Winter January 15, 2010

ACS Proposal: State Insurance Mandates and Cancer Prevention

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RESEARCH PLAN

A. SPECIFIC AIMS

Colorectal cancer is the third leading cause of cancer and the second leading cause of cancer death in the U.S., yet it is also one of the most preventable and curable forms of cancer if detected early.[1] An estimated 50 to 60 percent of colorectal cancer deaths might be prevented if all persons aged >50 years were screened routinely.[2] Despite recommendations for routine colorectal screening among people over age 50 and those with other risk factors, less than two-thirds of at-risk individuals receive screening at recommended intervals, and screening rates vary widely across states and communities.[3] Although they have increased modestly in recent years, screening rates for colorectal cancer continue to be lower than for other types of cancer, including mammography for breast cancer and pap smears for cervical cancer.[4,5] Despite recommendations for routine colorectal screening among people over age 50 and those with other risk factors, many at-risk individuals fail to receive screening. Moreover, significant disparities in screening, treatment, and survival persist among racial, ethnic, socioeconomic, and geographic subgroups[6-8]

Cost remains a significant barrier to screening for people who lack health insurance coverage or who have coverage that requires significant cost-sharing.[9] Insurers and employers have increased cost-sharing requirements dramatically in recent years by raising deductibles and copayments in an effort to constrain the growth in health insurance premiums.[10-12] The growth of high-deductible health plans and health savings accounts (HSAs) has been aided by a 2003 federal law giving these products favorable tax treatment. These trends raise significant concerns that current health plan designs and cost-sharing provisions are beginning to erode the past gains made in cancer screening rates. In the midst of these changes, some states have sought to increase financial access to colorectal screening by requiring state-regulated insurers to cover these screenings. These regulations, however, place no restrictions on the cost-sharing provisions used by insurers.

Despite significant changes in the design and regulation of health insurance products, research examining the effects of these changes on cancer screening and cancer outcomes has been lacking. To inform future clinical and policy decisions concerning cancer care, we propose to conduct a national, longitudinal study examining the effects of recent changes in health insurance designs and regulations on colorectal cancer screening, outcomes and disparities. The proposed study will accomplish three primary aims:

1. Estimate the effects of changes in health insurance benefit designs on cancer screening rates and disparities during the period 1999 to 2006. The specific benefit changes to be examined as causal and contributing factors include increases in consumer cost-sharing, the introduction of new high-deductible insurance products, and the introduction of new stand-alone cancer coverage policies. The effects of these changes on screening rates will be examined overall and across population subgroups defined by race, ethnicity, socioeconomic status, rural/urban residence, and geographic region in order to determine whether insurance changes have affected cancer disparities across these populations. While the focus of this analysis will be colorectal cancer screening, effects on other evidence-based cancer screenings will also be examined for comparison. National, longitudinal data from the Medical Expenditure Panel Survey and related federal data sources will be used for this analysis.
2. Estimate the effects of state colorectal insurance mandate regulations on colorectal cancer screening rates, stage at diagnosis, and survival during the period 1997 to 2006. Specific regulatory provisions will be examined in the 19 states that have passed colorectal cancer mandate laws as of 2006, with attention given to the types of insurance plans regulated, the types of coverage mandated, and the enforcement provisions used. Difference-in-difference statistical methods will be used to estimate the effects of the regulations by comparing outcomes in states that did and did not implement regulations across time periods both before and after implementation of the regulations. The analysis will also examine whether regulations have affected disparities in cancer screening and outcomes across racial, socioeconomic, and geographic subgroups.
3. Estimate how changes in health insurance benefits and regulations have affected the costs of colorectal cancer care and the distribution of these costs among private health insurers and public programs such as Medicare. Of particular interest, the study will investigate (1) whether state colorectal insurance mandates have precipitated changes in private health insurance premiums due to increased coverage of

screening services; and (2) whether changes in colorectal cancer screening among the privately insured have led to changes in Medicare spending for colorectal cancer care.

B. BACKGROUND AND SIGNIFICANCE

Under-utilization of effective cancer prevention and early detection interventions remains a persistent stumbling block in efforts to reduce cancer burden and disparities in the U.S. Three decades of research in health economics and health services research demonstrate that cost is a significant determinant of—and barrier to—health care utilization, particularly for preventive services and outpatient care for non-urgent conditions.[13-21] Cost is a particularly daunting barrier for low-income populations, but even higher-income individuals under-use preventive services when out-of-pocket spending is required.[22,23] Time preferences, which indicate the tendency to value immediate gains over future benefits, may explain some patterns of preventive health behavior and provide a reason for the lack of willingness to pay now for the future benefits of preventive care.[24-26] Another important reason appears to be consumers' tendency to under-estimate their future risk of disease that can be lowered through preventive care.[27,28] Finally, physicians and other health care providers may not aggressively encourage preventive services use when they perceive cost to be a barrier for their patients.[23,29]

In view of these findings, efforts to increase utilization of beneficial preventive services such as cancer screenings have focused on reducing patient costs and even offering explicit incentives to consumers.[30] Considerable evidence suggests that health maintenance organizations (HMOs) and other managed care organizations succeeded in increasing compliance with guideline-recommended cancer screenings and other preventive services during the 1990s, in part by offering their members first-dollar coverage for these services with no or little cost-sharing.[31-35] However, rapid growth in health insurance premiums and growing disfavor with managed care over the past several years has led insurers and employers to move away from these generous types of benefit designs and dramatically increase cost-sharing requirements by raising deductibles and copayments.[10-12] The marketplace trend toward high-deductible health plans and "consumer-driven" benefit designs is the most dramatic, and highly uncertain, development in the health insurance industry since the managed care revolution began more than three decades ago.[36,37]

Existing evidence predicts that as out-of-pocket costs increase, consumers will cut back on cancer screenings and other evidence-based preventive services, potentially undermining the recent progress made nationally in expanding use of these services.[38] This shift in benefit designs may disproportionately affect low-income populations and the seriously ill who have fewer resources available to devote to their care, thereby exacerbating existing disparities in health care and health outcomes.[22,23,38] Adding to this problem, insurers may lack strong economic incentives to cover and promote many cancer screening services and other prevention strategies because the potential cost savings often accrue over the space of several years, by which time screened patients may have changed employers, switched health plans, or aged into the federal Medicare program.[39,40]

In response to these problems, a growing number of states have passed insurance mandate laws requiring insurers to offer and/or provide coverage for cancer screenings and other preventive services. These laws have become increasingly popular among state policy-makers, resulting in a proliferation of mandated benefit laws in place in all 50 states and the District of Columbia.[41] However, the design and enforcement of these laws vary widely across states, and relatively little evidence exists concerning the impact of these laws.[42-44] Moreover, these laws have come under increasing scrutiny and criticism in recent years because of their potential to increase the cost of health insurance and place coverage out of reach for larger shares of employers and workers.[45-47] Such criticism is heaviest for laws involving clinical services that lack a strong evidence base concerning cost-effectiveness, such as PSA screening for prostate cancer detection.[48,49] For clearly cost-effective services like colorectal cancer screening, considerable uncertainty remains regarding the ability of insurance mandates to increase access to screening, particularly since these regulations place no restrictions on the cost-sharing provisions used by insurers.[17]

In view of these uncertainties, clinical and policy decision-makers require better evidence on how changes in health insurance designs and regulations are affecting access to cancer prevention and control services across the U.S. This information is vital for uncovering new pathways to ensure delivery of evidence-based cancer services to the populations who need them most.

C. PRELIMINARY STUDIES

The investigative team assembled for the proposed study has conducted a considerable amount of research on the nature of gaps and disparities in cancer prevention and on the influence of health insurance plans and policies on service delivery. Collectively, these findings and experiences inform the design of the proposed investigation.

C.1. Studies of Cancer Screening, Early Detection, and Disparities Reduction

Members of the investigative team have led an extensive array of studies to identify barriers to cancer screening and test novel solutions. The Arkansas Cancer Community Network (AR-CCN) is one of 25 projects funded nationally by the NCI Center to Reduce Cancer Health Disparities to discover new ways of reducing cancer burden and disparities through participatory research and community-based interventions. Led by Dr. Ronda Henry-Tillman, M.D., at the UAMS Arkansas Cancer Research Center, the AR-CCN is now in its second, five-year cycle of funding and has spawned a number of novel approaches to cancer prevention and disparities reduction.[50] AR-CCN has cancer control program activity in all five regions of the state of Arkansas, emphasizing primary and secondary prevention for breast, prostate, colorectal and lung cancers through community based participatory research methods. The project's significant accomplishments have included: increasing cancer control activities by 125% over the past four years as measured by the volume of screening and education programs and locally-sponsored health fairs across the state; increasing investigator-initiated research projects involving minority cancer control and clinical researchers by 75% over this period; and increasing minority accrual to clinical trials at UAMS by 77% over this period. The interventions under investigation by AR-CCN include:

- A physician educator/academic detailing intervention that cycles through rural primary care practices around the state conducting detail visits with physicians and other providers on evidence-based prevention and control strategies for reducing breast, cervical, colorectal, lung, and prostate cancer risks.
- A video-based cancer awareness and education intervention for colorectal, breast, and prostate cancer delivered to patients in the waiting rooms of their primary care physicians.
- A patient self-administered screening tool to identify colorectal cancer risks and prompt a discussion about recommended screening services between the patient and physician during the office visit.
- A physician focus group study to identify barriers to referring patients for colorectal screening
- A voucher pilot program that tested the impact of distributing vouchers for free colorectal screenings to uninsured adults through two alternative mechanisms: (1) physician practices and (2) community events.
- A policy analysis and evaluation unit that reviews and assesses cancer-related policies within the state and provides briefings and reports to state policy-makers concerning evidence-based strategies for reducing cancer burden and disparities. As a co-investigator on the AR-CCN, Dr. Glen Mays at the UAMS College of Public Health oversees this component of the initiative and Charlotte Lewellen-Williams serves as lead policy analyst.

These same members of the proposed investigative team are leading an investigation of a novel colorectal cancer demonstration program funded by a $1 million grant from the State of Arkansas. The investigators are conducting a demonstration trial comparing two alternative interventions for improving primary care physician advice and referral regarding colorectal screening: (1) an integrated intervention that involves professional education, practice management tools, prompts and reminders, and patient education and navigation services; and (2) a limited intervention that involves only physician education and patient education. Five primary care practices have been randomly assigned to each intervention arm for an 18-month trial period. Findings from the demonstration trial will be used to inform policy makers about the efficacy and cost-effectiveness of a statewide CRC program.

C.1. Studies of Health Insurance Design, Coverage and Cost

A considerable body of research conducted by the proposed investigators has focused on the design of health insurance products and their impact on access to preventive services, public health services, and primary care services, with a special focus on underserved populations. As part of this work, Dr. Mays led a national study funded by AHRQ examining how the growth of managed care contracting and capitated payment systems during the 1990s affected the ability community health centers to provide primary and

preventive services for the uninsured. Findings indicated that care for the uninsured declined significantly in areas served by small centers that had limited clinical and financial capacity to operate efficiently under managed care contracts, while care expanded modestly at larger centers that used their contracts to increase patient volume and cross-subsidize care for the uninsured.[51] A related series of studies funded by CDC found that the growth of managed care during the 1990s helped to increase access to public health services like immunizations and tobacco prevention activities in the community at large, particularly in communities where nonprofit insurers and Medicaid-serving health plans maintained significant market share.[52-57] Collectively, this body of work helped to inform state and federal policy efforts to retool public health and prevention programs for better interface with the private health insurance industry.

More recently, studies conducted by members of the investigative team have focused on assessing the impact of recent changes in health insurance benefit designs and care management strategies. As part of the longitudinal Community Tracking Study, Dr. Mays and colleagues at the Center for Studying Health System Change have found early evidence of diminishing access to care in communities where employers and insurers have moved more rapidly to high-deductible health plans and other insurance designs that increase consumer costs at the point of service.[58,] At the same time, the investigators have found some evidence of improved health care quality and outcomes in communities where private insurers have increased their investments in disease management, care coordination, and health promotion programs.[60,61] In a separate study funded by NCI in collaboration with Duke University, Mays found that buy-in from private health insurers (or lack thereof) was an important factor in determining whether community oncology practices adopted an efficacious health education program for family members of breast cancer patients.[62]

Members of the proposed investigative team have also engaged in applied research and translation activities at the state level to identify pathways for improving the health insurance system. In 2000, to address the growing crisis in health insurance coverage, the Arkansas Center for Health Improvement (ACHI) was charged with leading a comprehensive investigation of health insurance issues facing the state. To support this activity, ACHI secured significant funding from the HRSA State Planning Grant Program (PI Kevin W. Ryan) to conduct research and develop a platform of long-term strategic recommendations for the state. ACHI also received a $1.3 million Demonstration Grant from the RWJF State Coverage Initiative Program (Co-PI Kevin W. Ryan) that provides technical assistance and supports implementation of these recommendations.

As part of this work, ACHI and Dr. Ryan have completed the first empirical assessment and systematic evaluation of strategies to address uninsured Arkansans. A statewide survey of households and interviews with employers were conducted as part of this effort. With this new information, a roundtable consisting of 21 private-citizen members representing employers, consumers, and health insurance/providers examined all options for stabilizing and expanding health insurance coverage, and shaped development of a draft of strategic steps for local, state, and federal action. After legislative and executive review, these action steps were submitted to the US Department of Health and Human Services in March 2002 as Arkansas's final report and strategic plan for addressing a growing health and fiscal crisis. The Roundtable continues to meet on a regular basis and is serving as the platform for development of a 5-10 year strategic health policy plan for Arkansas.

In the fall of 2003, the Roundtable supported the formation of the Arkansas General Assembly Joint Interim Committee on Health Insurance and Prescription Drugs. This Committee serves as a permanently authorized body to study issues surrounding health insurance and prescription drugs and will make recommendations for legislation to be introduced in upcoming sessions. Dr. Mays, another member of the proposed investigative team, was appointed by the legislature to serve on this committee. Through the development of empirically based health policy recommendations, ACHI and the Arkansas Health Insurance Roundtable are committed to expanding health insurance coverage and increasing the quality of health care in our state and in our nation.

C.3 Expertise of the Investigative Team

Glen P. Mays, Ph.D., M.P.H., the proposed principal investigator, maintains an extensive research portfolio focusing on strategies for organizing and financing public health and preventive services, health insurance, and medical care services for underserved populations. He serves as principal investigator on a series of CDC- and RWJF-funded studies examining how public health services are organized, financed,

and delivered across local communities and what factors influence the availability and quality of these services. He also serves as co-PI of the AHRQ-funded Arkansas Consortium for Health Services Research, where he oversees investigations into the factors affecting access to care using large administrative databases from Medicaid, Medicare, and private insurers. His work in cancer research currently involves the study of state and local policies to reduce cancer disparities as part of the NCI-funded Arkansas Cancer Community Networks (AR-CCN) initiative, led by Dr. Ronda Henry-Tillman, MD (PI). Mays serves as co-investigator and director of the health policy component of this initiative. Dr. Mays' work in health insurance has included economic evaluations of state strategies to expand health insurance coverage as well as studies to identify the causes and consequences of change in private health insurance designs. As part of this work, he has served as a senior researcher on the RWJF-funded Community Tracking Study, where he analyzed the decisions of insurers and employers regarding health benefits and their impact on communities. Mays recently served on the National Academy of Sciences Institute of Medicine committee for studying the use of performance measures and incentives to improve health care quality. He has published more than 50 journal articles, books and chapters on issues involving public health systems, health insurance, and safety-net health care programs. He received Ph.D. and M.P.H. degrees in health policy and administration from the University of North Carolina at Chapel Hill, and completed a postdoctoral fellowship in health economics at Harvard Medical School. He currently serves as Associate Professor and Chair *Pro Tem* of the Department of Health Policy and Management at the UAMS Fay W. Boozman College of Public Health. As PI and lead researcher on the quantitative analyses, Dr. Mays will devote 30% effort to the project during Years One and Four and 35% effort during Years Two and Three.

Kevin Ryan, JD, MA, RN, a co-PI for the proposed investigation, leads studies in health insurance design and health law and regulation for the Arkansas Center for Health Improvement and the UAMS College of Public Health. Dr. Ryan's research interests center around public health law and the development of state and federal policies targeted to improve the current health care delivery and financing system. He directs the Arkansas State Health Insurance Expansion Initiative, a $2.5 million project funded by HRSA to study mechanisms for addressing the status of the uninsured in Arkansas, as well as the State Coverage Initiative, a $1.5 million project funded by RWJF to design and implement mechanisms to expand health insurance coverage and promote stabilization of the health care marketplace. Mr. Ryan graduated with High Honors from the University of Arkansas at Little Rock (UALR) William H. Bowen School of Law, where he was a member of the Law Review. He also has a Master of Arts in Health Services Management and clinical degrees in nursing and radiologic technology. As co-PI, Dr. Ryan will assist Dr. Mays in overseeing project operations as a whole, and will assume primary responsibility for designing and conducting the legal analysis of state cancer benefit mandates. He will also provide significant intellectual leadership for the analyses of health insurance benefit designs and cost-sharing provisions. Dr. Ryan will devote 25% effort to the project in Year 1 during the major data collection phase of the legal analysis, 10% in years 2 and 3 to support interpretation and use of legal data in the quantitative analyses, and 20% effort during the final 6 months of the project for development of manuscripts and presentations.

Ronda Henry-Tillman, MD, FACS, a co-investigator and clinical consultant for the proposed investigation, is an Associate Professor in the Department of Surgery, with an appointment and tenure in the Division of Breast Surgical Oncology. Her clinical expertise spans the arena of breast cancer, colorectal cancer and surgical endoscopy. She is the Director of the Women's Oncology Clinic. She has over seven years of experience in Cancer Control where she serves as Director at the Arkansas Cancer Research Center. Her major focus in cancer research includes clinical, translational, behavioral and health policy and has brought these components together to develop interventions and strategies targeting early detection, treatment and cancer health disparities. Dr. Henry-Tillman has several leadership roles serving as the Associate Director for the Breast Oncology Surgical Training Fellowship, Principal Investigator for the NCI Center to Reduce Cancer Health Disparities Community Network Program, Senior Principal Investigator on several pilot grants from the NCI, and Vice-President for the Faculty Diversity and Community Outreach Committee. She is committed to reducing cancer disparities at all level and will provide collaborative leadership as co-investigator with Dr. Mays at 10% support.

Lawrence S. Powell, Ph.D., who holds the Whitbeck-Beyer Chair of Insurance and Financial Services at the University of Arkansas-Little Rock School of Business, brings to the investigation extensive experience in studying regulatory actions in the insurance industry and pricing behavior of insurers. Dr. Powell's primary research focus is on the effects of regulation on insurance markets. Among his current projects are studies to measure the efficacy of laws intended to reduce automobile insurance fraud,[63] and

studies to measure the effects of states' legal environments and tort reform laws on automobile and medical malpractice insurance costs.[64,65] Two of Dr. Powell's recent studies have evaluated medical malpractice insurance companies' pricing and reserving practices,[66] and another study documented the effects of international reinsurance regulation on insurance prices.[67] As a consultant, Dr. Powell has worked on public policy issues with entities including the Health Coalition for Liability and Access, the Physician Insurers Association of America, the Institute for Defense Analysis, and the Manhattan Institute's Center for Legal Policy. He currently serves on the Arkansas Health Insurance Expansion Initiative Working Group and the Arkansas Insurance Commissioner's Regulatory Task Force. He earned a Ph.D. in Risk Management and Insurance from the University of Georgia. As co-investigator on the proposed investigation, Dr. Powell will lead the analysis of health insurance premiums and analysis of supplemental cancer policies, and will play significant roles in conducting the legal analysis of colorectal screening insurance mandates and the cost analysis of these mandates. He will devote 15% effort to the project in each year.

Charlotte Lewellen-Williams, M.P.H., will serve as research assistant and study manager for the proposed study. She brings to the investigation substantive experience in applied health policy analysis developed while serving as the lead health policy analyst for the NCI-funded Arkansas Cancer Community Network initiative to reduce cancer disparities. She will assist with the overall management and administration of the investigation and play substantive roles in the legal analysis and in the interpretation of policy implications from the quantitative analysis. She will devote 50% effort to the project in Year One during implementation of the legal analysis, and 20% effort in subsequent years.

D. RESEARCH DESIGN AND METHODS.

D.1. Overview of the Research Design

Assessing the health and economic impact of health insurance market developments and policy changes is complicated by the fact that experimental research designs are often politically, economically, and logistically infeasible. As an alternative, it is possible to design strong quasi-experimental research studies when economic trends and political processes give rise to cross-sectional and longitudinal variation in exposure to the insurance plans and policies of interest. The proposed investigation will use this approach to examine how changes in health insurance designs and regulations are affecting cancer screening and outcomes, capitalizing on the fact that insurance benefit designs and regulations vary widely across states and have changed considerably over the space of several years. The analytic methodologies and data sources we propose to use vary somewhat across the three aims of the study and are summarized in Table 1.

D.2. Aim I: Effects of Changes in Health Insurance Designs

Longitudinal survey data from the Medical Expenditure Panel Survey (MEPS) collected in years 1999 through 2006 will be used to estimate the effects of changes in health insurance benefit designs and cost-sharing on the rates of guideline-recommended cancer screenings among the privately insured. The specific screenings investigated will include colorectal, breast, cervical, and prostate, with the latter used as a contrast case due to the lack of clear evidence-based screening guidelines. Multivariate hierarchical regression models will be used to estimate the effects of consumer cost-sharing and out-of-pocket costs on the likelihood of receiving screening while controlling for other factors likely to influence screening use, including health and functional status, education, income, gender, marital status, age, race/ethnicity, usual source of care, proximity to care, and stability of insurance coverage. For people who enrolled in a high-deductible health savings account (HSA) product during the study period, a similar model specification will be used to estimate the effects of this enrollment on screening use. The models will include interaction terms between race, cost-sharing, and plan design variables in order to test for the effects of cost-sharing and plan design on disparities in screening use.

The following hypotheses will be tested empirically:

- H1.1: Compliance with guideline-recommended cancer screenings *decreases* among privately-insured individuals who experience increases in the deductible levels and copays required by their health plans
- H1.2: Compliance with guideline-recommended cancer screenings *decreases* among privately-insured individuals who experience increases in their out-of-pocket health care costs

Table 1: Overview of the Research Design

Research Questions	Data Sources	Design and Methods
Aim 1a: Effects of Changes in Health Insurance Benefit Designs on Cancer Screening		
Does compliance with guideline-recommended cancer screenings decline when consumers experience increases in cost-sharing requirements? Which screenings are most affected? Are consumers enrolled in HSAs less likely to receive screenings? Has screening uptake slowed or declined in markets where deductible/copay requirements have increased most rapidly? Are increases in deductible and copay requirements associated with increased disparities in screening across subgroups of interest?	MEPS annual household surveys 1999-06 MEPS-IC annual insurance surveys 1999-06 MEPS household-insurance linkage file	Hierarchical logistic regression models controlling for patient demographics, health status, plan features, rural area, region, and year Control endogeneity bias in HSA enrollment using instrumental variables analysis Test for disparities using interaction terms between cost-sharing and race/ethnicity, income, insurance source, and region
Aim 1b: Effects of Supplemental Cancer Insurance Policies on Cancer Screening		
Are consumers that enroll in supplemental cancer insurance policies more or less likely than counterparts to receive screenings? Which screenings are most affected? Are certain racial, income, demographic or geographic subgroups more likely than others to enroll in these policies? Has screening uptake changed in markets where cancer policies have grown most rapidly?	USAble enrollment and claims data 1997-2006 BRFSS annual surveys 1997-06	Descriptive analysis of characteristics of USAble members Coefficient estimates from Aim 1 used to compute observed vs. expected screening ratios for USAble members County-level ecological analysis of incidence and enrollment patterns using linked USAble-Registry data
Aim 2: Effects of CRC Coverage Mandate Laws on Cancer Screening and Outcomes		
How do state CRC laws vary in terms of requirements, exemptions, enforcement, incentives, and penalties? Are CRC laws associated with increases in screening? Do stronger laws precipitate larger gains in screening? Are CRC laws associated with lower risks of late-stage diagnosis and increased survival? Are CRC laws associated with reduced disparities in screening, diagnosis, and survival?	Legislative database of state statutes and regulations Key informant interviews with state insurance officials BRFSS annual surveys 1997-06 MEPS surveys 1997-06 SEER data 1997-2006	Content analysis and legal appraisal to code and classify each state law appropriately Multivariate difference-in-difference models controlling for patient demographics, health status, insurance type, rural area, region, and year Test for disparities using interaction terms between law and race/ethnicity, income, insurance source, and region
Aim 3: Effects of CRC Coverage Mandate Laws on Premiums, Costs, and Public Programs		
Are CRC laws associated with higher or lower health insurance premiums? Are CRC laws associated with higher or lower Medicare spending for CRC care? Are CRC laws associated with higher or lower disparities in Medicare spending for CRC care?	Legislative database NAIC insurance filings 1997-2006 CPS survey data 1997-2006 Linked SEER-Medicare files 1997-2006	Multivariate difference-in-difference models Test for disparities using interaction terms between law and race/ethnicity, income, insurance source, and region

- H1.3 Racial, ethnic, and income-related disparities in screening rates *increase* among privately-insured individuals who experience increases in the deductible levels and copays required by their health plans
- H1.4 Racial, ethnic, and income-related disparities in screening rates *increase* among privately-insured individuals who experience increases in their out-of-pocket health care costs
- H1.5 Compliance with guideline-recommended cancer screenings *decreases* among individuals who enroll in HSA high-deductible health insurance products, compared to those who remain in traditional health insurance products.

D.2.1. Data and Measures

This analysis will rely primarily on successive annual waves of survey data from MEPS, the most complete source of data on the cost and use of health care and health insurance coverage in the United States. The MEPS Household Component (MEPS-HC) obtains data annually on a representative national sample of households and individuals through a set of large-scale surveys of individuals, their medical providers, and employers. The panel design of the survey allows sampled individuals to be followed for two calendar years. Annual sample sizes for the household component survey range from 21,500 to 37,400 persons. The MEPS Insurance Component (MEPS-IC) surveys a nationally representative sample private and public sector employers to collect data on the number and types of private health insurance plans offered, benefits associated with these plans, premiums, contributions by employers and employees, eligibility requirements, and employer characteristics. Annual sample sizes for this component range from 35,400 to 43,700 establishments. The MEPS-IC sample includes the primary employers of adults who are surveyed in the MEPS-HC sample, and a special linkage file allows data from households and their corresponding employers to be analyzed together.

This analysis will use longitudinal data from both survey components and especially the linked data files from 1999 through 2006 to test the hypotheses of interest. The linked file provides the most detailed data available from any source about both receipt of cancer screening (from MEPS-HC) and about health insurance benefit provisions and cost-sharing requirements (from MEPS-IC). Data processing and initial analyses performed on the linked data files will be completed on-site at the AHRQ data center in Rockville due to data security and privacy protections. Once linkages are completed and all identifying information is expunged, an approved analytical data file will be transferred to UAMS for further analysis. We will secure advanced approval from AHRQ for all proposed analyses involving MEPS data.

The seven year period of 1999 to 2006 is proposed for this analysis because it spans a time when employers and insurers have been altering benefit designs and raising cost-sharing to consumers in an effort to constrain premiums. The economic recession of 2001-02 produced slackening labor markets in many areas of the country that created an opportunity for employers to reduce benefits and raise deductibles and copays with relatively little resistance from employees. Significant numbers of employers increased cost-sharing requirements in subsequent years to counter rapidly rising health insurance premiums, and some firms introduced HSA-compatible high-deductible health plans after these plans became eligible for new federal tax deductions in 2004. As a result, there is considerable variation in benefit designs and cost-sharing across employers over this time period.

A person-year analytical data file will be created by concatenating observations from each of the seven annual waves of the MEPS surveys. Most analyses focusing on insurance benefit design and cost-sharing will be limited to observations on individuals covered through private health insurance, either employer-provided or individually purchased. Furthermore, most analyses will be limited to observations on individuals who are age-appropriate and gender-appropriate for the specific cancer screening services of interest in this study, including breast cancer, cervical cancer, colorectal cancer, and prostate cancer.

Measures of Cancer Screening. Measures indicating receipt of guideline-recommended cancer screening services will be based on accepted evidence-based guidelines published by the U.S. Preventive Services Task Force. Measures will be based on recommended age groups, screening frequency, and screening modalities for average-risk individuals. Using the MEPS-HC, sampled individuals who are age- and gender-appropriate for screening during the year of the survey will be coded as 1 if they were in compliance with the screening recommendation that year, or 0 if not in compliance. Separate screening measures will be constructed for mammography screening for breast cancer, Pap screening for cervical cancer, and fecal occult blood test and/or colonoscopy for colorectal cancer. An additional measure for

PSA screening for prostate cancer will be constructed based on American Cancer Society recommendations for screening average-risk men over 50, using a two-year screening interval.

Measures of Benefit Design and Cost Sharing. Linked MEPS-IC data will be used to construct measures for each individual in the data file indicating the amount of the individual deductible and/or family deductible that is required to be met during the calendar year, as well as the amount of copayments or coinsurance required for office visits, diagnostic tests, and specialist consults. A measure indicating the maximum out-of-pocket spending limit for individuals and families will also be constructed from this source, as well as a measure indicating the amount of funds contributed by the employer into a health savings account (HSA) or similar consumer-directed spending account, if any. In addition to using these benefit design measures individually, we will test methods of constructing composite measures that reflect the overall level of generosity (or cost-sharing) offered by the individual's health insurance plan. One such composite measure will be constructed by using an average benchmark price for each service and procedure involved in a cancer screening (obtained from national data sources such as the Medicare fee schedule), combined with an individual's deductible and copayment requirements, to obtain a measure of an individual's expected out-of-pocket cost for each screening service. This measure will reflect the cost an individual patient would expect to pay for each service if no part of their annual deductible had been met previously.

Other Measures. A variety of other measures will be constructed from the MEPS data sources for possible use in the analysis as control variables, effect modifiers, and subgroup variables. These measures include age, gender, race/ethnicity, education, income, employment status, gender, marital status, usual source of care, proximity to nearest hospital and physician, rural/urban continuum code of residence, geographic region, type of insurance coverage and longitudinal stability of this coverage, self-reported health and functional status, disabilities, comorbidities, body mass index, prior and current health care utilization (hospitalizations, office visits, prescription drugs, other), and values and preferences concerning medical care.

D.2.2. Analytical Approach and Statistical Considerations

To isolate the effects of cost-sharing increases on screening rates, a hierarchical logistic regression model will be estimated for each type of cancer screening that expresses the likelihood of individual *i* in region *j* being in compliance with the screening recommendation in year *t* as:

[M.1] $$\Pr(\text{Compliance}_{ijt}=1)= \beta_0+\beta_1\text{Cost}_{ijt}+\beta_2\text{Patient}_{ijt}+\beta_3\text{Plan}_{ijt}+\beta_4\text{Provider}_{ijt}+\beta_5\text{Community}_{ijt}+\mu_i+\lambda_j+\varphi_t$$

where the *Cost* variable(s) capture cost-sharing levels due to deductible and copayment requirements. The model controls for a variety of potentially confounding factors including characteristics of the patient (e.g. age, race/ethnicity, income, education, health and functional status), health plan (e.g. open vs. closed network, referral requirements, employer-provided vs. individually purchased product, HSA vs. traditional insurance design), health care provider (usual source of care, practice type, specialty), and community (rural vs. urban, medically underserved area). The model also controls for unmeasured heterogeneity at the individual (μ_i) and regional (λ_j) levels and for general temporal trends (φ_t) that might otherwise lead to omitted variable bias in the analysis. The hierarchical structure of the model will be estimated using generalized estimating equations for longitudinal data.[68,69] The estimated coefficient β_1 and its standard error will be used to test the hypothesis that increases in cost-sharing are associated with reductions in screening compliance after controlling for other variables in the model.

Several variants of this model will be used to test other hypotheses of interest. For example, interaction terms between the cost-sharing variables and the race, ethnicity, and income variables will be used to test the hypothesis that increases in cost-sharing are associated with larger disparities in screening compliance. In other models, a measure of the actual out-of-pocket costs incurred by the individual will be added as a covariate in order to test the effects of this factor on screening compliance.

We will use additional methods to test for the possibility that our measures of cost-sharing and HSA enrollment are endogenous in the cancer screening analysis, thereby leading to bias in the estimates. Endogeneity bias may arise in the proposed analysis if unmeasured characteristics jointly influence an individual's propensity to enroll in a plan with high cost-sharing and their propensity to comply with cancer screening recommendations. For example, relatively healthy individuals with a high risk tolerance may be more willing than their counterparts to enroll in a high-deductible plan and to forego recommended cancer

screenings in order to reduce out-of-pocket health care costs.[70] Under this scenario, the model as specified may produce biased estimates if the identified covariates do not fully account for individual-level differences in health status and risk tolerance. To test for and correct this possible problem of endogeneity bias, we will use instrumental variables methods that rely on the identification of instruments that are correlated with an individual's selection regarding cost-sharing and HSA enrollment but are uncorrelated with their likelihood of cancer screening.[71] We will evaluate several employer characteristics for use as instruments in this model under the assumption that employers have significant influence over the health insurance options available to workers and families but they have little direct influence over screening decisions. These characteristics may include firm size, industry classification, ownership type, self-insurance, and involvement in collective bargaining. Standard specification tests for instrumental variables models will be used to evaluate the strength of the instruments and the degree of endogeneity bias that is present.

D.2.3. Analysis of Supplemental Cancer Insurance Policies

As a second component of the analysis of health insurance benefit changes, we will use administrative data from one of the nation's largest sources of supplemental cancer insurance policies to estimate the degree of take-up of these policies across the country and explore their possible effects on cancer screening and outcomes. Anecdotal evidence suggests that enrollment in supplemental cancer policies has been increasing in recent years, but relatively little is known about the design of these policies and their effects on cancer screening and treatment. These policies have the potential to reduce consumer out-of-pocket spending on screening services at the point of service and thereby promote greater compliance with screening guidelines. Alternatively, critics argue that supplemental policies have the potential to undermine demand for comprehensive health insurance policies that include more complete coverage for screening services, thereby eroding screening compliance. For these reasons we propose to conduct an exploratory investigation of supplemental cancer policies using data from a large insurance carrier, USAble Life, as a representative case study.

USAble insures over 1.1 million individuals in 48 states plus the District of Columbia, and has over $26.3 billion of insurance in force as of December 31, 2005. USAble's cancer policies offer supplemental coverage when health care expenses are incurred as a result of a diagnosis of cancer, regardless of whether the insurer has coverage from other sources such as a primary health insurance plan. The policies also offer a wellness benefit that includes reimbursement up to $75 per year for colorectal screening, mammography, pap smear, PSA, and other diagnostic tests for cancer. Because policy-holders receive a set nominal payment as reimbursement for any type of cancer screening procedure, the insureds are essentially pre-paying for cancer screening.

These policies have the potential to affect cancer screening behavior, particularly for individuals who do not have more generous coverage for cancer screening through a primary insurance policy. If supplemental cancer policies create a positive externality by encouraging insureds to be tested for cancer, policymakers should consider this information when regulating and taxing these products. We hypothesize that market penetration of supplemental cancer policies is positively related to the incidence rate of cancer screening. Alternatively, cancer policies might only be purchased by individuals who were already being screened regularly, suggesting that the policies are redundant.

Data and Measures. Individual- and claim-level data will be provided by USAble. Four calendar years of retrospective data on enrollment, demographics, and claims will be obtained for the years 2003-2006. These data will be matched with state-level data on cancer screening rates from the BRFSS.

Analytical Approach and Statistical Considerations. First, we will assess the rate of growth in enrollment in each state over the four year period and the demographic composition of enrollees. The trends observed for cancer policies in each state will be compared to trends observed in general health insurance policies in the same states. Next, we will measure the frequency of cancer screening claims processed in the cancer policies over the four year period and by state. Finally, we will assess the relationships between claim frequency for screenings in the cancer policies and overall cancer-screening rates by state. As part of this assessment, we will model the effect of supplemental cancer insurance on cancer-screening rates. At the state level, annual cancer screening rates will be regressed on annual market penetration measures for supplemental cancer insurance policies, along with a vector of control variables reflecting demographic, economic, and health insurance characteristics of the state population. Estimates

from this model will provide initial, ecological evidence about the association between cancer policy enrollment and cancer screening behavior. Findings will suggest issues for further study.

D.3. Aim 2: Effects of Insurance Mandates

In 1998, Illinois became the first state to pass a law requiring health insurers to provide coverage for colorectal cancer screening.[72] Missouri passed a comprehensive cancer screening law including coverage of colorectal cancer screening the following year, and in 2000, five additional states adopted screening laws. Currently 19 state legislatures, as well as the District of Columbia, have passed laws requiring insurance coverage for the full range of colorectal cancer screening tests, with recent adopters including Arkansas in 2005 and Alaska in 2006. Despite the growth of these laws, relatively little is known about their effectiveness in promoting access to cancer screening and about their impact on cancer outcomes, disparities, and costs. The need for such evidence is increasingly apparent as new states consider adopting similar measures and existing states consider dismantling their laws in an effort to reduce health insurance premiums.

To shed light on this important issue, we propose to conduct a detailed legal analysis of the attributes of state colorectal cancer screening mandates, noting how these policies vary in scope of coverage, enforcement provisions, and other key provisions. Using the resulting database of state CRC laws and regulations, we will conduct a series of quantitative analyses to estimate the impact of the mandates on screening rates, disparities in screening, and other outcomes of interest.

D.3.1. Legal Analysis of State Mandates

To achieve the goals of Aim 2, the project team will conduct a descriptive analysis of states that have adopted CRC benefit mandate laws to gain a granular picture of the legal environment in these states. These analyses will yield state-specific information regarding key provisions of the mandates in each state, including but not limited to coverage requirements, exemptions, implementation dates, and enforcement provisions. The analyses will also identify the provisions of related laws that grant exemptions and modifications to state insurance mandates, including laws allowing the sale of limited-benefit products.

Document review and analysis. We will start by extracting information on CRC laws from existing published reports and from established legislative tracking services and policy monitoring organizations, including the NCI's Legislative Database, the American Cancer Society, National Council of State Legislatures, National Governors Association and the National Association for State Health Policy. We will supplement these targeted searches with more general legal searches in the WestLaw and Lexux/Nexus databases. As a next step, the full text of all identified CRC statutes and related regulations will be retrieved and analyzed descriptively for design, content and key provisions. The investigative team will conduct detailed legal analyses of these provisions and their attending implementation and enforcement issues.

Interviews with state insurance commissioners. Information obtained from document analysis will be supplemented by qualitative information obtained by brief telephone interviews with the state insurance commissioners in each state that has adopted a CRC law. Interviews will confirm information gleaned from documents and will probe for additional issues concerning the design, operation, enforcement, and impact of the laws. Qualitative information about the how insurers and employers have responded to the laws will also be obtained through these interviews.

Summary database of laws and regulations. Findings regarding CRC laws will be collated and reported as a representational matrix of state level mandates, referred to as the state database of CRC laws and regulations. This database will be used to support the quantitative analyses of the impact of CRC laws on cancer screening, disparities, and outcomes.

D.3.2 Effects of Insurance Mandates on Colorectal Cancer Screening and Outcomes

As a second major aim, the proposed study will use a quasi-experimental research design to estimate the effects of state colorectal cancer benefit mandate laws on cancer screening, outcomes, and disparities. As of 2006, these laws exist in 19 states and vary considerably in their design and scope. All of these laws have gone into effect over the last eight years, leading to significant cross-sectional and longitudinal variation in exposure to the laws. The proposed analytical approach will capitalize on this variation by using a difference-in-difference research design that estimates the effects of the laws by comparing outcomes in states that did and did not implement the laws across time periods both before and after implementation of

the laws. The 31 states without laws, along with the pre-implementation time periods in the remaining states, will serve as statistical "control groups" for the analysis. As an additional level of control, the proposed design will compare screening rates and outcomes for CRC to similar screening rates and outcomes for breast, cervical, and prostate cancer. Because implementation of CRC laws should have no *direct* effects on screening for breast, cervical or prostate cancer, these other conditions will serve as control conditions in the proposed analysis. The following hypotheses will be tested empirically:

- H2.1: States that adopt CRC benefit mandate laws experience *higher* rates of compliance with guideline-recommended CRC screening after implementation than do states without these laws
- H2.2: States that adopt more stringent CRC laws experience *higher* rates of compliance with guideline-recommended CRC screening after implementation than do states with less-stringent laws.
- H2.3 States that adopt CRC laws experience *smaller* racial, ethnic, and income-related disparities in screening after implementation than do states without these laws
- H2.4 State CRC laws have *smaller* effects on the screening patterns of individuals who have *larger* cost-sharing requirements in the form of deductibles and copayments
- H2.5 States that adopt CRC benefit mandate laws have a *larger* proportion of their new CRC cases diagnosed at early stages after implementation than do states without these laws

To test these hypotheses, the database of state CRC laws and regulations created as part of the legal analysis will be combined with longitudinal, person-level data from three different sources. Data from the CDC's Behavioral Risk Factor Surveillance System (BRFSS) and the AHRQ MEPS survey will be used to examine the effects of state colorectal cancer laws on screening patterns, and the NCI Surveillance, Epidemiology, and End Results (SEER) system will be used to examine the impact of these laws on stage at cancer diagnosis. The analytical plan will vary somewhat across each of the three data sources.

D.3.2.1 Analysis of Screening Patterns Using BRFSS

Data and Measures. To test hypotheses concerning screening patterns, we will use national, longitudinal data from BRFSS for years 1997 through 2006. BRFSS is well suited for examining the effects of changes in state laws and regulations because its sampling design of more than 350,000 adults annually provides relatively precise state-level estimates of health behaviors and health care utilization, including cancer screenings. Each year BRFSS surveys a representative sample of adults age 18 years and older in each state by telephone to collect self-reported information about patterns of behavior, health services utilization, problems accessing needed care, and a variety of individual and household characteristics including insurance status, race/ethnicity, socioeconomic and employment information, and demographic information. Questions included on the BRFSS core instrument are implemented in all 50 states and the District of Columbia, and in 2004 the overall response rate for the core survey was 53 percent.

The BRFSS has included questions about colorectal cancer screening on its core instrument at least every two years since 1993, and since 1997 it has used question wording that has remained sufficiently consistent over time to allow longitudinal comparisons of screening rates.[73] These questions are asked of all survey respondents 50 years of age and older. In 2004, 142,000 respondents answered these questions. For the proposed analysis, we will build a person-year longitudinal data file containing observations on all adults 50 years of age or older who were included in the 1997, 1999, 2000, 2001, 2002, 2004, or 2006 BRFSS surveys. Each of these surveys included the colorectal questions of interest. The baseline year of 1997 in this data file is two years prior to implementation of the first state colorectal cancer law. In each wave of the survey we will exclude respondents who are enrolled in Medicare in order to avoid confounding due to the implementation of Medicare policies concerning CRC screening coverage. We may also exclude respondents with Medicaid coverage if we find evidence of significant confounding due to changes in state Medicaid policies for CRC coverage that are unrelated to the CRC mandate laws.

Colorectal screening measures will be constructed from the BRFSS data for use as the dependent variables in the analysis. Survey interviewers ask respondents age 50 years and older whether they have ever had a blood stool test using a home test kit (i.e., FOBT), whether they have ever had a sigmoidoscopy or colonoscopy, and when their latest test was performed. Responses to these questions will be used to construct a series of three screening measures for each person, indicating (1) whether an FOBT test was

received in the past year, (2) whether a sigmoidoscopy or colonoscopy was received in the past 10 years, and (3) whether at least one of these services was received during the recommended interval.[†]

Measures of each state's legal environment will be extracted from the database of state CRC laws and regulations to serve as the key independent variables of interest in this analysis. These measures will be merged onto the BRFSS person-year longitudinal data file using state and year as the identifying variables. These measures will vary by state and by year, and will be structured as a series of indicator variables denoting key provisions of each state's legal environment relevant to CRC screening, including: (1) whether a CRC coverage mandate existed in the state at the time of each survey-year; (2) the length of time during which the mandate had been in effect at the time of each survey-year; (3) whether the mandate requires insurers provide coverage on all policies vs. offer coverage to all purchasers; (4) whether coverage mandate provisions are consistent with screening guidelines of the U.S. Preventive Services Task Force or similar evidence-based guidelines; (5) whether the state has provisions that exempt certain types of purchasers or insurance policies from coverage mandates; (6) the relative strength of any incentives, penalties, or other enforcement provisions for coverage mandates; and (7) whether the screening mandate also includes outreach and education provisions such as notification requirements, media campaigns, or special screening programs for the uninsured or other groups not covered by the mandate. Provisions 3 through 6 will be used to indicate the relative stringency of each state's CRC law. Based on these characteristics we will develop a stringency index for each state to use in testing whether more stringent laws are associated with higher screening rates (hypothesis 2.2).

A number of other measures will be constructed from the BRFSS for possible use in the analysis as control variables, effect modifiers, and subgroup stratification variables. These measures include age, gender, race/ethnicity, education, income, employment status, gender, marital status, usual source of care, rural/urban continuum code of residence, type of insurance coverage, self-reported health and functional status, disabilities, comorbidities, and body mass index.

Finally, several state-level measures will be constructed from other secondary data sources and used as additional control variables in the model. These state-level measures will be designed to control for key differences across states in health resources, policies, and programs that may influence CRC screening. Because access to physicians may influence screening, the Area Resource File maintained by HRSA will be used to construct measures of the number of primary care physicians per 1000 residents and the number of gastroenterologists per 1000 residents in each state during each year of the analysis. The same data source will be used to construct a measure of the proportion of state residents residing in medically underserved areas each year. State-specific measures of endoscopic capacity are available from 15 states that participated in CDC's State-level Survey of Endoscopic Capacity (SECAP) during 2002-2005. Although these measures are not available for all states, we will conduct a sub-analysis that controls for state-level differences in endoscopic capacity using data from the 15 SECAP states.

Because state and local cancer prevention and control programs are likely to influence screening compliance, the U.S. Census Bureau's Consolidated Federal Funds Report database will be used to construct a measure of the total amount of federal CDC funding for cancer prevention and control programs allocated to grantees within each state during each year of the analysis. The Federal Catalog of Domestic Assistance will be used to identify relevant federal cancer programs to include in this measure. We will also construct a measure of which states are funded to implement specific CRC programs as part of their statewide cancer control plans through the CDC's National Comprehensive Cancer Control Program, using information from CDC's Division of Cancer Prevention Control. A total of 21 states are currently funded to implement such strategies.

Analytical Approach and Statistical Considerations. The analysis will begin with a thorough distributional analysis of the screening measures, legal measures, and control variables to detect any anomalous, missing or outlier values. Analysis of missing value patterns in the screening measures will be conducted to assess possible selection bias due to selective non-response to the colorectal screening questions. This analysis will test for demographic, socioeconomic, and other differences between groups of respondents who did and did not answer the screening questions. This analysis will also test for differences in missing value patterns between states and have and do not have CRC coverage laws. If selective non-

[†] Because the BRFSS survey questions do not distinguish between sigmoidoscopy and colonoscopy, an interval of 10 years is used for both procedures.

response patterns are identified, we will consider the use of re-weighting techniques to adjust for these patterns. For other variables to be used as control variables or effect-modification variables, we will we will examine rates of missing data patterns between states with and without CRC laws to assess their impact on study estimates. We will impute missing data for these variables using a multivariate MCMC algorithm appropriate for the arbitrary missing data mechanism to reduce vulnerability to selection bias.[74] If results indicate that data are missing according to a non-ignorable mechanism, alternative imputation mechanisms will be considered.

Bivariate chi-square tests of association will be used to assess the magnitude and significance of differences in screening rates between states that do and do not have CRC coverage mandates and differences in screening rates before and after implementation of the mandates. Unadjusted difference-in-difference tests will be used to assess these differences collectively using the following specification:

[M.2] $$DID = (Rate_{mandate,\ post} - Rate_{mandate,\ pre}) - (Rate_{non\text{-}mandate,\ post} - Rate_{non\text{-}mandate,\ pre})$$

where states are classified into mandate and non-mandate states based on the existence of a CRC law. To isolate the effects of the CRC laws and control for confounding factors, a hierarchical, difference-in-difference logistic regression model will be estimated that expresses the likelihood of individual *i* in state *j* being in compliance with CRC screening recommendation in year *t* as:

[M.3] $$Pr(Compliance_{ijt}=1) = \beta_0+\beta_1 Mandate_j+\beta_2 Post_{jt} +\beta_3 Mandate_j*Post_{jt} +\beta_4 Patient_{ijt}+\beta_5 State_{jt}+\lambda_j+\varphi_t$$

where the *Mandate* variable indicates those states that have passed CRC mandate laws and the *Post* variable indicates whether the year of the survey *t* is before or after implementation of the law in state *j*. The model controls for a variety of potentially confounding factors including characteristics of the patient (e.g. age, race/ethnicity, income, education, health and functional status, insurance source) and characteristics of the state (e.g. physician resources per capita, federal and state public health spending, prior-year CRC incidence and mortality rates). The model also controls for unmeasured heterogeneity at the state level (λ_j) and for general temporal trends (φ_t) that might otherwise lead to omitted variable bias in the analysis. The hierarchical structure of the model will be estimated using generalized estimating equations for longitudinal data.[68,69]

The coefficient β_3 associated with the interaction of the mandate and post variables will be used to test the hypothesis that implementation of mandate laws are associated with increases in CRC screening rates after controlling for other variables in the model (H2.1). This coefficient is the multivariate difference-in-difference estimate of impact.

Separate models will be estimated for subgroups of respondents based on insurance status due to the possibility that CRC laws have different mechanisms of effect on these different subgroups. Separate models will be estimated for (1) individuals with private insurance; (2) individuals with Medicaid coverage; and (3) individuals without any private or public coverage. For privately insured individuals, the effects of the laws may depend on whether coverage is obtained from fully-insured or self-insured employers.[‡] For Medicaid recipients, the effects of the laws may be modified by state Medicaid policies and programs. For uninsured individuals, the laws are likely to have only indirect effects on screening rates through their impact on providers of screening services and their willingness and ability to serve the uninsured. Unmeasured socioeconomic, health and behavioral differences among these subgroups may also contribute to differences in their responses to CRC laws. These possibilities will be investigated empirically by comparing estimates from the separate models.

Several variants of this model will be used to test other hypotheses of interest. First, interaction terms between the mandate, post, and race/ethnicity variables will be used to test the hypothesis that CRC mandate laws are associated with reduced disparities in screening compliance (H2.3). Similarly, interaction terms between the mandate, post, and income variables will be used to test the hypothesis that CRC mandate laws are associated with reduced screening disparities among income subgroups.

We will use additional methods to test for the possibility that state CRC mandate laws are endogenous in the cancer screening model, thereby leading to bias in the model's estimates. Endogeneity bias may arise in the proposed model if unmeasured characteristics in the population jointly influence the state's propensity

[‡] Self-insured employers are exempt from state insurance regulations due to the federal ERISA law, but they may voluntarily comply with some state regulations.

to adopt CRC laws as well as the propensity of residents in that state to comply with cancer screening recommendations. For example, states with strong CRC advocacy and service organizations may be more likely to secure the passage of CRC laws and, simultaneously, more successful in mounting CRC education and outreach programs within the state that encourage screening. Under this scenario, the model as specified may produce biased estimates if the identified covariates do not fully account for state-level differences in CRC advocacy and outreach intensity. To test for and correct this possible problem of endogeneity bias, we will use instrumental variables methods that rely on the identification of instruments that are correlated with a state's likelihood of adopting CRC laws but are uncorrelated with factors that affect cancer screening within the state. We will investigate several possible measures to use as instruments, such as the number and types of other health insurance mandates adopted previously in the state, and the existence, age and membership size of the state cancer coalition. Standard specification tests for instrumental variables models will be used to evaluate the strength of the instruments and the degree of endogeneity bias that is present.

Confirmatory Analyses. Finally, we will conduct a series of confirmatory analyses to provide further evidence on the effects of state CRC laws. The confirmatory analyses will be based on the expectation that the effects of CRC laws should be largely isolated to CRC screening behavior and should have minimal spill-over effects on screening take-up for other cancer risks. As a result, if CRC laws are effective we should expect to see larger increases in CRC screening after passage of the laws than in screening for other cancers such as breast, cervical, and prostate. Although other activities and interventions have been implemented during the study period to promote screening for other cancers, these activities are unlikely to coincide closely with the pattern of adoption observed for state CRC laws across the nation. To test this hypothesis, we will estimate a series of multivariate models that follow the specification outlined for model [M.3] above but that use measures of screening compliance for breast, cervical, and prostate cancer as dependent variables. Results will be compared with those from the CRC models described above to determine whether the findings are consistent with the hypothesis that CRC laws, rather than generalized temporal trends, are contributing to increases in compliance with CRC screening recommendations.

Limitations of the Analysis: Findings from this analysis will be subject to several limitations. First, BRFSS data may overestimate actual colorectal cancer screening rates because the survey does not determine the indication for the test (i.e., screening versus diagnostic use) and because the question assessing endoscopy use within 10 years includes persons who had sigmoidoscopy more than 5 years preceding the survey and, therefore, were not compliant with screening recommendations. Second, because BRFSS is administered by telephone, only persons with land-line telephones will be represented in the analysis. Third, BRFSS data are self reports and not validated by medical record review, making the data vulnerable to recall bias. Finally, BRFSS survey response rates are relatively low (53 percent in 2004), raising the possibility of selection bias that limits the external validity of results. Nevertheless, we do not expect the incidence of these data limitations to be substantially different in states with and without CRC laws, and therefore we do not expect these limitations to cause substantial bias in our estimates of the association between laws and screening compliance.

D.3.2.2 Analysis of Screening Patterns Using MEPS

To investigate how CRC laws interact with insurance designs to influence screening patterns (hypothesis 2.4), a similar multivariate analysis will be conducted using longitudinal panel data from MEPS. MEPS uses a considerably smaller sample size than BRFSS and lacks sufficient sampling in each state to allow for precise estimation of state-level policy effects. However, MEPS collects much more detailed information on health insurance design features than other available national surveys. As such, MEPS provides the best opportunity for investigating how CRC laws interact with health insurance designs and cost-sharing requirements in influencing compliance with CRC screening recommendations. For this reason, we propose to repeat the multivariate analysis of screening patterns outlined for use with BRFSS data, but instead use MEPS data and a more detailed set of variables on insurance design available from this data source.

Data and Measures. This analysis will use data from the 1997 to 2006 waves of the MEPS household and insurance components. The same measures of CRC cancer screening, insurance benefit design and cost sharing, and patient characteristics used in Aim 1 (Section D.2.1) will be constructed and used for this analysis. Information on the state of residence for each individual in the 1997-2006 combined survey sample will be used to link each observation to the corresponding set of state legal environment variables

from the database of state CRC laws and regulations. This linkage and the subsequent analysis will require analysis of protected data from MEPS; therefore, these activities will be performed at the AHRQ data center in Rockville. As additional control variables, the analysis will use the state-level measures of health resources, policies, and programs constructed for the BRFSS analysis described above.

Analytical Approach and Statistical Considerations. A hierarchical, difference-in-difference logistic regression model will be estimated that uses the same form and specification as used in model [M.3] for the BRFSS data. As in the earlier model, the dependent variable indicates whether an individual is in compliance with CRC screening recommendations, and the model controls for individual-level and state-level characteristics plus unmeasured state-level heterogeneity and general temporal trends. Variables reflecting health insurance designs and cost-sharing requirements will be added as additional independent variables of interest in this model. Of primary interest, we will include in the model an interaction term between the *mandate* variable (indicating states that did and did not implement CRC laws), the *post* variable (indicating periods before and after implementation of mandates), and the *cost-sharing* variable (indicating the level of cost-sharing required by the insurance plan). The estimated coefficient for this interaction term, along with its standard error, will be used to test the hypothesis that state CRC laws have differential effects on the screening patterns of individuals with different cost-sharing requirements (H2.4).

D.3.2.3 Analysis of Early Detection Patterns Using SEER

As a third component of this analysis, we will combine the legal variables from the database of state CRC laws and regulations with person-level, longitudinal data from the Surveillance Epidemiology and End Results (SEER) system from 1997-2006 in order to estimate the effects of the CRC laws on stage of colorectal cancer at diagnosis. If CRC laws are effective in increasing compliance with CRC screening recommendations, these higher compliance rates can be expected to lead to larger proportions of cancer cases detected at early stages.[75,76] More distal outcomes may include reductions in CRC mortality as cancer patients initiate treatment at earlier stages, as well as reductions in CRC incidence as larger numbers of at-risk individuals have pre-cancerous lesions detected and removed.[77]

Data and Measures: SEER is the only comprehensive cancer data source in the U.S. that includes stage of cancer at the time of diagnosis and patient survival data. SEER collects cancer incidence and survival data from population-based cancer registries covering approximately 26 percent of the US population, including 23 percent of African Americans, 40 percent of Hispanics, and 53 percent of Asians. This system includes cancer data from all or parts of five states that have adopted CRC laws over the past six years: New Jersey, Louisiana, Georgia, Connecticut, and Alaska. Eight other states without CRC laws are represented in SEER. As a result, SEER is the best existing data source for investigating the effects of state CRC laws on patterns of cancer diagnosis and outcomes.

The SEER databases will be used to develop a patient-level analytical data file containing all patients diagnosed with colorectal cancer during the study period 1997 to 2006. Because SEER data for 2006 will not be available until Year 3 of the proposed study, we will construct an initial data file using earlier years of SEER data and add subsequent years later in the project as they become available. Using information on the year and state of residence of each cancer case, we will merge in corresponding state-level variables on the legal environment from this project's database of state CRC laws and regulations.

The primary outcome variable of interest for this analysis is the proportion of CRC cases diagnosed at each AJCC stage each year. A summary variable distinguishing early-stage and late-stage diagnoses will also be used in the analysis. As an additional outcome measure, we will examine the adjusted risk of death (through 2006) among cases diagnosed prior to 2004. The independent variables of primary interest in this analysis are the measures of state CRC laws and the interaction of these laws with race and ethnicity.

Analytical Approach and Statistical Considerations. We will begin by assessing bivariate relationships between the existence of state CRC laws and the proportion of CRC cases diagnosed at each stage, making comparisons both before and after implementation of the laws. Chi-square tests will be used to assess the statistical significance of these relationships. Unadjusted difference-in-difference tests will be used to assess differences in the rate of late-stage cancer diagnoses between states with and without CRC laws at time periods before and after implementation of the laws. The specification shown in equation [M.2] above will be used for this comparison.

If significant baseline differences are found between mandate states and non-mandate states in the rates of late-stage diagnoses or in the distribution of important covariates such as age, gender and race/ethnicity, we will use propensity score matching methods to identify a subgroup cases in the non-mandate states each year that are well-matched to the cases identified in the mandate states.[78,79] These matched groups of cases will be used in subsequent analyses to estimate the effects of CRC laws on stage at diagnosis.

To isolate the effects of the CRC laws and control for confounding factors, a hierarchical, difference-in-difference logistic regression model will be estimated that expresses the probability of being diagnosed at a late stage as a function of exposure to state CRC laws (based on state of residence and year of diagnosis) along with available patient characteristics including age, gender, race and ethnicity. The hierarchical model specification will also control for unmeasured heterogeneity at the state/registry level and for general temporal trends, as indicated in the model specification shown in equation [M.3] above. The hierarchical structure of the model will be estimated using generalized estimating equations for longitudinal data. The estimated coefficients from this model will be used to construct regression-adjusted odds ratios expressing the risk of a late-stage cancer diagnosis in states with and without CRC laws. The model will also include interaction terms between the CRC law variable and race and ethnicity variables, thereby supporting a test of whether CRC laws are associated with reductions in the disparity of late-stage cancer diagnoses across racial and ethnic subgroups.

A complicating factor for this analysis is the possibility that an individual's stage of cancer at diagnosis is related not only to the existence of a CRC law but also to the length of time that the law has been in effect. When states first adopt such laws, increased screening may lead to increased diagnoses of mid-stage (regional) and late-stage cancers because of the historically low rates of CRC screening. As screening rates persist over time and undiagnosed cancer cases are identified and moved into treatment, the rates of early-stage diagnoses may increase. To test for this possibility, a measure of the elapsed time since implementation of the CRC law will be added to the model as an explanatory variable.

As a final analysis, we will examine the association between CRC laws and the two-year adjusted risk of death among persons diagnosed with CRC using Cox proportional hazards regression analysis. Hazard rates will be adjusted for exposure to state CRC laws and for other patient characteristics that may be associated with mortality, such as age, sex, race and ethnicity, and year. The model will use a generalized estimating equations (GEE) specification to control for unobserved heterogeneity at the state/registry level that causes correlation among observations from the same geographic area.[68] Interaction terms between CRC laws and race and ethnicity variables will be included to test for the laws' possible effects on disparities in mortality. The model will be limited to patients diagnosed with CRC between 1997 and 2004 in order to allow for a minimum mortality follow-up period of 2 years for all patients. Estimates from the model will be used to compare the adjusted risk of death in states with and without CRC laws, both overall and within racial and ethnic subgroups.

D.4. Aim 3: Effects of Mandates on Insurance Premiums and Distribution of Costs

D.4.1. Analysis of Insurance Premiums

The detailed legal information concerning state colorectal cancer insurance mandates assembled under Aim 2 will be combined with insurer-level, longitudinal information on health insurance premiums from the National Association of Insurance Commissioners (NAIC) from 1997-2006 in order to estimate the effects of the colorectal mandate laws on private health insurance premiums. This analysis will test two hypotheses: (1) the introduction of mandated coverage laws for CRC are associated with increases in the price of insurance; and (2) the price increases associated with CRC laws are associated with reductions in health insurance coverage.

Data and Methods: To test the first hypothesis, we will link state-level data on CRC laws from the database assembled under Aim 2 with longitudinal data from NAIC on insurance premiums and medical losses for each insurer operating in each state during each year of study. Bivariate t-tests will be used to test for differences in annual premium increases between states with and without CRC laws. Using the specification shown in equation [M.2] above, unadjusted difference-in-difference tests will be used to assess differences in premiums between states with and without CRC laws at time periods before and after implementation of the laws. Next, OLS and logarithmic regression models will be used to estimate the association between CRC laws and insurance premium increases while controlling for confounding variables including individual-, state-, and insurer-level factors such as demographics and firm size. A

quantile regression model will also be used to assess the distributional effects of CRC laws on insurers of varying sizes.

To test the second hypothesis regarding prices and insurance coverage, the state-level data on CRC laws and premiums will be linked with individual-level data on health insurance coverage, demographic characteristics, and socioeconomic characteristics from the Current Population Survey (CPS) Annual Demographic Survey (March Supplement) for the same period 1997-2006. The CPS-ADS surveys a nationally representative sample of approximately 50,000 households each March, including sub-samples in each U.S. state. Using this combined dataset, bivariate tests of association will be used to examine the associations between CRC laws, premium increases, and health insurance coverage. A multivariate logistic regression model will then be used to estimate the association between premium increases and health insurance coverage while controlling for a variety individual, household, and state characteristics affecting coverage decisions. To control for the potential endogeneity of premium increases, an instrumental-variables approach will be employed that uses the measures of CRC laws as instruments to predict premium increases.

D.4.2. Analysis of Medicare Treatment Costs

As a final component of this analysis, we will combine the legal information from Aim 2 with person-level, longitudinal data from the linked SEER-Medicare claims database from 1997-2006 in order to estimate the effects of the CRC insurance mandates on Medicare cancer treatment costs. If the mandates are successful in increasing CRC screening rates among the privately-insured pre-Medicare population, this has the potential to reduce the volume of cancer cases aging into the Medicare program and thereby reduce the intensity of CRC treatment funded by Medicare. Under this hypothesis, CRC laws would lead more patients to be diagnosed at earlier stages—perhaps undergoing treatment before even becoming eligible for Medicare—and some cancer cases would be prevented altogether. If Medicare savings can be documented empirically, this evidence could become a powerful economic justification for expanding CRC mandates and investing in other outreach activities to improve screening rates. The primary hypotheses to be tested are: (H3.1) cancer patients residing in states with CRC laws have their cancers diagnosed at earlier stages compared to patients in states without CRC laws; and (H3.2) cancer patients residing in states with CRC laws generate lower overall Medicare spending compared to patients in states without CRC laws. The approach for testing hypothesis H3.1 will be identical to those used the analysis of SEER data in Aim 2. The remainder of this section presents the approach for testing the spending hypothesis H3.2.

Data and Measures: The SEER-Medicare linked claims database contains cancer incidence and survival data from the SEER population-based cancer registries, wherein each cancer case that receives Medicare coverage is linked to its corresponding Medicare claims records that contain documentation on all inpatient and outpatient health care utilization (except outpatient prescription drugs). As in the analysis of SEER data under Aim 2, we will develop a patient-level analytical data file containing all Medicare patients diagnosed with colorectal cancer during the study period from 1997 to 2004. Using the linked Medicare claims files through calendar year 2006, for each patient we will aggregate claims records and construct measures of inpatient, physician, outpatient, and home health care utilization and expenditures for a minimum two-year period (or until death). Because SEER-Medicare data for 2006 will not be available until Year 3 of the proposed study, we will construct an initial data file using earlier years of SEER data and add subsequent years later in the project as they become available.

Using information on the year and state of residence of each cancer case, we will merge in corresponding state-level data on the legal environment from the project's database of state CRC laws and regulations. We will then classify each patient based on their residence in a mandate or non-mandate state and based on whether their Medicare eligibility and cancer diagnosis occurred before or after implementation of the mandate (if any).

Analytical Approach and Statistical Considerations: After conducting detailed distributional assessments of all variables and their missing and extreme values, Bivariate chi-square tests of association will be used to assess the magnitude and significance of differences in Medicare spending between patients in states that do and do not have CRC laws, as well as differences in spending before and after implementation of the laws. Unadjusted difference-in-difference tests will be used to assess these differences collectively using the specification noted in Aim 2 (equation M.2). To better isolate the effects of the CRC laws and control for confounding factors, a hierarchical, difference-in-difference semilogarithmic regression model will be

estimated that expresses the log of Medicare spending as a function of being diagnosed in a state with or without CRC laws, being diagnosed in the pre-implementation or post-implementation period, and a series of patient-level control variables including demographics, race/ethnicity, and comorbidities unrelated to cancer. The model will also control for unobserved heterogeneity at the state/registry level and general time trends. The coefficient on the interaction term between the CRC law variable and the pre/post implementation variable will be used to test the hypothesis that spending is significantly lower in the CRC law states after implementation of the laws. An additional interaction term between CRC law, post-intervention, and the race/ethnicity variables will be used to test whether disparities in spending are lower after implementation of the CRC laws.

We will perform a large number of specification tests and robustness tests on the expenditure estimation model, including using a multi-part model rather than a single semi-logarithmic model to account for skewness, outlier observations, and mass-points at zero on the spending variables.[80,81] As in Aim 2, we will test for the endogeneity of the CRC laws in this model and use appropriate instrumental-variable methods of correction if this problem is identified.

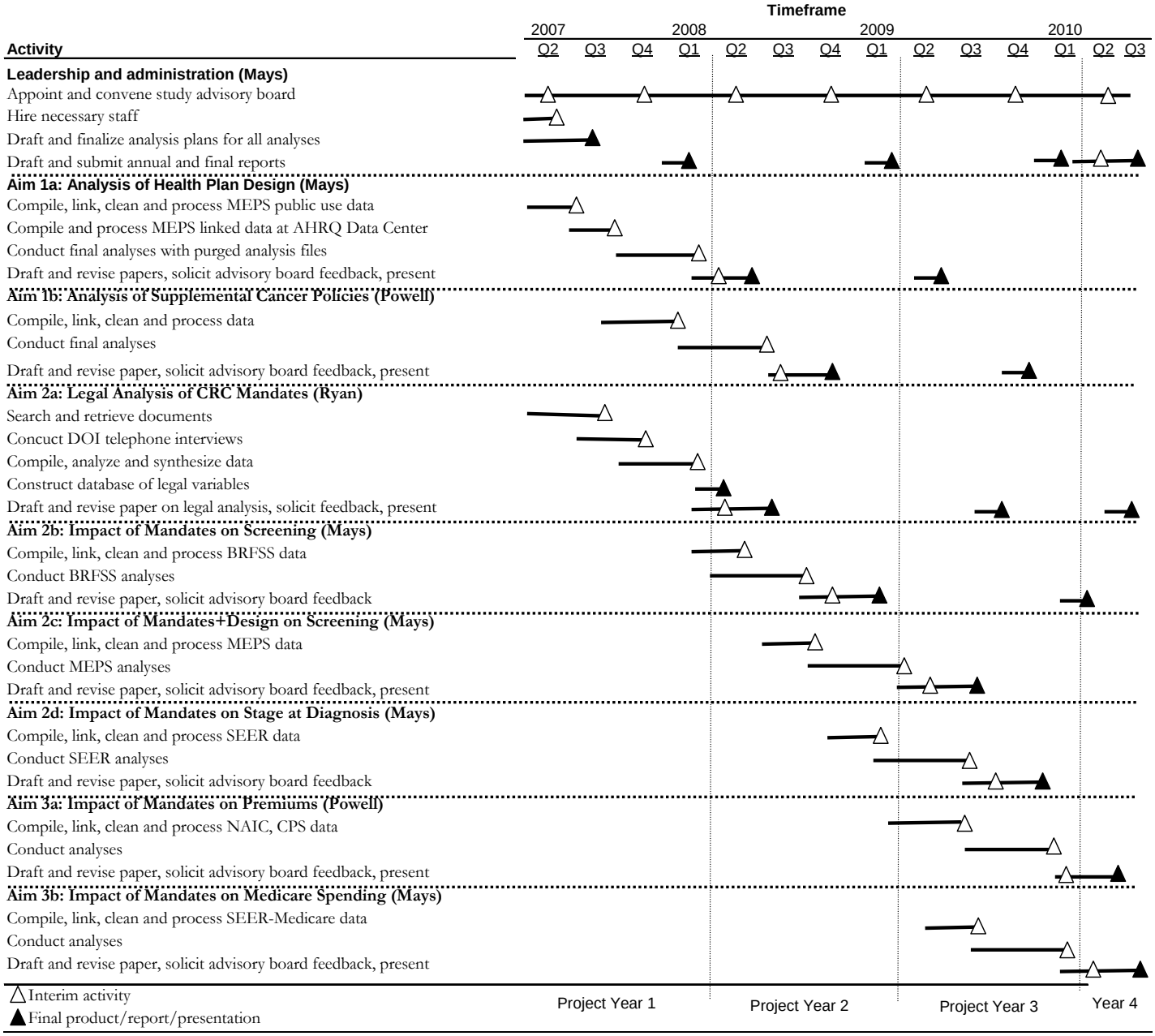
D.5. Work Plan, Time Line, and Dissemination of Products

Due to the relatively large number of analyses and the complexities of the different data sources used, the proposed investigation will be implemented on a staged basis over a 3.5 year period. Each of the proposed quantitative analyses is modular and separable, while the legal analysis is integrated and used in nearly all of the other components of the investigation. As a result, it will be possible to implement a subset of the proposed quantitative analyses if sufficient resources are not available to complete all analyses as proposed. **Figure 1** displays the proposed work plan and timeline for the investigation. As noted, an advisory board will be appointed to provide guidance in the design and conduct of the research activities. The board will be comprised of 5 voluntary members who are either local or national experts in cancer research and/or health services research. Board members will be convened twice per year by teleconference to review analysis plans and comment on research products.

E. STATEMENT OF CANCER RELEVANCE

The proposed study will allow clinical and policy decision-makers, as well as private-sector decision-makers, to better understand how health insurance designs and regulatory provisions are affecting colorectal cancer screening and related cancer outcomes and disparities. Findings from the research will point to opportunities for improving access to cancer screening through alternative ways of designing health insurance benefits and through alternative policy and regulatory initiatives involving health insurance. Specifically, the findings from this investigation will suggest new directions for insurance policy, outreach and assistance initiatives, and private sector purchasing practices in order to reduce colorectal cancer burden and disparities.

Figure 1: Timeline and Work Plan for the Proposed Project



FACILITIES

Computer resources to be used by study investigators are high-capacity personal computers with high-speed Pentium processors linked by a secure, password protected local area network. Two password, secure SAS servers are available and currently house administrative and survey data. Software to be used for data analysis include SAS, STATA, TreeAge, and Atlas.ti.

Office: Investigators have access to general office equipment including copiers, printers, and scanners. Research staff also have private offices with full telecommunications capacities for conducting telephone interviews.

Other: A full-service health sciences library is available on the UAMS campus providing investigators with electronic and print access to a comprehensive array of journals and books for literature reviews. Large meeting rooms are available for hosting focus groups and advisory group meetings.

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