



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Office of Research, Development & Information
7500 Security Boulevard
Baltimore, MD 21244-1850

Department of Health and Human Services (DHHS)

The Centers for Medicare & Medicaid Services (CMS)

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2005 EDITION – INITIAL ANNOUNCEMENT

**CANCER PREVENTION AND TREATMENT DEMONSTRATION
FOR ETHNIC AND RACIAL MINORITIES**

Funding Opportunity Number CMS-5036-N

CFDA No. 93.779

Application due date: **March 23, 2005**

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FUNDING OPPORTUNITY ANNOUNCEMENT**OVERVIEW INFORMATION:**

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Centers for Medicare & Medicaid Services
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Ethnic and Racial Minorities

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Award Announcement	June-July 2005
Cooperative Agreement Period	3-5 years after award

Executive Summary

Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Cooperative Agreements

CMS is soliciting proposals from interested parties to implement and operate cooperative agreement demonstration projects under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities as required by Section 122 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). This legislation requires the Secretary of the Department of Health and Human Services (DHHS) to evaluate best practices and design, implement and evaluate demonstration projects for targeted ethnic and racial minorities. These demonstration projects will focus on new and innovative intervention models that improve the quality of items and services provided to target individuals in order to facilitate reduced disparities in early detection and treatment of cancer; improve clinical outcomes, satisfaction, quality of life, and appropriate use of Medicare-covered services and referral patterns among those target individuals with cancer; eliminate disparities in the rate of preventive cancer screening measures, such as pap smears and prostate cancer screenings, among target individuals; and promote collaboration with community-based organizations to ensure cultural competency of health care professionals and linguistic access for persons with limited English proficiency. Each project will stress the use of evidence-based, culturally competent models that will target efforts to decrease risk factors and increase screening rates and access to treatment and survival for cancers of the breast, cervix, colon, or prostate.

The Congress authorized the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities project for a potentially indefinite period of time, and appropriated \$25 million in funding for the initial phase of the program. The demonstration projects will have a 3- to 5-year operation period. CMS will consider an award of up to \$50,000 per demonstration project to cover initial implementation costs. The entire award will not be made initially but will be distributed incrementally between the time of conditional award and the approval of the demonstration by the Office of Management and Budget. CMS expects the costs of conducting these demonstration projects to range from \$400,000 to \$1.5 million per project per year. These costs will be reimbursed through capitation payment to the demonstration site. No State or local matching funds are required. CMS encourages applicants to propose innovative intervention models with the appropriate payment requirements and operational processes required to successfully implement the models. Through the solicitation, CMS intends to award at least 9 demonstration projects. CMS anticipates that projects will be awarded in mid-2005, and that project startup activities would begin immediately after completion of the waiver cost process (in late 2005).

Each of the following four legislatively-mandated target populations are required to be the subject of two separate demonstration projects: American Indians (including Alaskan Natives, Eskimos, and Aleuts), Asian Americans and Pacific Islanders, Blacks, and Hispanics. In addition, of the nine demonstration projects, at least one must take place in a rural area and one

in an inner-city area. Finally, one of the demonstration projects must be implemented in the Pacific Islands.

The facilitation activities to be funded within this solicitation will focus on three areas of cancer disparity reduction: screening, diagnosis, and treatment. The applicant will provide facilitation services for two populations: (1) Medicare beneficiaries belonging to a defined ethnic or racial minority group who do not have a current diagnosis of cancer prior to enrollment in the demonstration project; and (2) Medicare beneficiaries belonging to a defined ethnic or racial minority who have been diagnosed with cancer prior to enrollment in the demonstration project. For the first population, the applicant must propose strategies for improving outcomes for cancers of the breast, cervix, colon and/or rectum, and prostate through facilitation of: (1) cancer screening services; (2) follow-up of abnormal findings and diagnosis; and (3) improved access to and follow-up of treatment and adjuvant treatment services. For the second population, the applicant must propose facilitation strategies to improve access to and follow-up of treatment and adjuvant treatment services for confirmed diagnosis of at least one of the demonstration-specified cancers and/or lung cancer. Projects are expected to use the best available scientific evidence to identify promising models of cancer detection and treatment to promote health and the appropriate utilization of Medicare covered services, in order to eliminate disparities in cancer detection and treatment among ethnic and racial populations of Medicare beneficiaries.

FULL TEXT OF ANNOUNCEMENT

I. Funding Opportunity Description: Request for proposals

A. Project Description

CMS is soliciting proposals from interested parties to implement and operate cooperative agreement demonstration projects under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities as required by Section 122 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000. This legislation requires the Secretary of the Department of Health and Human Services (DHHS) to evaluate best practices in the private sector, community programs, and academic research to identify methods that reduce disparities among individuals of ethnic and racial minority groups in the prevention and treatment of cancers. Based on this information, the Secretary is required to design and implement at least nine demonstration projects in specified target populations for the purpose of developing models and evaluating methods that: (1) improve the quality of items and services provided to target individuals in order to facilitate reduced disparities in early detection and treatment of cancer; (2) improve clinical outcomes, satisfaction, quality of life, and appropriate use of Medicare-covered services and referral patterns among those target individuals with cancer; (3) eliminate disparities in the rate of preventive cancer screening measures; and (4) promote collaboration with community-based organizations to ensure cultural competency of health care professionals and linguistic access for persons with limited English proficiency.

The Congress authorized the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities project for a potentially indefinite period of time, and appropriated \$25 million in funding for the initial phase of the program. The demonstration projects will have a 3-to-5-year operation period. CMS will consider an award of up to \$50,000 per demonstration project to cover initial implementation costs. The entire award will not be made initially but will be distributed incrementally between the time of conditional award and the approval of the demonstration by the Office of Management and Budget. CMS expects the costs of conducting these demonstration projects to range from \$400,000 to \$1.5 million per project per year. These costs will be reimbursed through capitation payment to the demonstration site. No State or local matching funds are required. CMS encourages applicants to propose innovative intervention models with the appropriate payment requirements and operational processes required to successfully implement the models. Through the solicitation, CMS intends to award at least 9 demonstration projects. CMS anticipates that projects will be awarded in June-July 2005, and that project startup activities would begin immediately after completion of the waiver cost process (in late 2005).

Each of the following four legislatively-mandated target populations are required to be the subject of two separate demonstration projects: American Indians (including Alaskan Natives, Eskimos, and Aleuts), Asian Americans and Pacific Islanders, Blacks, and Hispanics. Each of the two projects for the four populations must target different ethnic subpopulations; for example:

- (1) American Indians includes Alaskan Natives, Eskimos, Aleuts, and South and Central American
- (2) Asian Americans and Pacific Islanders includes Far Eastern, Southeast Asian, Cambodian, Chinese, Indian, Japanese, Korean, Malaysian, Pakistani, Philippine Islander, Thai, Vietnamese, and Native Hawaiian.
- (3) Black includes African American, Haitian, or a person having origins in any of the black racial groups of Africa.
- (4) Hispanic and Latino includes Mexican, Cuban, Puerto Rican, South or Central American, or other Spanish culture or origin.

In addition, of the nine demonstration projects, at least one must take place in a rural area and one in an inner-city area. A Metropolitan Statistical Area (MSA) is a county or group of counties that includes a city of 50,000 or more or an urbanized area with at least 50,000 people that is in itself part of a county or counties with at least 100,000 residents. The definition of a “rural area” is an area outside a Metropolitan Statistical Area. The definition of an “urban area” is an area located within a Metropolitan Statistical Area. For the purposes of this solicitation, “inner cities” are defined as core urban areas that currently have higher unemployment and poverty rates and lower median income levels than the surrounding MSA.

Furthermore, Section 122(b)(2)(B) of the legislation specifies that a demonstration project must be implemented in the Pacific Islands. Section 122(e)(1)(A) specifies that the Medicare Trust Funds legislated for this demonstration effort are to be applied *only* to those projects implemented within the *States*. Regarding the funding of the Pacific Islands project, however, Section 122(e)(1)(B) states that in the case of a demonstration project described in subsection (b)(2)(B), amounts must be available only as provided in any Federal law-making appropriations for the territories.” No subsequent legislation has provided specific funding for a Territory project. Therefore, CMS will not implement a project in the territories but does plan to implement at least one project in Hawaii, since Hawaii is a Pacific Islands State, and Native Hawaiians are considered Pacific Islanders. (According to U.S. Census 2000, the definition of a Pacific Islander is “a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. It includes people who indicate their race as “Native Hawaiian,” “Guamanian or Chamorro,” “Samoaan,” and “Other Pacific Islander.”)

Finally, the legislation states that if the initial demonstration evaluation indicates that these projects—(1) reduce Medicare expenditures; or (2) do not increase Medicare expenditures, reduce ethnic and racial health disparities, and increase beneficiary and health care provider satisfaction, the existing demonstration projects will continue, and the number of demonstration projects may be expanded in the future.

The facilitation activities to be funded within this solicitation will focus on three areas of cancer disparity reduction: screening, diagnosis, and treatment. The applicant will provide facilitation services for two populations: (1) Medicare beneficiaries belonging to a defined ethnic or racial minority group who do not have a current diagnosis of cancer prior to enrollment in the demonstration project; and (2) Medicare beneficiaries belonging to a defined ethnic or racial minority who have been diagnosed with cancer prior to enrollment in the demonstration project. For the first population, the applicant must propose strategies for improving outcomes for

cancers of the breast, cervix, colon and/or rectum, and prostate through facilitation of: (1) cancer screening services; (2) follow-up of abnormal findings and diagnosis; and (3) improved access to and follow-up of treatment and adjuvant treatment services. For the second population, the applicant must propose facilitation strategies to improve access to and follow-up of treatment and adjuvant treatment services for confirmed diagnosis of at least one of the demonstration-specified cancers and/or lung cancer. Projects are expected to use the best available scientific evidence to identify promising models of cancer detection and treatment to promote health and the appropriate utilization of Medicare covered services, in order to eliminate disparities in cancer detection and treatment among ethnic and racial populations of Medicare beneficiaries.

Participation in this demonstration will be voluntary and will not change the amount, duration or scope of a beneficiary's fee-for-service Medicare benefits. Claims for medical services provided to participating beneficiaries will continue to be covered, administered, and paid for under Medicare. Beneficiaries who are enrolled in managed care plans or who are institutionalized are not eligible to participate in this demonstration project. Special demonstration billing codes will be established to allow reimbursement for the annual cancer screening assessment for the intervention group, the entrance and exit cancer screening assessment for the control group, and the monthly capitated rates for cancer screening, diagnostic, and treatment facilitation services. No beneficiary coinsurance or deductible will be applied to the monthly capitated rates. Providing these services to beneficiaries without cost eliminates a potential financial barrier to willingness to participate and avoids a layer of complexity in the billing requirements both for CMS and the demonstration projects. A site may choose to waive coinsurance for cancer screening services and pay the difference out of its budget.

B. Background

1. Evidence of Cancer Disparities in Incidence, Mortality, and Survival

Since 1993, key indicators have shown that our Nation's health has greatly improved. However, this result does not apply to all Americans, a fact that has been recognized by leading organizations and health care researchers across the United States. Cancer is currently the second leading cause of death in the United States, and substantial evidence indicates that a disproportionate share of cancer incidence and mortality falls on minority populations. The recently published National Healthcare Disparities Report, prepared by the Agency for Healthcare Research and Quality (AHRQ), provides a summary of the state of disparities in the United States (<http://www.ahrq.gov/qual/nhdr03/nhdrsum03.htm#References>). It provides a comprehensive view of the scope and characteristics of differences in health care quality and access associated with patient race, ethnicity, income, education, and place of residence. The report reflects seven key findings: inequality in quality exists; health care disparities are costly; differential access may lead to disparities in quality; opportunities to provide preventive care are frequently missed; knowledge of why disparities exist is limited; improvement is possible; and data limitations hinder targeted improvement efforts.

A Trans HHS Cancer Health Disparities Progress Review Group (PRG) convened by the National Cancer Institute (NCI) recently completed a report entitled "Making Cancer Health

Disparities History” that examined and made recommendations to reduce and eliminate health disparities associated with cancer (<http://www.chdprg.omhrc.gov/pdf/chdprg.pdf>):

As the background paper makes clear, most of the research to date has focused on identifying disparities, the purported factors creating and perpetuating the disparities, and the trends over time. Less research has focused on studies of interventions designed to reduce disparities. [Nevertheless] A large body of research focused largely, but not exclusively, on White, middle-class populations appears to provide adequate scientific evidence to suggest that an increased investment in a coordinated dissemination of evidence-based cancer prevention and early detection interventions would reduce disparities in cancer risk factors and late-stage disease, and eventually eliminate disparities in cancer mortality.... The failure to deliver evidence-based programs and products of health research to high-risk and medically underserved populations contributes to health disparities.... Moreover, intervention approaches to reduce health disparities cannot exclusively focus on individual behavior change. Future efforts should include evidence-based family-focused approaches and institutional, system and public policy changes to synergistically reinforce evidence-based individual behavior change approaches.... We believe that the barriers [to eliminating cancer health disparities] are ultimately surmountable and that progress can be made toward eliminating disparities in delivery of cancer services through....increased interest in and evaluation of the use of health advisors who can educate and assist individuals from tribal and other communities in a culturally competent manner. Patient advocates, patient navigators, community lay workers, *promotoras*, and certified medical interpreters can ensure that patients understand their risks, diagnoses, and treatment options and can improve access to the continuum of care required for favorable outcomes.

According to 1996 through 2000 data from NCI’s Surveillance, Epidemiology, and End Results (SEER) Program, cancer mortality rates were falling, but incidence rates were steady. Black (African-American) men and women had the highest mortality rates for all common cancers except lung cancer, and Black males had the highest incidence rates for colorectal and prostate cancers. Blacks and American Indians (including Alaska Natives, Eskimos, and Aleuts) had the lowest 5 year cancer survival rates. In addition, American Indians (including Alaska Natives, Eskimos, and Aleuts) had the highest relative risk of dying from most cancers when compared to non-Hispanic Whites.

Elderly minority populations, in particular, are disproportionately affected by cancer. While 7.5 percent of White males will develop cancer between the ages of 60 and 79, 9.1 percent of Black males will do so. Although older Black females develop cancer at lower rates than their White counterparts, Black survival rates are significantly lower. Five-year relative survival rates for Black males are also lower. Five-year survival rates for White males ages 65 to 74 are 66.7 percent for Black males of the same age, 61.8 percent. Five-year survival rates for White

females ages 65 to 74 are 58.9 percent, versus 44.2 percent for Black women of the same age group (<http://www.chdprg.omhrc.gov/pdf/chdprg.pdf>).

Men and women in Hispanic, American Indian (including Alaskan Natives, Eskimos, and Aleuts), and Asian and Pacific Islander groups have much lower rates of cancer, although they may still experience lower survival rates. However, cancer and ethnic or racial differences observed in death records and SEER data must be viewed with caution, since both sources may underestimate mortality for Hispanic, American Indian (including Alaskan Natives, Eskimos, and Aleuts), Asian, and Native Hawaiian and Other Pacific Islander populations because of inaccurate or missing coding of ethnic or racial group (Blustein, 1994; Izquierdo and Schoenbach, 2000, Becker, et al., 2002).

2. Evidence of Cancer Disparities in Detection and Treatment

Despite the fact that nearly all elderly Americans are covered by a core health insurance package (Medicare), thus eliminating, or at least minimizing, one of the most obvious barriers to health care (that is, the ability to pay for services), disparities have been noted with regard to rates of cancer screening among minorities relative to White elderly, as well as in the more broadly defined category of utilization of care (http://www.qualitytools.ahrq.gov/qualityreport/download_report.aspx). While Medicare covers screening services for breast, colorectal, prostate, and cervical cancers, the rate of use of these services is erratic (Wennberg, 1999). Elderly Black (African-American) women are less likely to have had a mammogram than their White peers despite Medicare reimbursement for the service, and Hispanic women are less likely to be screened for breast cancer than White women. Particularly for elders living alone, loss of mobility, social isolation, and poverty hamper access to health care services even if they are available in the community. Gaining entry to the health care system and having a usual source of care are positively associated with the use of preventive and/or screening services (Merzel *et al.*, 2002).

CMS commissioned Brandeis University to conduct a literature review of ethnic and racial differences in cancer incidence, detection, treatment and outcomes, as well as a review of best practices mandated by the statute authorizing this demonstration. Brandeis conducted a review of the literature and developed case studies of promising programs and emerging models that have not yet been described or evaluated in the published literature to inform the design of the demonstration.

The Brandeis report indicates that cancer screening rates are lower than desirable for all Medicare beneficiaries, but notably lower for ethnic and racial minorities. Further, their review found that for each of the cancers studied, the final diagnosis and staging of cancer requires a multi-step process involving multiple and sequential tests, procedures and professional consultations, with ample opportunities for failures in care continuity. For breast and prostate cancer, there is evidence that minority women and Black men are less likely to complete the diagnostic process. Further, for breast cancer, there is evidence that Black women are less likely to receive complete diagnostic workups and valid clinical staging, while for both breast and colorectal cancer, there is evidence that older persons are less likely to receive complete diagnostic processes. Finally, there are consistent patterns of less than complete treatment across

all of the cancers of interest to this demonstration project. Black elders and other ethnic and racial minorities are less likely to receive complete primary treatments and secondary radiation or chemotherapy. Chapter 3 of the Brandeis evidence report provides more specific information about ethnic and racial disparities in cancer screening, diagnosis, and treatment. The full text of the report can be found online at (<http://cms.hhs.gov/healthyaging/CancerPrev.pdf>).

Evidence suggests that much of the disparity in cancer outcome may be more of a reflection of type, timeliness and continuity of cancer care rather than the disease itself. For example, there is mounting evidence of unequal use of Medicare-reimbursed health care services across ethnic, racial, and other socially defined groups after controlling for appropriateness of care (Shavers *et al.*, 2002; Bach *et al.*, 2002). These patterns may be affected by many factors largely outside of Medicare's influence, for example, availability of health care professionals who are members of ethnic or racial groups, cultural or racial attitudes of White health care professionals, maldistribution of health care resources, and safety net social services availability. Health care disparities may occur with respect to health risk management; benefit coordination; screening adherence management; appropriate diagnostic procedures and timely diagnosis; primary, secondary and adjuvant treatments; and follow-up or relapse monitoring. Further, it is possible that different ethnic and racial groups among the Medicare population experience barriers to appropriate care at different phases in the process. Two major recent reviews of cancer treatment studies found that, with few exceptions, Whites and minority persons (primarily Blacks [African Americans]) do not receive similar care for similar diseases. But when Whites and minority persons do receive similar care for similar diseases, they also have similar health outcomes (Bach *et al.*, 2002; Shavers *et al.*, 2002). This implies that, on average, ethnic or racial differences in cancer outcomes are more likely associated with access to quality care than with the relative efficacy of cancer diagnostic and treatment technologies across ethnic and racial groups.

3. Findings from Brandeis University Review of Best Practices

Based on the Brandeis University literature review, case studies, and technical expert feedback, the report concludes that the use of enabling services staff (for example, case manager, education specialist, outreach worker, health care facilitator, community health worker, *promotores de salud*, and patient navigator) as a part of a health care team holds great promise as an effective strategy in delivering appropriate cancer prevention, detection, and treatment services. The report highlights the importance of: (1) employing enabling services staff with strong understanding of and empathetic relationships with ethnic and racial populations of Medicare beneficiaries and the health system; (2) focusing the efforts of enabling services staff on improving accessibility and continuity of cancer prevention, detection and treatment services rather than only on patient education; and (3) supporting these workers with new health care information systems and decision-making supports.

Several published randomized controlled trials (RCTs) form the foundation of an expanding literature on the effectiveness of the enabling services staff model. While the results have been mixed and methodological issues limit the generalizability of the findings of many of these studies, the preponderance of the evidence indicates the potential for benefit of the enabling services staff model when appropriately employed. While RCTs by Olds (2002) and Malotte *et*

al. (2001) call into question the efficacy of such a model in the pediatric population and with tuberculosis control, RCTs by Levine *et al.* (2003), Larkey *et al.* (2002), Sung *et al.* (1997), Weber *et al.* (1997), Gary *et al.* (2003), Hill *et al.* (2003), Navarro *et al.* (1998), and Voorhees *et al.* (1996) tend to support the utilization of enabling services staff as an important intervention model for the prevention of cardiovascular disease, hypertension control, cervical and breast cancer screening, diabetes self-management, and general disease prevention and health promotion.

Perhaps the most striking finding from the case studies is the predominance of programs around the country employing enabling services staff (for example, community health workers (CHWs)) as the primary mechanism for cultural tailoring of facilitation interventions. This experience has led many sites to believe that the mediating and facilitating roles played by enabling services staff must be part of an effective strategy to address barriers to care faced by ethnic and racial elders.

Based on the Brandeis findings, three core sets of enabling services were identified. These include (1) health risk management (HRM), (2) screening adherence and detection facilitation (SADF), and (3) treatment and follow-up facilitation (TAFF). Each of these core services could be performed as an integral component of and link to the local health care system. For this reason, in a demonstration context, a particular health system might be able to reconfigure one or more of these services as the responsibilities of a single staff member or group of employees. In each service context, the enabling services staff member could collaborate both with other health care clerical, financial, and administrative staffs, and with health care professionals such as, physicians, nurses, social workers, and case managers when providing patient education, care continuity, and self-care empowerment services, while also providing specific support and linkage services. Furthermore, each service context could include the use of data management technology to improve the accuracy of data collection and reduce the amount of administrative time spent by each staff member.

The Brandeis University report recommended that the Secretary of HHS evaluate the efficacy and feasibility of employing the combination of new patient tracking and decision support tools (cancer screening assessment instrument) and an enabling services staff intervention model (for example, community health workers, *promotores de salud*, or patient navigators) as a promising strategy to effectively address both cultural and health care system barriers associated with cancer disparities.

C. Study Design Components

The demonstration as a whole consists of facilitating cancer screening, diagnosis, and treatment. The following is a basic representation of the general demonstration design and outlines the elements that each applicant must address in its proposal. Respondents to this solicitation are strongly encouraged to design a demonstration that will permit the drawing of scientifically valid inferences from their results. Successfully funded proposals will demonstrate significant attention to at least the following three areas: (1) interventions to facilitate cancer screening, diagnostic, and treatment services based on best available evidence; (2) a sound study methodology; and (3) a clear payment methodology. Each component is discussed in greater

detail below. (See Section IV for specific elements to be addressed within the applicant's proposal.)

1. Recruitment

Specific eligible inclusion criteria: (1) membership in one of the legislatively identified ethnic and racial minority groups as defined by Section 1707 of the Public Health Service Act; (2) entitlement to benefits under Part A and enrollment under Part B of Title XVIII of the Social Security Act; (3) persons without a current diagnosis of cancer prior to enrollment in the demonstration project; and (4) persons previously diagnosed with cancer of the breast, cervix, colon and/or rectum, prostate or lung prior to demonstration project enrollment. Enrollees who confirm participation will be presumed to be "participants" until they either become ineligible (for example, by joining a Medicare Advantage Plan), or by notifying the awardee or CMS that they no longer wish to participate. Beneficiary participation is voluntary and may be terminated at any time. Beneficiaries who are enrolled in managed care plans or who are institutionalized are not eligible to participate in this demonstration project.

CMS requires that each site recruit a sample sufficient to show an overall 10-percent increase in cancer screening at $\alpha = 0.05$ and $\beta = 0.80$ for a two-tailed test relative to the control group. This requirement applies only to the sample of participants at risk for cancer, but without a current diagnosis upon entry into the demonstration. We are not specifying a specific sample size for persons diagnosed with cancer prior to enrollment. Applicants should provide an estimate of the population that they expect to enroll, including evidence of the ability to actually recruit participants in sufficient numbers so as to achieve statistically significant results and the difference that may be measured with the expected sample size at the specified alpha and beta values. Applicants must provide the specific measures they will employ to analyze the improvements in treatment services.

Applicants must specifically outline the recruitment strategy that they will employ to enroll minority Medicare beneficiaries in the target populations. They must also clearly cite the evidence and/or organizational experience that demonstrate the efficacy of this approach in minority communities.

Applicants must provide projections as to the number of beneficiaries required to contact for sufficient enrollment volume, the percent of beneficiaries anticipated to confirm participation, the percent of beneficiaries anticipated to decline, the percent of beneficiaries they expect they will be unable to reach, and the percent of participants anticipated to terminate participation.

Awardees must maintain records of beneficiary contact and confirmation of their participation in the program. Awardees must report beneficiary eligibility and participation status (that is, whether a beneficiary declined to participate or terminated participation) to CMS on a regular basis for randomization and payment purposes. Programs will be evaluated based on health and cost outcomes of the intervention group as compared to the control group.

Awardees must also identify and enroll those Medicare beneficiaries within their target population who have already received a diagnosis of cancer. These individuals will receive the treatment facilitation services required in Section 5 below.

2. Cancer Screening Assessment

Following recruitment into the demonstration, awardees will provide CMS with participant information for the randomization process. CMS will randomize all enrollees into either a control group that receives usual care or an intervention group that receives the screening, diagnostic, and treatment facilitation services being offered under this demonstration. (A CMS support contractor will perform all randomization activities relative to this demonstration.)

All enrollees will receive an initial uniform cancer screening assessment instrument that will evaluate their general health status, previous and current use of cancer screening services, and level of exposure to the most common cancer risk factors. CMS will provide a cancer screening assessment instrument that will be used by all sites. Subsequently, individuals in the intervention group will be administered the cancer screening assessment instrument once per demonstration project year. Individuals in the control group will be administered the cancer screening assessment instrument upon entry into and exit from the demonstration project.

Based upon the results of the screening assessment, individuals in the control group will receive a one-time, generic feedback report that includes general information on cancer and Medicare-covered services via mail. Based upon the results of the screening assessment, individuals in the intervention group will receive tailored services to facilitate appropriate cancer screening procedures.

3. Facilitated Screening

The targeted cancer screening services to reduce cancer health disparities will include:

- a. Pap testing for cervical cancer.
- b. Prostate-specific antigen (PSA) and digital rectal examination (DRE) for prostate cancer.
- c. Fecal occult blood testing with or without combined flexible sigmoidoscopy or colonoscopy testing for colon and/or rectum cancer.
- d. Mammography for breast cancer.

The control group will receive usual care. (Under usual care, people receive treatment for cancer if their clinicians diagnose it, but there is no systematic screening program.)

The intervention group will receive services to promote adherence to screening referrals as necessary or appropriate, based on their cancer diagnosis status prior to enrollment. Participants in this group who receive negative cancer screening results will remain in the demonstration and continue to receive an annual cancer screening assessment, tailored feedback and screening adherence facilitation services.

Medicare screening coverage guidelines, as well as the U.S. Preventive Services Task Force's screening recommendations, are described in greater detail in Section VIII. The applicant must detail its approach to screening its population for each of the cancers required to be addressed within this demonstration project; that is, what are the applicant's clinical and decision-making protocols for each of the screening procedures shown in Section VIII?

4. Facilitated Diagnosis

The control group participants will receive usual care. (Under usual care, people receive treatment for cancer if their clinicians diagnose it, but there is no systematic screening program.)

Individuals in the intervention group who screen positive for cancer will require additional confirmatory diagnostic testing. Individuals who have already received a confirmed diagnosis of cancer may also require additional confirmatory diagnostic testing. Facilitation services must be provided to ensure follow-up of positive test results and adherence to confirmatory diagnostic testing. Participants in this group who receive negative cancer diagnostic results will remain in the demonstration and continue to receive an annual cancer screening assessment, tailored feedback and screening adherence facilitation services.

5. Facilitated Treatment

The control group participants will receive usual care. (Under usual care, people receive treatment for cancer if their clinicians diagnose it, but there is no systematic screening program.)

Individuals in the intervention group with a confirmed diagnosis of cancer at any time will receive intervention services designed to facilitate their cancer treatment (for example, activities that result in increased access to and compliance with care) such programs should consider placing an emphasis on methods that allow the minority patient to successfully navigate the health care system (<http://cms.hhs.gov/healthyaging/CancerPrev.pdf>; <http://crchd.nci.nih.gov/initiatives/>; Zuvekas *et al.*, 1999) so as to maximize their care and health outcomes.

Individuals in the intervention group who do not have cancer at any time will remain in the demonstration and continue to receive an annual cancer screening assessment, tailored feedback and screening adherence facilitation services.

6. Intervention Model

Respondents are expected to propose cancer screening, diagnosis, and treatment intervention models based on best available evidence for improving the delivery and utilization of health care services to members of the particular minority population or subpopulation they target. Interventions (methods to enhance screening rates and treatment facilitation) should be based upon strategies identified as effective in the peer-reviewed literature (for example, <http://cms.hhs.gov/healthyaging/CancerPrev.pdf>, <http://www.thecommunityguide.org/cancer/default.htm>, <http://www.ahrq.gov/clinic/cps3dix.htm#cancer>) or, at a minimum, have plausible scientific

justification for their use. The use of extant evidence-based models or programs (for example, <http://www.ahrq.gov/clinic/canconinv.htm>, <http://cancercontrol.cancer.gov/rtips/>) in this effort is encouraged, but applicants are also free to propose an alternate intervention model that is based on the best available scientific evidence, but that has not yet been evaluated or published in a peer-reviewed journal. In either case, the applicant must clearly support the applicability and validity of the chosen model in ethnic or racial populations through reference to the scientific literature.

All models must clearly demonstrate how they are or can be tailored to the unique needs of the population or subpopulation being served. For example, is this a model that has only been tested in the general population? If so, how has it been modified to meet the identified needs of the targeted population? Why (based on what evidence) have you chosen to modify the intervention in this way? How is this modification a valid approach to dealing with the particular needs of the population in question?

Proposals must focus on the continuum of cancer care, tracking a population's experience beginning at the point of project enrollment, through screening, clinical follow-up of abnormal findings and diagnostic workup, and on through treatment and follow-up care. Proposals must also focus on cancer treatment and post-treatment facilitation and/or monitoring services for participants with a confirmed diagnosis of cancer upon enrollment. CMS will make the final determination regarding the validity of any proposed intervention approach. Strong justification and rationale must be presented for all proposed approaches.

The applicant's intervention model must: (1) improve the utilization of cancer screening services (for example, mammography, colonoscopy, etc.); (2) facilitate access to and utilization of needed Medicare-covered diagnostic services for patients with abnormal screening findings; (3) facilitate access to and utilization of needed Medicare-covered treatment services (for example, completion of multi-modality therapy including, as appropriate, surgery, radiation, or taking chemotherapeutic medications as prescribed); and (4) improve post-therapeutic monitoring and follow-up. Models may also include provisions for ancillary services that will assist the demonstration participant in accessing services (for example, assistance with the provision of transportation). However, the proposal must clearly document the need for such additional services among the target population, taking into consideration the limited funding available for this demonstration effort.

7. Study Methodology

Examples of study design characteristics that increase the likelihood of producing meaningful results include sample sizes of sufficient magnitude to permit detection of statistically significant differences, randomization (by CMS) of participants into intervention and control groups, clearly defined and measurable outcome measures, and comprehensive procedures for the collection and analysis of data. (A CMS support contractor will perform all randomization activities relative to this demonstration.) While each respondent is free to suggest scientifically valid approaches to address the above characteristics, all proposals must employ a basic methodological design that specifically addresses the following design elements:

- Step 1 – Population recruitment plan (followed by group assignment via CMS randomization)
- Step 2 – Cancer screening assessment of all study participants
- Step 3 – Implementation of the intervention model in the intervention group and provision of cancer and Medicare information to the control group
- Step 4 – Procedures to prevent contamination of the control group by interventions delivered to the intervention group members
- Step 5 – Appropriate tracking and data collection of all study participants, including identification of data elements
- Step 6 – Continuous monitoring of site activities

Those proposals demonstrating due consideration of these minimum design characteristics and those proposing strong study methodologies will be assessed more favorably than those lacking such features.

8. Payment Methodology

Applicants must propose an overall payment methodology and budget that are appropriate for the administration of the cancer screening assessment and proposed cancer screening, diagnosis, and treatment facilitation services. Since the demonstration projects will operate from 3 to 5 years, applicants must submit budgets for a 3-year, a 4-year, and a 5-year demonstration. Applicants must submit evidence demonstrating the accuracy of the financial assumptions used in their proposed payment methodology and project budget. The applicant's payment methodology must propose an all-inclusive capitated rate for each enrolled beneficiary per month. CMS must approve capitated rate amounts by agreement with each awardee.

A two-tiered payment system will be used for this demonstration. The first tier payment covers the administration of the cancer screening assessment instrument. This payment is made per enrollee in both the control and intervention groups. However, the intervention group participants will receive this assessment once per year of the demonstration, while control participants will receive it upon entry and at the end of the demonstration. The second tier payment covers the cancer screening, diagnosis, and treatment facilitation services. The applicant must propose a monthly capitated rate for these facilitation services based on its estimate of the average cost of the services.

The applicant must propose a fee for administering the cancer screening assessment and a monthly capitated rate for facilitating cancer screening, diagnostic, and treatment services. The monthly capitated rate proposed to cover these facilitation services must be reasonable given the scope of services provided under this demonstration. The derivation of the monthly capitated rate for these facilitation services must be specified in the applicant's proposal. The proposed rate must include the projected cost for each cancer care facilitation service, including personnel costs, ancillary services (for example, transportation and data collection) and any other relevant services. These costs must be presented in aggregate and per participant.

Applicants must also include in their proposal provision for attendance of up to two organizational representatives at (four) annual meetings for the purpose of project discussions at a site determined by CMS.

CMS expects the costs of administering the two-tiered payment system covering the cancer screening assessment instrument and providing screening, diagnosis, and treatment facilitation services to range per project from \$400,000 to \$1.5 million per year of the demonstration. Therefore, CMS will impose a cap to ensure expenditures do not exceed the total funding authorized by Congress.

CMS will consider an award of up to \$50,000 per demonstration project to cover initial implementation costs. The entire award will not be made initially but will be distributed incrementally between the time of conditional award and the approval of the demonstration by the Office of Management and Budget. We are willing to consider requests for assistance with the following kinds of initial implementation costs: modification of existing protocols, services, outreach, and educational materials. Applicants must submit a detailed project budget with documentation of how the requested startup funds would be used. The site must clearly demonstrate its need for financial assistance for its request to be approved.

9. Claims Processing

Special demonstration billing codes will be established to allow reimbursement for the annual cancer screening assessment for the intervention group, the entrance and exit cancer screening assessment for the control group, and the monthly capitated rate for cancer screening, diagnostic, and treatment facilitation services. No beneficiary coinsurance or deductible will be applied to the cancer screening assessment and the monthly capitated rate for facilitation services. Providing these services to beneficiaries without cost eliminates a potential financial barrier to willingness to participate and avoids a layer of complexity in the billing requirements both for CMS and the demonstration projects.

Participation in this demonstration will be voluntary and will not change the amount, duration or scope of a beneficiary's fee-for-service Medicare benefits. Claims for medical services provided to participating beneficiaries will continue to be covered, administered, and paid for under Medicare. A site may choose to waive coinsurance for cancer screening services and pay the difference out of its budget.

II. Award Information

CMS intends to award at least 9 cooperative agreement demonstration projects. The initial demonstration projects will have a 3-to-5-year operation period. However, the Congress authorized the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities project for a potentially indefinite period of time. The legislation states that if the initial demonstration evaluation indicates that these projects—(1) reduce Medicare expenditures; or (2) do not increase Medicare expenditures, reduce ethnic and racial health disparities, and increase beneficiary and health care provider satisfaction, the existing demonstration projects will continue, and the number of demonstration projects may be expanded in the future.

The Congress authorized an additional \$25,000,000 appropriation from the Medicare Trust Funds beyond the aggregate payments that would be made under the Medicare program for the

prevention and treatment of cancer had the demonstration projects not been implemented. CMS expects the costs of administering the cancer screening assessment instrument and providing screening, diagnosis, and treatment facilitation services to range per project from \$400,000 to \$1.5 million per year of the demonstration. Therefore, CMS will impose a cap to ensure expenditures do not exceed the total funding authorized by the Congress. No State or local matching funds are required.

CMS will consider an award of up to \$50,000 per demonstration project to cover initial implementation costs. The entire award will not be made initially but will be distributed incrementally between the time of conditional award and the approval of the demonstration by the Office of Management and Budget. CMS is willing to consider requests for assistance with the following kinds of initial implementation costs: modification of existing protocols, services, outreach, and educational materials. Applicants must submit a detailed project budget with documentation of how the requested startup funds would be used so as to clearly demonstrate the need for financial assistance.

The CMS Administrator will make the final selection of projects for the demonstration from among the most highly qualified applicants, taking into consideration a number of factors including operational feasibility, geographic location, populations served, and program priorities (for example, testing a variety of approaches for delivering services, targeting beneficiaries, and payment). Applicants must be aware that proposals may be accepted in whole or in part. In evaluating applications, we rely on our past experience with successful and unsuccessful demonstrations. We reserve the right to conduct one or more site visits before making awards.

CMS anticipates that projects will be awarded in mid-2005, and that project startup activities would begin immediately after completion of the waiver cost process (in late 2005).

The administrative and funding instrument used for this program is a cooperative agreement, an “assistance” mechanism (rather than an “acquisition” mechanism) in which substantial CMS programmatic involvement with the awardees is anticipated during performance of the activity. Under the cooperative agreement, the CMS purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume prime responsibility or a dominant role in the activity. Consistent with this concept, the dominant role and prime responsibility for the activity reside with the awardees for the project as a whole, although specific tasks and activities in carrying out the studies will be shared among the awardees and CMS. CMS shall be represented by a Project Officer; this representative will be referred to as the CMS Project Officer.

III. Eligibility Information

1. Eligible Applicants

Potentially qualified applicants include, but are not limited to: disease management organizations, health insurers, physician group practices, coordinated care services providers, provider-sponsored organizations, academic medical centers, comprehensive cancer centers, special population networks, community clinical oncology programs, community-based health

organizations, community health centers, federally qualified health centers, minority institutions such as, among others, Historically Black Colleges and Universities, Hispanic Serving Institutions, Hispanic health organizations and associations, tribal organizations, a consortium of such entities, or any other legal entity that the Secretary determines to be appropriate.

CMS strongly encourages the establishment of collaborative consortia for this demonstration.

2. Cost Sharing or Matching

No state or local matching funds are required.

3. Other

Applicants must demonstrate the ability to effectively facilitate, on a capitated basis, the delivery of cancer screening, diagnosis, and treatment services to any of the following target populations: Black, Hispanic, Asian American and Pacific Islander, and American Indian (including Alaskan Natives, Eskimos, and Aleuts) Medicare beneficiaries.

Beneficiaries who are enrolled in managed care plans or who are institutionalized are not eligible to participate in this demonstration project.

Applicants may submit proposals pertaining to more than one target population. However, each population must be addressed in a separate, complete proposal.

IV. Application and Submission Information

1. Address to Request Application Package

This solicitation serves as the application package for this cooperative agreement and contains all the instructions that a potential applicant requires to apply for cooperative agreement funding. The application should be written primarily as a narrative with the addition of standard forms required by the Federal Government for all cooperative agreements. You may obtain copies of these forms directly from the DHHS website at www.grants.gov or www.cms.hhs.gov/researchers/priorities/grants.asp.

2. Content and Form of Application Submission

Application Format

Each application must include all contents described below, in the order indicated, and in conformance with the following specifications:

- Use White paper only.

- Use 8.5 x 11" pages (on one side only) with one-inch margins (top, bottom and sides). Paper sizes other than 8.5 x 11" will not be accepted. This is particularly important because it is often not possible to reproduce copies in a size other than 8.5 x 11".
- Use a font not smaller than 12-point.
- Double-space all narrative pages. The project abstract may be single-spaced.
- No more than 40 pages for the narrative portion, excluding cover letter, executive summary, resumes, forms, supporting documentation, budgetary information, required appendices, letters of support, assurances and certifications. Pages other than the 12-point, double-spaced narrative may be single-spaced; however, no smaller than 12-point font is permitted.
- Additional documentation may be appended; however, material should be limited to information relevant but not essential to the specific scope and purpose of the cooperative agreement. Please do not include critical details in an appendix since appendices will not be included for purposes of the ratings process.
- Do not bind copies. Secure pages with a binder clip, paper clip, or 3-ring binder.

What to Send

Applicants are required to submit one (1) original and one (1) copy of the application and one (1) 3 1/4" floppy disk containing the application. For the 3 1/4" floppy disk, please send this information on a standard disk that hold at least 1.44 megabytes and is high density.

CMS prefers that documents be submitted in Microsoft® Word and Microsoft® Excel.

Submissions by facsimile (FAX) transmission will not be accepted.

Applicants may submit proposals pertaining to more than one target population. However, each population must be addressed in a separate, complete proposal.

Required Content

A complete proposal consists of the following material organized in the sequence indicated. Please ensure that the project narrative is page-numbered. The sequence is:

- First: Cover letter
- Second: Table of Contents
- Third: Standard forms from the Application Forms Kit (www.grants.gov or www.cms.hhs.gov/researchers/priorities/grants.asp)
- Fourth: Executive summary (limited to not more than three pages)
- Fifth: Statement of problem
- Sixth: Project narrative
- Seventh: Budget narrative and justification (including startup funds budget)

- Eighth: Letters of agreement, endorsement and support
- Ninth: Required appendices
- Tenth: Supporting documentation

a. Cover Letter

Must include the title, project director and a brief description of the proposed project; indicate the target population and urban or rural site; and identify any and all CMS provider numbers assigned to the applicant, a contact person and contact information. The letter must also include the names of all organizations collaborating in the project and indicate that the applicant organization has clear authority to perform the proposed activities and is capable of convening a viable working group of all relevant partners.

b. Table of Contents

c. Standard Forms from Application Forms Kit

To apply for the initial implementation costs request for assistance, the following standard forms must be completed with an original signature and enclosed as part of the proposal.

COOPERATIVE AGREEMENT IMPLEMENTATION APPLICATION KIT

- SF-424: Application for Federal Assistance
- SF-424A: Budget Information
- SF-424B: Assurances-Non-Construction Programs
- SF-LLL: Disclosure of Lobbying Activities
- Biographical Sketch
- Additional Assurances

You may obtain copies of these forms directly from the DHHS website at www.grants.gov or www.cms.hhs.gov/researchers/priorities/grants.asp.

d. Executive Summary (Limited to not more than three pages).

e. Statement of Problem

Applicants must demonstrate a thorough understanding of the project purpose, goals, objectives and requirements. Applicants must demonstrate a thorough understanding of the health problem (cancer) within their target population and the strategies required to address this health issue. Applicants must describe the proposed program and explain how the proposed interventions will improve the overall health outcomes and achieve savings for the target population. Proposals that merely restate the project requirements without providing substantive descriptions of the planned research will be considered technically unacceptable.

f. Project Narrative

Applicants must make a clear and concise presentation of the technical approach chosen for this project; this must be complete and cover all aspects of the project requirements. All aspects of the program must be based on the best available scientific evidence of effectiveness. All criteria used to assess the following requirements must be based upon standards established within the peer-reviewed literature and/or by entities with professional expertise in the area (for example, AHRQ).

Applicants must describe characteristics of the targeted population in the selected geographic area, including:

- Geographic, demographic, and socio-economic characteristics.
- Incidence of disease in the geographic area to be served by the project.
- Evidence of existing disparities in the proposed target population.
- Need for the proposed services in the respective population they intend to serve.
- Rationale for targeting each proposed area and population.
- Access to and utilization of health care services.
- Characteristics of the health care delivery system.
- Obstacles and/or barriers to providing cancer care intervention services.

Applicants must describe how each of the proposed interventions (that is, screening, diagnosis, and treatment facilitation) is likely to have a positive effect upon health status for the proposed population within the proposed geographic area. If available, applicants should show evidence of positive outcomes from prior and current efforts. Specifically, the applicant must describe how proposed activities will result in:

- Improvement in the quality of items and services provided to target individuals in order to facilitate reduced disparities in early detection and treatment of cancer.
- Improvement in clinical outcomes, satisfaction, quality of life, and appropriate use of Medicare-covered services and referral patterns among those target individuals with cancer.
- Elimination or reduction of disparities associated with the rate of preventive screening measures.
- Promotion of collaboration with community-based organizations to ensure cultural competency of health care professionals and linguistic access for persons with limited English proficiency.

Applicants must provide clear and convincing evidence that their program design will improve quality of care and reduce disparities for the chosen target population and reduce aggregate costs to Medicare, including (with any applicable supporting materials):

- Intervention strategy, including plan for development and implementation of care management plans and protocols.
- The cultural, educational, and resource-appropriate nature of each service being delivered to a particular population, including the ways in which the applicant will collaborate with community-based organizations to further the cultural competency of health care

professionals and bolster health care access for persons with limited English language proficiency. Furthermore, applicants must provide sample communications and educational materials to be used with beneficiaries and providers and explain any plans to customize them for Medicare.

- Adequate mechanisms for handling beneficiaries with more intensive needs

In this section, applicants must explain how the proposed program will address each of the following specific design activities:

(1) Recruitment

- Provide power estimates showing the number of persons needed for recruitment for both control and intervention groups in order to estimate a given effect and validate the evaluation result.
- Provide evidence of the site's ability to recruit a sample sufficient to show an overall 10-percent increase in cancer screening at $\alpha = 0.05$ and $\beta = 0.80$ for a two-tailed test. This requirement applies only to the sample of participants at risk for cancer, but without a current diagnosis upon entry into the demonstration.
- Provide evidence of the site's ability to recruit a sample of participants with a confirmed diagnosis of cancer that is large enough for valid statistical analyses. We are not specifying a specific sample size for persons diagnosed with cancer prior to enrollment. Applicants should provide an estimate of the population that they expect to enroll.
- Describe the method(s) to be used to recruit eligible persons into the demonstration, including justification for the use of the particular method(s).
- Describe the strategies the applicant will use to increase awareness in the professional community regarding the purpose of the demonstration and its potential utility.

(2) Cancer Screening Assessment

- Describe methods and procedures for all data collection activities, including specific data elements that will be collected.
- Provide a description of the administrative protocol(s) to be employed in administering the cancer screening assessment instrument (include as an appendix to the proposal).
- Describe the outcome variables for cancer screening assessment efforts (in the form of table shells).
- Provide previous experience in conducting screening assessment efforts of the type addressed in this solicitation, including successes, failures and lessons learned.

(3) Screening

- Describe methods and procedures for all data collection activities, including specific data elements that will be collected.
- Provide the outcome variables for screening efforts (in the form of table shells). These could include an estimate of the number of people screened, the number or proportion of abnormal findings among those screened, the number of those with abnormal findings that will have cancer, and the stage of disease at diagnosis of the cancers.

- Describe cancer screening facilitation services, to include methods and procedures to increase screening rates in the demonstration population and inform the patient of the results of their screen(s).
- Describe the measures the applicant will take to assure the validity and reliability of the screening tests.
- Provide previous experience in conducting screening efforts of the type addressed in this solicitation, including successes, failures and lessons learned.

(4) Diagnosis

- Describe methods and procedures for all data collection activities, including specific data elements that will be collected.
- Provide a description of systems that will ensure timely follow-up of abnormal results and promotion of continuity of care.
- Describe the outcome variables for treatment efforts (in the form of table shells).
- Provide a description of providers delivering diagnostic services.
- Provide a description of the administrative protocol(s) resulting in facilitated diagnosis (include as an appendix to the proposal).

(5) Treatment

- Describe methods and procedures for all data collection activities, including specific data elements that will be collected. Provide a description of providers delivering treatment services.
- Provide a description of the administrative protocol(s) resulting in facilitated treatment (include as an appendix to the proposal).
- Describe the outcome variables for treatment efforts (in the form of table shells).
- Describe the quality of care measures that will be collected. This could include, for example, appropriate consultation with a multi-disciplinary team, evidence of stage-appropriate treatment options being offered to the patient, disease-free margins from surgery, physician visit and medical and/or physical check every five radiation therapy treatments, total chemotherapy dose delivered as prescribed by medical oncologist. For further information on cancer specific treatments, see <http://cancer.gov/cancerinfo/treatment/>.

(6) Implementation and Performance

Applicants must provide sufficient detail to indicate a technical understanding and capability of performing the requirements of the project. Applicants must provide clear and convincing evidence that the organization can produce a positive effect on the targeted population in the selected geographic area, including:

- Positive outcomes from prior and current efforts to recruit ethnic and racial populations for screening and treatment services, including quantified results.
- Willingness to work with CMS to determine data to be collected and procedures for submission of those data.
- Willingness to cooperate in independent formal evaluations of demonstration projects.

Applicants must:

- Describe the proposed implementation strategy and plan including tasks and costs.
- Provide schedule with timelines for all essential tasks.
- Describe protocols used to guide intervention services delivery and management, as well as processes and responsibilities for updating them (protocols must be derived from best available evidence or nationally accepted practice guidelines).
- Describe modifications to protocols, services, outreach, education initiatives, and timelines, as applicable.
- Describe project monitoring and reporting strategies and structures.
- Describe the interactive relationship between the patient and the provider, health care professional, or ancillary services staff for all the major components of the demonstration design.

(7) Organizational Structure and Capabilities

Applicants must demonstrate that they have the management capacity and organizational infrastructure to carry out this demonstration project. Applicants must explain how the organization has demonstrated capacity in each of the specific areas listed below:

(a) Organizational Background, Structure and References

- Describe the organization's history (including how long the organization has been in existence), ownership (including any relevant predecessor companies), and current structure, products and services.
- Provide references (including name, title, and telephone number) at two organizations for which the applicant has developed and currently administers programs of similar scope and complexity as the proposed program.
- With respect to collaborative consortia, applicants must describe how the *new* entity will achieve the organizational capacity functions outlined within this section ("Organizational structure and capabilities"). Consortia may draw from the organizational qualifications of each of the collaborators, but applicants must emphasize the capabilities of the collective consortium. Consortia must describe the interrelationships between the collaborators, a plan for dedicated resources to develop infrastructure, and seamless program cohesion (including integrated interventions, communications, and information systems), and a plan for a consortium governance and management structure with dedicated staffing and resources.
- For consortia, provide evidence of a track record of working together if it is an existing consortium, or a track record of working with partners on similar endeavors if it is a new consortium.
- Describe how applicant interacts with local providers, for example, community organizations, advocacy groups, and academic institutions, to promote their active involvement in encouraging effective public and private partnerships.

(b) Staff

- Provide a breakout of staff responsibilities.
- Describe type and level of staff and level of effort required to provide the service.
- Describe staff-to-participant ratios and required qualifications of staff who will be providing services to the targeted beneficiaries.
- Describe similar detailed information on any services to be performed on a sub-contracted or affiliated basis. List full name and address of any subcontractors involved in the services to be performed. Describe all handoffs and coordination arrangements.
- Describe qualifications of the nonclinical staff who will be responsible for the information systems, data analysis, and other major program functions.
- Provide a listing of key personnel.
- Among the key staff named and CVs provided, identify the individual who will be the liaison to CMS for this demonstration project

(c) Facilities

- Describe locations that will be used to operate the demonstration project.
- Describe typical hours of operation in terms of hours per day and days per week, including types of staff available during these hours of operation. (If the organization is not open 24 hours per day, 7 days a week, what process do beneficiaries follow to contact professional staff?)

(d) Equipment

Describe equipment, including any participant monitoring equipment.

(e) Information and Financial Systems

- Describe the organization's information and financial systems, including the organization's computer systems capabilities and how the applicant collects, integrates, analyzes, and reports data necessary to support program components. Describe the data repository, and how the applicant's computer systems can transmit data to CMS.
- Describe data to be collected and data sources, such as, recruitment sampling, beneficiary contacts, participant enrollments, and facilitation intervention activities.
- Provide samples of clinical, financial and management information reports used in program operations.
- Describe modification of existing data systems, if necessary.

(f) Quality Assurance

- Describe the organization's quality assurance process and plan for this effort. Describe what quality assurance process improvements the organization has made in the last 12 months related to providers, patients, health plans, communication, health education and/or training.

(8) Payment Methodology

Applicants must propose an overall payment methodology and budget that are appropriate for the

administration of the cancer screening assessment and proposed cancer screening, diagnosis, and treatment facilitation services. Since the demonstration projects will operate from 3 to 5 years, applicants must submit budgets for a 3-year, a 4-year, and a 5-year demonstration. Applicants must submit evidence demonstrating the accuracy of the financial assumptions used in their proposed payment methodology and project budget. The applicant's payment methodology must propose a fee for the cancer screening assessment and a capitated rate for cancer screening, diagnosis, and treatment facilitation services for each enrolled beneficiary per month. CMS must approve payment amounts by agreement with each awardee.

A two-tiered payment system will be used for this demonstration. The first tier payment covers the administration of the cancer screening assessment instrument. This payment is made per enrollee in both the control and intervention groups. However, the intervention group participants will receive this assessment once per year of the demonstration, while control participants will receive it upon entry and at the end of the demonstration. The second tier payment covers the cancer screening, diagnosis, and treatment facilitation services. The applicant must propose a monthly capitated rate for these facilitation services based on its estimate of the average cost of the services.

The fee proposed to cover the cancer screening assessment and the monthly capitated rate proposed to cover cancer screening, diagnosis, and treatment facilitation services must be reasonable given the scope of services provided under this demonstration. The derivation of the monthly capitated rate for facilitation services must be specified in the applicant's proposal. The proposed monthly capitated rate must reflect the costs involved in conducting these facilitation services, and must also include personnel, administrative, travel, screening assessment instrument administration, and participant recruitment costs; ancillary services, for example, transportation, data collection, and any other relevant services. These costs must be presented in aggregate and per participant.

Applicants must also include in their proposal provision for attendance of up to two organizational representatives at (four) annual meetings for the purpose of project discussions at a site determined by CMS.

CMS expects the costs of administering the two-tiered payment system covering cancer screening assessment instrument and providing screening, diagnosis, and treatment facilitation services to range per project from \$400,000 to \$1.5 million per year of the demonstration, and will impose a cap to ensure expenditures do not exceed the total funding authorized by the Congress for this demonstration.

CMS will consider an award of up to \$50,000 per demonstration project to cover initial implementation costs. The entire award will not be made initially but will be distributed incrementally between the time of conditional award and the approval of the demonstration by the Office of Management and Budget. We are willing to consider requests for financial assistance with modification of existing protocols, services, outreach, and educational materials. Applicants must submit a detailed project budget with documentation of how the requested startup funds would be used. The site must clearly demonstrate its need for financial assistance for its request to be approved.

The applicant must estimate the expected total yearly Medicare expenditures for the target population as well as the control population, and the net savings to Medicare resulting from providing cancer screening, diagnosis, and treatment facilitation services. Estimates of expenditures must include the cancer facilitation services covered under this demonstration as well as payments for traditional Medicare benefits provided to the intervention group.

Applicants must show the basis for the assumptions used in their proposed payment methodology and project budget. The strength of the evidence supporting these estimates will be considered in evaluating the proposals. Further, applicants selected for award must be required to submit data supporting their utilization and financial assumptions (that is, current cancer screening and treatment utilization, and costs) prior to implementation of the demonstration. CMS will use the information provided by the applicant, as well as Medicare claims and other data, to determine an estimate of what CMS would have to pay to provide care for a population similar to the projected enrolled population both with and without cancer care facilitation services.

g. Budget Narrative and Justification

If applying for the initial implementation costs request for assistance, in the budget recorded on form SF 424A, provide a breakdown of the aggregate numbers detailing their allocation to each major set of implementation activities. The proposed budget for the implementation activity should distinguish the proportion of implementation funding designated for each activity. The budget must separate out funding that is administered directly by the lead agency from funding that will be subcontracted to other partners.

h. Letters of Agreement, Endorsement and Support

Provide a set of endorsements from collaborating organizations outlining their contributions, roles and responsibilities relative to the program and commitments that have been pledged for the proposed project. Include individual letters of support as appropriate.

i. Required Appendices

- (1) Organizational Charts – depicting the organization’s operational relationships within the lead agency for this cooperative agreement.
- (2) Memoranda of Understanding –reflecting the collaborative relationships between relevant agencies.
- (3) Key Staff Qualifications – including a biographical sketch or resume of key staff describing their qualifications.

j. Supporting Documentation

3. Submission Dates and Times

To be considered for funding under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreement, applications must be postmarked by March 23, 2005.

Applications mailed through the U.S. Postal Services or a commercial delivery service will be considered “on time” if received by close of business on the closing date, or postmarked (first class mail) by the date specified. If express, certified, or registered mail is used, the applicant should obtain a legible dated mailing receipt from the U. S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailings. Applications postmarked after the closing date, or postmarked on or before the closing date but not received in time for panel review, will be considered late applications. Those submitting late applications will be notified that their applications were not considered in the competition and will be returned without review.

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission.

CMS will not provide acknowledgements of receipt of applications.

4. Intergovernmental Review of Federal Programs

Executive Order 12372 or “Intergovernmental Review of Federal Programs” (45 CFR Part 100) is not applicable to this program.

5. Funding Restrictions

There are no funding restrictions applicable to this initiative.

6. Other Submission Requirements

Where to send the application:

All application forms and related materials must be submitted to:

Centers for Medicare & Medicaid Services
Office of Operations Management
AGG, Cooperative Agreements Management Staff
Attn: Judith L. Norris
7500 Security Boulevard, Mailstop C2-21-15
Baltimore, Maryland 21244-1850

Dun and Bradstreet Number

Beginning October 1, 2003, applicants are required to have a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS

number is a 9-digit identification number which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access the website www.dunandbradstreet.com or call 1-866-705-5711. This number should be entered in the block with the applicant's name and address on the cover page of the application (Item 5 on the Form SF-424, Application for Federal Assistance), with the annotation "DUNS" followed by the DUNS number that identifies the applicant. The name and address in the application should be exactly as given for the DUNS number.

V. Application Review Information

1. Review Criteria

a. Statement of Problem (10 points)

- The applicant demonstrates a thorough understanding of the project purpose, goals and objectives. The applicant demonstrates a thorough understanding of the health problem (cancer) within their target population and the strategies required to address this health issue. The applicant adequately describes the proposed program and explains how the proposed interventions will improve the overall health outcomes and achieve savings for the target population.

b. Soundness of Demonstration Design (30 points)

- The applicant makes a complete and concise presentation of the technical approach chosen for this project that covers all aspects of the project requirements. The proposal provides clear and convincing evidence and supporting materials that proposed cancer care facilitation services are appropriate for the targeted population, likely to improve quality of care and reduce disparities for the target population and reduce aggregate costs to Medicare.
- The proposed program design provides for voluntary participation of a sufficient number of Medicare beneficiaries to allow for validity of the evaluation results.

c. Ability to Implement and Perform Demonstration (20 points)

- The proposal provides sufficient detail to indicate a technical understanding and capability of performing the requirements of the project.
- The proposed project implementation strategy and plan are detailed and appropriate.
- The implementation plan supports an independent evaluation of the project.

d. Soundness of Organizational Structure and Capabilities (25 points)

- The proposal provides clear and convincing evidence that the organization has the organizational infrastructure and management capacity to ensure adequate delivery of the proposed cancer care intervention services and conduct the demonstration project effectively.

- The proposal discusses the types and degrees of collaborative consortia, if any, supporting the proposed program that have already been established or that may be expected between the organizations. The collaboration model includes specific information about the roles and responsibilities of each collaborator on the project. The proposal contains letters of support from collaborating organizations outlining their contributions, roles and responsibilities relative to the program.
- The proposal contains adequate mechanisms for ensuring provider integration with the project.
- The proposal provides evidence of the availability and adequacy of facilities, equipment, personnel, and financial management systems to successfully conduct the proposed program.
- Adequate specific information is provided concerning how the personnel are to be organized in the program, to whom they will report, and how they will be used to accomplish specific objectives or components of the program.
- The data to be collected, data sources, and data collection and analysis systems proposed are specified in detail and are sufficient to ensure optimal intervention management.
- The proposal provides evidence that effective continuous quality improvement processes are being employed and can be successfully transferred to the demonstration project.

e. Payment Methodology (15 points)

- The proposal provides justification and explanation for the proposed payment amounts.
- The proposal provides clear and convincing evidence that the proposed payment amounts for the cancer care facilitation services are appropriate to improve quality of care and reduce disparities for participating beneficiaries and reduce aggregate costs to Medicare.

2. Review and Selection Process

A panel of experts will conduct an independent, objective review of all responsive applications. The panelists will assess each application based on the review criteria to determine the merits of the proposal and the extent to which it furthers the purposes of the demonstration program. A panel of experts will conduct a review of responsive proposals. This technical review panel will convene in the months following the due date for submission of proposals. The panelists' recommendations will contain numerical ratings based on the evaluation criteria, the ranking of all responsive proposals, and a written assessment of each applicant.

CMS reserves the right to request that applicants revise or otherwise modify certain sections of their proposals based on the recommendations of the panel. CMS reserves a limited right to assure adequate reasonable geographic and other representation among sites receiving cooperative agreements. However, we will not exercise this right if there is a major qualitative

difference between high-ranked applications and any application that would remedy a geographical imbalance.

The CMS Administrator will make the final selection of projects for the demonstration from among the most highly qualified applicants, taking into consideration a number of factors including operational feasibility, geographic location, populations served, and program priorities (for example, testing a variety of approaches for delivering services, targeting beneficiaries, and payment). Applicants must be aware that proposals may be accepted in whole or in part. In evaluating applications, we rely on our past experience with successful and unsuccessful demonstrations. We reserve the right to conduct one or more site visits before making awards. CMS anticipates that the Administrator will make project award decisions in mid-2005 and that project startup activities would begin immediately after completion of the waiver cost process (in late 2005).

3. Anticipated Announcement and Award Date: June-July 2005

VI. Award Administration Information

1. Award Notices

Cooperative agreement awards will be issued within the constraints of available Federal funds and at the discretion of CMS. The official award document is the “Notice of Cooperative Agreement Award.” It will provide the amount of the award, purpose of the award, terms of the agreement, duration of the project period for which funding is available, and any special terms and conditions of the cooperative agreement. Once signed by the awarding office, the “Notice of Cooperative Agreement Award” package will be mailed directly to the authorized official as indicated on the form SF 424 face page.

2. Administrative and National Policy Requirements

Applicants should be aware that they might be required to comply with Special Terms and Conditions that may apply specifically to a particular applicant’s proposal. These terms and conditions are used to clarify particular cooperative agreement activities and assure that cooperative agreement funding is being used in a permissible manner. Because these terms and conditions are written specific to a particular cooperative agreement, it is not possible to review them prior to application submission.

3. Reporting

Awardees must agree to cooperate with any Federal evaluation of the program and provide quarterly, annual and final reports as prescribed by CMS (including the SF-269a Financial Status Report forms). The reports will be designed to outline how cooperative agreement funds were used and to describe program goals, objectives, progress and barriers. Awardees also agree to provide data on key aspects of their system improvements, scaled to the size of their cooperative agreement award.

In order for CMS to monitor awardees' efforts toward reaching the legislative goals for these demonstration projects, awardees must submit the following required reports throughout the period of performance:

Quarterly

The awardee must report, by the 10th working day after the close of each project quarter, information reflecting the experience of the intervention group compared to the relevant control group beginning at the point of project enrollment, through screening, clinical follow-up of abnormal findings and diagnostic workup, and on through treatment and follow-up care, including cancer treatment and post-treatment facilitation and/or monitoring services for participants with a confirmed diagnosis of cancer upon enrollment. Specifically, awardees must report beneficiary eligibility, enrollment, and participation status; cancer screening assessment activities and results according to proposed protocols and outcome variables; and screening, diagnostic, and treatment facilitation activities and results according to proposed protocols and outcome variables.

Annual

The awardee must report, by the 30th working day after the close of each project year, information reflecting the impact of the awardee's project activities on the target population. Specifically, awardees must report measurable effects of intervention activities that have: (1) improved the utilization of cancer screening services; (2) facilitated access to and utilization of needed Medicare-covered diagnostic services for patients with abnormal screening findings; (3) facilitated access to and utilization of needed Medicare-covered treatment services (for example, completion of multi-modality therapy including, as appropriate, surgery, radiation, or taking chemotherapeutic medications as prescribed); and (4) improved post-therapeutic monitoring and follow-up. These reports must also include information on lessons learned during the past year and proposed project enhancements for the next year.

Final

The awardee must report, by the 60th working day after the close of their demonstration, project information reflecting the impact of the awardee's intervention efforts on the target population in light of the legislative goals for these demonstration projects. Specifically, awardees must report measurable effects of intervention activities relative to their target population that have eliminated or reduced disparities in cancer screening rates, facilitated timely diagnostic testing and appropriate treatment modalities, enhanced appropriate use of health services, demonstrated the cost-effectiveness of the demonstration project, improved the quality of services provided, and increased beneficiary and provider satisfaction. This report must include, but is not limited to: information that allows the drawing of scientifically valid inferences from project results, discussion of the efficacy and positive effect upon health status of the project approach in the target population, and resultant health and cost outcomes of the intervention group as compared to the control group.

Formal evaluation

Through a competitive selection process independent of this solicitation, CMS will contract with an evaluation contractor who will conduct a formal evaluation of program results. The independent evaluator will analyze the experience of the intervention group in each area

compared to the relevant control group and to the relevant Medicare population-at-large by addressing such issues as the elimination or reduction of disparities in cancer screening rates, timely facilitation of diagnostic testing, timely facilitation of appropriate treatment modalities, use of health services, the cost-effectiveness of each demonstration project, the quality of services provided, and beneficiary and provider satisfaction. The demonstration awardee shall make clear in their proposal that they will cooperate fully with the independent evaluator in all phases of the evaluation including, but not limited to, submission of cost and other program data and site visits by the evaluation contractor.

A CMS evaluation contractor will prepare an initial project assessment report based on 12 months of project data. This report will be used by CMS to form the basis for a Report to the Congress for submission within 24 months of the initiation of the demonstration projects. In accordance with BIPA 2000 Section 122(b)(3), if the findings indicate that demonstration projects reduce expenditures under the Medicare program under Title XVIII of the Social Security Act, or do not increase expenditures under the Medicare program and reduce ethnic and racial health disparities in the quality of health care services provided to target individuals and increase satisfaction of beneficiaries and health care providers, the Secretary shall continue the existing demonstration projects and may expand the number of demonstration projects. It should be noted, however, that Section 122 of BIPA makes no provision for any additional funding for the continuation and/or expansion of these demonstration projects.

VII. Agency Contacts

Questions regarding cooperative agreements administration should be submitted to:

Centers for Medicare & Medicaid Services
Office of Operations Management
AGG, Cooperative Agreements Management Staff
Attn: Judith L. Norris
7500 Security Boulevard, Mailstop C2-21-15
Baltimore, Maryland 21244-1850
Telephone: (410) 786-5130
FAX: (410) 786-9088
E-mail: CPTDEMO@cms.hhs.gov

Technical questions regarding applications for cooperative agreement award should be directed to:

Centers for Medicare & Medicaid Services
Office of Research Development and Information
Attention: C. Diane Merriman, Project Officer
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850
Telephone: (410) 786-7237
FAX: (410) 786-4005
E-mail: CPTDEMO@cms.hhs.gov

VIII. Other Information

Meetings

Applicants must include in their proposal provision for attendance of up to two organizational representatives at (four) annual meetings for the purpose of project discussions at a site determined by CMS.

Other Evidence-based Resources to Reduce Cancer Health Disparities

A number of additional useful resources for addressing cancer health disparities have been compiled that may identify other evidence-based approaches to reducing or eliminating cancer health disparities. One web-based resource is the Cancer Control PLANET (Plan, Link, Act, Network with Evidence-based Tools) (<http://cancercontrolplanet.cancer.gov/>). In partnership, the Agency for Health Care Research and Quality (AHRQ), the American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and the Substance Abuse and Mental Health Services Administration (SAMHSA) have developed this universal “portal” website. Designed to bridge the research discovery program delivery gap and increase the adoption of evidence-based approaches across the cancer control continuum, this web portal allows easy access to five regularly updated research and practice partnership websites. Cancer Control PLANET website tools include:

1. State Cancer Profiles (CDC/NCI)

- ✓ Identify the high-risk populations in your community using national, state and county-level cancer and behavioral surveillance data.
- ✓ Learn which states and counties have the highest cancer incidence and mortality rates, and which states have the lowest screening rates. Download graphical data displays that can be used in the demonstration application.

2. Partners for Cancer Prevention and Control (ACS, CDC, NCI)

- ✓ Find cancer control service partners and research partners in your state to collaborate with on the demonstration application.

3. Guide to Community Preventive Services (Federally-sponsored Website)

- ✓ Determine the effectiveness of different intervention approaches based on systematic reviews of the published research literature. Best practices can help guide targeted intervention efforts.
- ✓ Find the community-based approaches that are recommended by the Task Force on Community Preventive Services, and where additional research evidence may be needed.

4. Guide to Clinical Preventive Services (AHRQ)

- ✓ Provide the latest available guidance on clinical preventive interventions: screening tests, counseling, and medication regimens for prevention and early detection of specific cancers.
- ✓ Access recommendations online from the U.S. Preventive Services Task Force (USPSTF) based on evidence reviews of effectiveness.

5. Research-Tested Programs for Cancer Prevention and Control (NCI/SAMHSA)

- ✓ Find information on evidence-based intervention programs and products, by population and delivery setting, developed and evaluated by researchers in the field of cancer control.
- ✓ View detailed program summary information and program ratings.
- ✓ Download, at no charge, or order intervention products on CD-Rom (brochures, pamphlets, training guides, videos) tested through intervention evaluation research.

6. Program Planning and Evaluation (AHRQ/CDC)

- ✓ Access cancer control planning and evaluation information.
- ✓ Find state-specific comprehensive cancer control plans, as well as contact information for comprehensive cancer control planning in your state.
- ✓ Find guidelines and tools to increase the appropriate use of clinical preventive services.

In addition, the National Cancer Institute has compiled approximately 300 systematic research reviews and other evidence-based reports across the cancer control continuum including early detection, treatment and survivorship. Organized by topic area and cancer site, links to the reports and/or summaries can be found on the NCI Research Diffusion and Dissemination website (<http://cancercontrol.cancer.gov/d4d/>).

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CANCER COVERAGE AND SCREENING GUIDELINES

MEDICARE BENEFIT	DEDUCTIBLE	COINSURANCE	MEDICARE COVERAGE/FREQUENCY GUIDELINES	U.S. PREVENTIVE SERVICES TASK FORCE SCREENING RECOMMENDATIONS
Screening mammography	Waived	Applies	<p>All women with Medicare age 40 and older. Also one baseline mammogram between 35-39.</p> <p>One every 12 months. Medicare also covers new digital technologies.</p>	<p>Mammography, with or without clinical breast examination (BCE).</p> <p>Every 1-2 years for women age 40 and older.</p>
<p>Screening pap smears and pelvic exams:</p> <ul style="list-style-type: none"> -Pap smear (lab test) - Physician exam (Pap test collection, clinical breast exam, pelvic exam) 	<p>Waived</p> <p>Waived</p>	<p>Waived</p> <p>Applies</p>	<p>All women with Medicare.</p> <p>One every 24 months. One every 12 months if high risk for cervical or vaginal cancer, or childbearing age and have had an abnormal pap test in past 36 months.</p>	<p>Pap smear in women who have been sexually active and have a cervix.</p> <p>Women older than 65 years of age with “adequate recent screening with normal pap tests” and are not otherwise at high risk, or who have had total hysterectomy for benign disease, do not need routine screening.</p>
<p>Prostate cancer screening:</p> <ul style="list-style-type: none"> -Prostate-specific antigen (lab test) -Other procedures 	<p>Waived</p> <p>Applies</p>	<p>Waived</p> <p>Applies</p>	<p>All men with Medicare age 50 and older (coverage begins the day after the 50th birthday).</p> <p>PSA test - One every 12 months</p> <p>Digital rectal examination - One every 12 months</p>	

CANCER COVERAGE AND SCREENING GUIDELINES

MEDICARE BENEFIT	DEDUCTIBLE	COINSURANCE	MEDICARE COVERAGE/FREQUENCY GUIDELINES	U.S. PREVENTIVE SERVICES TASK FORCE SCREENING RECOMMENDATIONS
<p>Colorectal cancer screening: -Fecal-occult blood (lab test) -Other procedures</p>	<p>Waived Applies</p>	<p>Waived Applies</p>	<p>All people with Medicare age 50 and older. There is no minimum age for having a colonoscopy.</p> <p>FOBT - One every 12 months</p> <p>Flex. sig. - One every 48 months</p> <p>Colonoscopy - One every 24 months if you are high risk; if not, one every 10 years, but not within 48 months of flex. sig.</p> <p>Barium enema - instead of flex sig. or colonoscopy</p>	<p>All people age 50 and older.</p>