rather than the ACS 2008 joint screening guidelines, excluding screening coverage for CT colonography and sDNA as well as other screenings for adults *under* age 50 or performed more frequently than the intervals recommended by the USPSTF.

HMSA's HMO plan, UHA, and MDX provide coverage for average risk adults aged 50 and over for colonoscopy, flexible sigmoidoscopy, and FOBT tests. HMSA's PPO plans cover only one fecal test (FOBT) for average risk adults aged 50 and over. Kaiser provides screening coverage in average risk adults aged 50 and over for flexible sigmoidoscopy, FOBT and FIT, but covers colonoscopy only for diagnostic, not screening, purposes. Effective January 2010, HMSA plans to include colonoscopy and flexible sigmoidoscopy as colorectal cancer screening options for its PPO members aged 50 and over who are considered average risk or asymptomatic.

Exhibit 2.3 illustrates the extent of insurance coverage for colorectal screening using each option specified in the ACS 2008 guideline.

**Exhibit 2.3  
Insurance Coverage for Each Colorectal Screening Option**

Screening Option	HMSA	Kaiser	UHA	Summerlin	MDX
Colonoscopy	HMO=Yes PPO=No	No	Yes	Yes	Yes
Flexible Sigmoidoscopy	HMO=Yes PPO=No	Yes	Yes	Yes	Yes
Double Contrast Barium Enema	Only in certain circumstances	No	Yes	Yes	No response
CT Colonography	No	No	No	Yes	No response
Fecal Occult Blood Test (FOBT)	Yes	Yes	Yes	Yes	Yes
Fecal Immunochemical Test (FIT)	Only in certain circumstances	Yes	Yes	Yes	No response
Stool DNA Test (sDNA)	No	No	No	Yes	No response

Source: Office of the Auditor, based on responses by health insurance carriers

**3. If coverage is not generally available, the extent to which the lack of coverage prevents adults aged 50 and over from obtaining colorectal cancer screening.**

As shown in Exhibit 2.3, respondents have colorectal cancer screening programs where some screening options are available, provided the test is ordered by a physician. For example, HMSA’s HMO plans traditionally provide a higher level of coverage for preventive services such as screenings compared to PPO plans. However, HMSA believes that since many health care providers assume a screening colonoscopy is not covered by any of their plans, it sees a higher than normal percentage of colonoscopies coded as diagnostic rather than screening. Screening colonoscopy is not available to 77,368 adults aged 50 and over in Kaiser’s health plans.

**4. If coverage is not generally available, the extent to which lack of coverage results in unreasonable financial hardship on those persons needing colorectal cancer screening.**

As explained in Item 3 above, some procedures and fecal tests, when ordered by a physician, are available for diagnostic rather than screening purposes, and coverage is provided. Respondents report

the cost of structural exams (colonoscopy, flexible sigmoidoscopy, double contrast barium enema, and CT colonography) to be from \$145 for double contrast barium enema to \$4,000 for colonoscopy. According to HMSA and MDX, the cost of sDNA ranges between \$500 and \$1,200. Exhibit 2.4 illustrates the costs, negotiated rates, or eligible charges under the HMSA, UHA, Summerlin and MDX plans that are reimbursed to providers who perform colorectal cancer tests.

**Exhibit 2.4  
Estimated Costs for Specific Screening Options**

Test	HMSA	Kaiser	UHA	Summerlin	MDX
Colonoscopy	\$500 to over \$2,250	No response	\$930	\$2,000	\$500 to \$4,000
Flexible Sigmoidoscopy	No response	No response	\$407	No response	\$1,500
Double Contrast Barium Enema	No response	No response	\$145	No response	\$1,500
CT Colonography	No response	No response	No response	No response	\$1,500
Fecal Occult Blood Test (FOBT)	\$5	No response	\$7	No response	\$50
Fecal Immunochemical Test (FIT)	No response	No response	\$18	No response	No response
Stool DNA Test (sDNA)	\$1,200	No response	No response	No response	\$500 to \$1,000

Source: Office of the Auditor, based on responses by health insurance carriers

**5. The level of public demand for colorectal cancer screening.**

The level of public demand is not clear. Neither the health insurance respondents nor the American Cancer Society provided any data to us on this point. Both HMSA and Kaiser reported they have received requests for colonoscopy as screening options for colorectal cancer for average risk or asymptomatic adults aged 50 and over, but this information was not quantified.

**6. The level of public demand for individual or group insurance coverage for colorectal screening.**

The level of public demand for individual or group insurance coverage is not evident. Both HMSA and Kaiser responded that,

anecdotally, a few members have asked for colonoscopy screening, but none have maintained these requests on a formal basis.

**7. The level of interest of collective bargaining organizations in negotiating privately for colorectal screening coverage in group contracts.**

This level of interest is unknown because we did not contact any public or private sector collective bargaining organizations for this study. Since the 2001 Legislature established a single health trust fund—the Hawai‘i Employer-Union Health Benefits Trust Fund—by consolidating the public employee health fund and union health plans for public employees and retirees, public collective bargaining organizations, except the Hawai‘i State Teachers Association (HSTA), no longer negotiate separate health insurance programs. Responsibility for negotiating benefits for teachers with individual health care insurance carriers rests with the HSTA Voluntary Employees’ Beneficiary Association Trust. Private unions each negotiate separate and independent contracts which include health benefits with individual employers.

**8. The impact of providing coverage for colorectal screening (such as morbidity, mortality, quality of care, change in practice patterns, provider competition, or related items).**

As discussed in Chapter 1, periodic screening coverage for colorectal cancer using some procedures and stool tests is effective in reducing the mortality rate and incidence of colon or rectal cancer. Based on the ACS 2008 guideline and the recommendations of the 2008 U.S. Preventive Services Task Force, screening coverage using colonoscopy, flexible sigmoidoscopy, and the gFOBT and FIT are effective methods for achieving the goal of colorectal screening, which is to reduce mortality and the incidence of colon or rectal cancer. For example, although not the infallible gold standard as the ACS guideline notes, colonoscopy is considered the standard against which the sensitivity of other screening tests is compared.

The gFOBT is the only colorectal cancer screening test for which there is evidence of efficacy from prospective, randomized controlled trials. Three trial studies of between eight and 13 years each showed significant reductions in colorectal cancer mortality of 15 to 33 percent using the gFOBT. According to the ACS 2008 joint guideline, annual screening with high-sensitivity gFOBT “in an asymptomatic population is an acceptable option for colorectal screening in average-risk adults aged 50 years and older.” In comparison, the FIT is more specific for human blood than are guaiac-based tests. Unlike gFOBT, FIT is not subject to false-

negative results in the presence of high-dose vitamin C supplements and are more specific for lower gastrointestinal bleeding. There are no randomized trials that have tested FIT “where the outcome of interest is colorectal cancer mortality.”

Although contrast barium enema is an acceptable option under the ACS 2008 guideline, its effectiveness in reducing the incidence or mortality in average risk adults is unknown as no controlled trials of efficacy have been done. In addition, the use of this test “in average-risk adults will continue” to decline, along with the likelihood of fewer radiologists adequately trained to perform this procedure, due to the low volume of studies and professional interest.

Because there is no consensus among prevention and primary care experts as to the effectiveness of extending life-years using computer tomographic colonography and stool DNA tests, the impact of providing coverage for these tests to reduce the incidence of the disease or mortality is unknown.

According to Kaiser, having all members over age 50 use FIT and allowing only those who have positive tests use colonoscopies is cost effective. Based on clinical research, FITs detect cancer in 60 to 85 percent of patients, and colonoscopies detect cancer in more than 95 percent. In one study, FITs identified patients with colon cancer in 87.5 to 94.1 percent of those tested. When considered in terms of the number of patients that could be screened and the cost to screen the population of adults over 50 years old, Kaiser asserts that FITs are excellent for screening individuals at average risk.

In UHA’s opinion, CT colonography and stool DNA testing are expensive, not cost-effective, and lead to increased testing without benefit of improving cancer detection and treatment. In the case of stool DNA, testing is investigational at best.

The other screenings listed in HB 823 are cost-effective and appropriate for colorectal screening.

**9. The impact of any other indirect costs upon the costs and benefits of coverage.**

House Bill No. 823 can be expected to increase indirect costs such as administrative expenses to reprint materials for UHA, administrative expenses and premiums for HMSA, and premiums for Kaiser. HB 823 would not cause any change in costs for Summerlin. As an HMO, Kaiser expects to incur additional expenses in the purchase of equipment and supplies. HMSA expects increases in processing of credentialing and licensure of providers.

## ***Financial impact***

### **1. The extent to which insurance coverage of the kind proposed would increase or decrease the cost of colorectal cancer screening.**

In our opinion, the cost of screening using colonoscopy, flexible sigmoidoscopy, FOBt and FIT, should not be a barrier to enacting the proposed legislation (as amended – see Appendix A). According to all respondents, except UHA, regardless of who pays, no change in the per unit cost of each screening procedure or test available is expected, as this is determined by the provider or facility providing the screenings. However, UHA noted that CT colonography and sDNA tests are expensive and would increase costs.

### **2. The extent to which the proposed coverage might increase the use of colorectal cancer screening.**

House Bill No. 823 may cause an increase in the use of screening colonoscopy not available for members in Kaiser’s health plan and HMSA’s PPO plan, as discussed under the social impact Items 1 and 2 (above). However, our respondents provided no clear answers on the extent to which the use might increase. Some health insurers felt there would be no change, or could not provide information in the use of colorectal screening options, while one insurer felt that there would be increases in the use of colonoscopy, CT colonography, and sDNA testing. HMSA told us it has found that, typically with these types of screenings, the barrier to an individual receiving the screening is not financial, but based on other factors, including an unwillingness to have the test performed. Kaiser told us it has no data to indicate whether there would be a change in the usage of any specific screening method. Summerlin anticipated no increase, as all screening options are currently covered. MDX told us there would be no change in the usage of screening except for colonoscopy, CT colonography, and sDNA. MDX estimates a 50 percent increase in the use of colonoscopy and CT colonography, and a 100 percent increase in sDNA testing.

### **3. The extent to which mandating coverage for colorectal cancer screening might serve as an alternative for more expensive treatment for colon or rectal cancer.**

For every adult aged 50 and over, the benefits of screening ought to outweigh its costs. Treatments such as surgery, chemotherapy, and radiation therapy for an adult with colon cancer can be costly. In fact,

the USPSTF concludes that, for fecal occult blood testing, flexible sigmoidoscopy and colonoscopy to screen for colorectal cancer, there is high certainty that the net benefit is substantial for adults aged 50 to 75 years.

**4. The extent to which insurance coverage of the health care service or provider can be reasonably expected to increase or decrease insurance premiums and administrative expenses of policyholders.**

Summerlin is the only insurer that does not expect increases in insurance premiums and administrative expenses if screening coverage proposed in HB 823 is enacted. MDX quantified the increase in premiums from 1 to 2 percent. The others were not able to quantify expected increases. UHA also identified increases in administrative expenses for reprinting member information.

**5. The impact of this coverage on the total cost of health care.**

Although the financial impact would be on plans which currently do not cover all the screening options proposed in HB 823, three respondents—HMSA, Kaiser, and UHA—could not determine the total financial impact of enacting HB 823. Only MDX quantified the financial impact to be a cost (premium) increase of 1 to 2 percent with little, if any, improvement in overall health status of members. Summerlin, the only health insurer that already provides coverage for all the screening options proposed in HB 823, sees no impact to the total cost of health care it already provides. In addition, Summerlin expressed that any such costs would be negligible compared to the importance of making screenings available as a preventive measure. Although Kaiser agrees that early detection is best and reduces the overall cost per patient by reducing the need for more dramatic treatments necessary for cancer detected at a later stage, it does not believe that HB 823 would be effective in increasing the number of people screened.

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**An Amended  
House Bill No. 823  
Should Be  
Enacted**

The American Cancer Society and the U.S. Preventive Services Task Force differ in their guidelines for the standard of care, procedures and tests to be used, and recommended testing intervals for colorectal cancer screening. For example, CT colonography and sDNA are two newer procedures listed as acceptable screening options of the ACS, but are not recommended by the USPSTF because there is insufficient evidence with which to assess their benefits and harms. For this reason, we could not assess the social impact of providing coverage using these two newer tests to reduce the incidence of colorectal cancer or mortality. We conclude that HB 823 should amend the standard of care for colorectal screening to include the procedures and tests recommended by the USPSTF in 2008.

***The two newer tests lack sufficient clinical evidence***

The ACS 2008 guideline added two new screening tests, CT colonography and stool DNA, to its list of acceptable options. Prior to 2008, the standard of care and screening options for colorectal cancer recommended by the ACS and USPSTF were identical. In 2002, both organizations recommended periodic colorectal screening in adults aged 50 and over. Both organizations included flexible sigmoidoscopy; a combination of FOBT and flexible sigmoidoscopy; annual FOBT; colonoscopy; or double-contrast barium enema as recommended screening options. The laws of 16 states and the District of Columbia that mandate colorectal screening coverage follow the recommendations of the American Cancer Society, and two states follow the U.S. Preventive Services Task Force guidelines.

**CT colonography**

Because CT colonography is a relatively new procedure, there are fewer data relative to other screening tests for evaluating its benefits, limitations, and harms as a screening technique. Studies in symptomatic populations show the risk of perforation associated with screening CT colonography in a research setting is estimated at zero to six per 10,000. The harms of radiation exposure are uncertain, but one model predicts that one additional individual per 1,000 would develop cancer in his or her lifetime at the level of exposure reportedly used for this examination.

**Stool DNA**

Where gFOBT and FIT collect a sample of stool or water surrounding the stool, the sDNA test requires the entire stool specimen. According to the ACS 2008 guideline, data on program performance of sDNA are lacking and information on the sensitivity and specificity of colorectal cancer and adenoma detection comes from an evaluation of results from a single test. The available data on patient and provider acceptance indicate sDNA is preferred by some individuals, and among others it is at least as acceptable as testing with gFOBT. The sDNA test has been compared to a low-sensitivity gFOBT in one large, prospective study of 2,507 average-risk individuals using three screenings: sDNA, gFOBT and colonoscopy. The study showed sDNA was much less sensitive in the detection of all advanced adenomas (15.1 percent) but performed better in comparison to gFOBT (10.7 percent).

There are pros and cons to having a range of options for colorectal cancer screening. For example, despite the primary barriers to screening—lack of health insurance, physician recommendation, and awareness of the importance of colorectal screening—the historical evidence shows that adults have different preferences and patterns of use among the tests available. In the last decade, growth in the technologies for screening and commercial versions of stool tests has been accompanied by changing patterns in the proportion of adults using different tests.

Hence, flexible sigmoidoscopy rates are declining, colonoscopy rates are increasing, use of stool blood tests are remaining somewhat constant, and use of double contrast barium enema is now very uncommon. In addition, not all options are available to the entire population, and transportation, distance, and financial barriers to some screening technologies may endure for some time.

***Differences in the standard of care***

Regular colorectal cancer screening for all average risk or asymptomatic adults aged 50 years or older is the standard of care based on the American Cancer Society 2008 guideline as well as that of the U.S. Preventive Services Task Force. The latter is a leading independent panel of private sector prevention and primary care experts sponsored by the Agency for Healthcare Research and Quality (AHRQ) within the U.S. Department of Health and Human Services. According to the AHRQ, the USPSTF recommendations are considered the ‘gold standard’ for clinical preventive services. However, differences in the standard of care are found in the procedures and tests used as well as the intervals recommended by the ACS and USPSTF updated in the 2008 screening guidelines as shown in Exhibit 2.5. Compared to the acceptable screening options endorsed by the American Cancer Society, the U.S. Preventive Services Task Force recommends three regimens since two tests—CT colonography and sDNA—lack sufficient evidence, and use of the barium enema is in decline and was not considered in 2008. Although double contrast barium enema is an acceptable option for colorectal cancer screening under the ACS 2008 guideline, its effectiveness as a screening option to reduce incidence or mortality in average risk adults is unknown, as no controlled trials evaluating efficacy have been done.

**Exhibit 2.5**

**Recommended Intervals of Colorectal Screening Options for Asymptomatic Adults Aged 50 and Over**

<b>Colorectal Cancer Screening Option</b>	<b>2008 Joint Guideline of the American Cancer Society</b>	<b>U.S. Preventive Services Task Force Recommendation Statement</b>
Colonoscopy	Ten years	Ten years for adults to age 75 years
Flexible Sigmoidoscopy	Five years	Five years, combined with high-sensitivity fecal occult blood testing every three years for adults to age 75 years
Fecal Occult Blood Test & Fecal Immunochemical Test	Annually	Annually for adults to age 75 years
Double Contrast Barium Enema	Five years	Not addressed
Computed Tomographic Colonography	Five years	No recommendation. Insufficient evidence for assessment
Stool DNA Test	Interval uncertain	No recommendation. Insufficient evidence for assessment

Source: Office of the Auditor, based on 2008 Joint Guideline of the American Cancer Society and 2008 Recommendation Statement of the U.S. Preventive Task Force

The USPSTF 2008 update focused on four key elements:

- Demonstrated benefit in reducing colorectal cancer mortality;
- Efficacy of newer screening technologies—the high-sensitivity gFOBT, FIT, sDNA and CT colonography;
- Effectiveness of optical colonoscopy and flexible sigmoidoscopy in community practice; and
- Harms of newer screening technologies, optical colonoscopy and flexible sigmoidoscopy.

Based on its review and analysis, the USPSTF found convincing evidence that colorectal cancer screening is effective in reducing mortality in adults, beginning at age 50 and continuing until age 75. The USPSTF recommendations are:

- Annual high-sensitivity fecal occult blood test;
- Flexible sigmoidoscopy every five years combined with high sensitivity fecal occult blood testing every three years; and
- Colonoscopy at ten year intervals.

It is important to note that the American College of Physicians, American Academy of Family Physicians, American College of Preventive Medicine, and Centers for Disease Control and Prevention have issued recommendations similar to, or have endorsed, the USPSTF recommendation. The American College of Obstetricians and Gynecologists recommends colonoscopy as the “preferred method.”

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## **Conclusion**

Our study was unable to answer all questions on the social and financial impacts of mandating insurance coverage for each of the colorectal screening options defined as the standard of care in House Bill No. 823. Nevertheless, we conclude that legislation would be beneficial for a majority of Hawai‘i’s insured population of average risk or asymptomatic adults between the ages of 50 to 75 who are currently unable to select colonoscopy every ten years as a screening option. However, we believe that including computed tomographic colonography and stool DNA tests among the methods for colorectal screening may be premature because there is no consensus on the efficacy of these newer procedures among preventive health care experts.

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## **Recommendation**

Enactment of an amended House Bill No. 823 is recommended. The standard of care for colorectal screening should include the procedures and tests recommended by the U.S. Preventive Services Task Force 2008 guideline. A draft of the proposed amended legislation is provided in Appendix A.

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## Responses of the Affected Agencies

### **Comments on Agency Responses**

We submitted a draft copy of this report to the Departments of Health and Commerce and Consumer Affairs on January 27, 2010. A copy of the transmittal letter to the Department of Health is included as Attachment 1. A similar letter was sent to the Department of Commerce and Consumer Affairs. Both departments opted not to respond.

**ATTACHMENT 1**

STATE OF HAWAII  
**OFFICE OF THE AUDITOR**  
465 S. King Street, Room 500  
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**MARION M. HIGA**  
State Auditor

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January 27, 2010

***COPY***

The Honorable Chiyome L. Fukino  
Director of Health  
Department of Health  
Kīna'u Hale  
1250 Punchbowl Street  
Honolulu, Hawaii'i 96813

Dear Dr. Fukino:

Enclosed for your information are three copies, numbered 6 to 8, of our confidential draft report, *Study of Proposed Mandatory Health Insurance Coverage for Colorectal Cancer Screening*. We ask that you telephone us by Friday, January 29, 2010, on whether or not you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit them no later than Wednesday, February 3, 2010.

The Department of Commerce and Consumer Affairs, Governor, and presiding officers of the two houses of the Legislature have also been provided copies of this confidential draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

A handwritten signature in cursive script, appearing to read "marion m higa".

Marion M. Higa  
State Auditor

Enclosures