Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities

Frequently Asked Questions

Question: What is the correct application due date for Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities grants/cooperative agreements?

Answer: **(1-3-05)** The correct application due date for Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities grants/cooperative agreements is **March 23, 2005.**

Question: What organizations are eligible to apply for a Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreement?

Answer: **(1-3-05)** Any healthcare-related organization, whether alone or in combination/ collaboration with any other healthcare-related organizations, that can successfully meet, and submit an application that clearly demonstrates the ability to fulfill, **all** the requirements of the Funding Opportunity Announcement is eligible to apply for a Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreement. Otherwise, there are no restrictions regarding the type of healthcare-related organization that can apply for these cooperative agreements. Because of the diverse range of skills and expertise that sites are required to have to meet the criteria for this demonstration, we encourage organizations to develop consortia or partnerships.

Question: How many awards will be made under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreements?

Answer: **(1-3-05)** CMS will award at least nine (9) cooperative agreement projects under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities.

Question: Will CMS accept more than one application from the same organization for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities funding opportunity?

Answer: **(1-3-05)** Yes. The same organization may submit more than one proposal for addressing the different population groups to be targeted in the demonstration.

Question: Please explain the funding for facilitation services and implementation costs mentioned in the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement.

Answer: **(1-3-05)** CMS expects the costs of providing screening and facilitation services to range from $400,000 to $1.5 million per project per year. These costs will be reimbursed through monthly capitation payments to each demonstration site over a 3- to 5-year project period via a cooperative agreement mechanism. Offerors should submit one rate for administering the cancer screening assessment instrument, and a second rate for cancer screening, diagnosis and treatment facilitation services.

CMS will also consider a one-time grant award of up to $50,000 per demonstration project to cover initial implementation costs. This grant award will not be distributed on a lump sum basis up front, but will be distributed incrementally between the time of conditional site award and completion of the waiver cost process.

Question: What is the definition of "special population networks" as mentioned in the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement?

Answer: **(1-3-05)** The National Cancer Institute defines "special population networks" for their program as groups that promote cancer awareness within minority and medically underserved communities and launch from the communities more research and cancer control activities aimed at specific population subgroups. These networks are groups that address ways of building relationships between large research institutions and community based subgroups. We are using this definition for this demonstration.

Question: What is the definition of "capitated monthly payment" in the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement?

Answer: **(1-3-05)** In the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement "capitated monthly payment" refers to a reimbursement methodology that allows sites to be paid on a per-member-per- month basis. The capitated monthly payment rate is up to each individual applicant to propose and should be based on the estimated costs for the specific facilitation services the site will be providing for a set number of individuals over the course of the demonstration. The capitated monthly payment methodology allows for a continual cash flow to the site.

Question: What is the definition of a "control group" that receives "usual care" in the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement?

Answer: **(1-3-05)** The Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement states, "The control group will receive usual care...." This means that control group Medicare patients would receive whatever care they would ordinarily receive, including screening tests as ordered by their healthcare providers, as if this demonstration were not occurring. Therefore, clinical protocols would continue to be applied to control group patients according to an organization's customary practice. This demonstration is not attempting to dictate or change providers' healthcare delivery protocols or guidelines. Rather, CMS is testing the efficacy of introducing a facilitation intervention to help minority beneficiaries "navigate" the healthcare system in a more timely and informative manner.

Question: Are U.S. territories eligible to apply for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreements?

Answer: **(1-19-05)** According to Section 122(e)(1)(B) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000, the Congress specified that funding for any demonstrations conducted in the U.S. territories must be "provided in any Federal law-making appropriations for the territories." Since Congress did not provide appropriations to fund these demonstrations in the territories, we have no way of financially supporting any demonstrations in the U.S. territories.

Question: Must each application for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreements address all four cancers; i.e., breast, cervix, prostate **and** colon/rectum?

Answer: **(1-19-05)** Yes, all four cancers (i.e., breast, cervix, colon and/or rectum, and prostate) targeted by the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities must be addressed by the applicant, as well as treatment of confirmed diagnoses of lung cancer.

Question: Can Quality Improvement Organizations apply for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreements? Must the proposed grant project differ substantially from the work being performed under the QIO contract?

Answer: **(1-19-05)** Yes. Any healthcare-related organization, whether alone or in combination/ collaboration with any other healthcare-related organization(s), that can successfully fulfill **all** the requirements of the solicitation is eligible to apply for a Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities cooperative agreement. Because of the diverse range of skills and expertise that sites are required to have to meet the criteria for this demonstration, we encourage organizations to develop consortia or partnerships. We anticipate that because of

the requirements of the solicitation, QIO CPTD projects will differ substantially from the work being performed under regular QIO contracts.

Question: If Medicare beneficiaries are enrolled to participate in the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities and they subsequently drop their Medicare membership to become members of an HMO instead, what happens to their demonstration enrollment status?

Answer: **(1-19-05)** They will no longer be enrolled in the demonstration. According to Section I.C.1. of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement, "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….Beneficiaries who are enrolled in managed care plans or who are institutionalized are <u>not</u> eligible to participate in this demonstration project."

Question: Are the expected costs of $400,000 to $1.5 million for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities for direct costs only, or do they include indirect costs as well?

Answer: **(1-19-05)** CMS expects the costs of conducting these demonstration projects to range from $400,000 to $1.5 million per project per year. These are **total** project costs which will be reimbursed through capitation payment to the demonstration site.

Question: Is there a range for the target number of eligible participants to get screened and/or treated under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities?

Answer: **(1-19-05)** As stated in Section I.C.1. of the Funding Opportunity Announcement, "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…."

Question: Can projects address more than one State for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities?

Answer: **(1-19-05)** Yes. Since the emphasis is on target populations, as well as rural and urban areas, State lines do not apply to participant recruitment for these projects.

Question: Can a project site retain access to the data being collected for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities in order to carry out its own analyses of these data, understanding that the data will be pooled with data from other projects for the CMS contractor's evaluation analysis?

Answer: **(1-19-05)** Yes.

Question: Can a project site augment or complement funds awarded by CMS with additional dollars from either private foundations or from industry? If so, must private and public dollars be kept separate and distinct, not only in terms of the accounting but in terms of what they support?

Answer: **(1-19-05)** Yes, the project site can complement CMS funds with funds from other sources. However, the CMS funds must be kept separate and distinct from other sources.

Question: Must the screening for cervical cancer be limited to Pap testing or could it include HPV testing as well?

Answer: **(1-19-05)** Since Medicare reimburses only for Pap testing, HPV testing would not be reimbursed by Medicare.

Question: How is contamination of a control group's cancer screening rates to be avoided if navigators are approaching beneficiaries during the recruitment phase and before randomization occurs?

Answer: **(1-19-05)** There is no issue regarding contamination of a control group's cancer screening rates during the recruitment phase. Recruitment and navigation activities are different. While a site may choose to use the same personnel to recruit and help beneficiaries navigate the healthcare system, the activities involved in recruitment and facilitation are quite different.

Question: To be considered a project with a rural (or inner-city) focus, must the project include only rural (or only inner city) beneficiaries or have a certain percentage of rural (or inner-city) beneficiaries? Can a project address both rural (or only inner city) and non-rural (or only inner city) Latino beneficiaries? If so, how is the project categorized?

Answer: **(1-19-05)** The target population can be rural/urban mixed. CMS will determine whether a proposed target population meets the criteria for a rural or urban project.

Question: How does a research proposal differ from a demonstration project?

Answer: **(1-19-05)** Research is a systematic study, including research development, testing and evaluation designed to develop or to contribute to generalized knowledge. The Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities is intended to establish or demonstrate the feasibility of new methods or new types of services; i.e., implementation of cancer screening, diagnosis and treatment facilitation services in Medicare, and evaluation of their impact on health and cost outcomes.

Question: **(1-19-05)** Do study subjects have to be Medicare recipients only? Or can Medicare recipients be a subset of the study population? Are Medicaid recipients eligible to participate? Is the goal to improve health for the entire minority patient population within our healthcare system or just Medicare recipients?

Answer: **(1-19-05)** Enrollees may be dually enrolled in Medicare and Medicaid, but they cannot be Medicaid recipients only. The statute defines target individuals as being "entitled to benefits under Part A, and enrolled under part B, of title XVIII of the Social Security Act [Medicare]." The goal of the demonstration is to improve health for Medicare beneficiaries enrolled in the study, which may include people who are dually enrolled in Medicare and Medicaid.

Question: Please clarify what is meant by a "phase-down" plan.

Answer: **(1-19-05)** The "phase-down" stage of a demonstration project consists of the activities involved in beginning to discontinue the project. CMS cannot state with certainty at this time that Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minority projects will be involved in "phase-down" activities. This will depend upon a CMS evaluation contractor's 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. Therefore, the applicant must address all requirements of the application process.

Question: Is the current Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement a one-time solicitation activity, or will there be another competition under this project next year?

Answer: **(1-19-05)** The current Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities solicitation process is the only competition for this effort for the foreseeable future. These demonstration projects are projected to have a 3-to-5-year operation period. Applicants are required to submit budgets for a 3-year, a 4-year, and a 5-year demonstration.

Question: Must a project under the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities address only one racial/ethnic group, or can it address more than one?

Answer: **(1-19-05)** Each project must address one target minority population. However, applicants can submit more than one proposal, each addressing a different target population.

Question: Section I.C.1. of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement 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. Would this increase be based on some composite of screening for breast, cervical, prostate and colon/rectum, or solely on one type of cancer screening?

Answer: **(1-19-05)** The 10-percent increase will be based on a composite of all the targeted cancer screenings.

Question: If a group of organizations form a consortium for a Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities project, who is the applicant; i.e., is it the consortium or one of the members? If it is one of the members, does CMS have any preference concerning which consortia member should serve as the applicant; i.e., the organization conducting the outreach and screening, the academic entity contributing the treatment expertise, or the physician group employing the clinicians, etc.?

Answer: **(1-19-05)** CMS has no preference concerning which consortia member should serve as the applicant. The applicant must be prepared to assume overall responsibility for the implementation of the demonstration.

Question: Will the CMS randomization process include ALL Medicare eligible patients in the chosen region for screening, or will we be able to have the random selection of a pre-specified number of patients?

Answer: **(1-19-05)** Awardees will provide CMS with participant information for the randomization process. Awardees must maintain records of beneficiary contact and confirmation of their participation in the program, and 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. Following recruitment into the demonstration, 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.

Question: Please define "treatment facilitation."

Answer: **(1-19-05)** For the purposes of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities project, "treatment facilitation" means that the awardee will provide services to assist project enrollees in navigating the health care system to receive and adhere to needed cancer treatment services, such as (but not limited to) completion of multi-modality therapy (e.g., surgery, radiation, chemotherapeutic medications, etc.) and post-therapeutic monitoring and followup.

Question: Please clarify the capitation payment system for reimbursement of Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities facilitation services.

Answer: **(1-19-05)** Under the capitation payment system for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities, awardees will be paid a set amount per member for each month that the person is enrolled in the project. The payment is the same no matter how many facilitation services or what type of facilitation services each patient actually gets. The monthly payment is derived from the overall budget for delivering cancer screening, diagnosis and treatment facilitation services to a target number of beneficiaries specified by the awardee.

Question: Is a single capitation rate (per enrollee per month) to be developed, or can different capitation rates be developed depending on whether or not the enrollee is diagnosed with one of the specified cancers (for both those diagnosed before or during the demo)?

Answer: **(1-19-05)** CMS will negotiate capitation rates with awardees during the waiver cost process period (after site selection by the Administrator). Negotiated rates will be based on information submitted by applicants as required in the Funding Opportunity Announcement. CMS will consider negotiating individual enrollee capitation rates depending upon the enrollee's cancer diagnosis status at the time of project enrollment (see Section I.C.1. of the Funding Opportunity Announcement).

Question: Can the capitation rate be adjusted during the demonstration, particularly if cost or enrollment projections turn out to be inaccurate?

Answer: **(1-19-05)** CMS will consider renegotiating capitation rates with awardees under certain circumstances such as if costs or enrollments change substantially from the awardee's original projections. However, any capitation rate adjustments will ultimately be contingent upon the overall availability of Medicare trust funds remaining for this demonstration.

Question: Please clarify how the various assessment and facilitation services required by the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities will be reimbursed.

Answer: **(1-19-05)** 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. The annual cancer screening assessment for the intervention group and the entrance and exit cancer screening assessment for the control group will be reimbursed as separate capitated costs derived from the overall budget specified by the awardee. The cancer screening, diagnosis, and treatment facilitation services delivered to project enrollees will be reimbursed under the capitation payment system.

Question: Please clarify how the clinical cancer screening, diagnosis and treatment services required by the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities will be reimbursed.

Answer: **(1-19-05)** Medical services that are currently covered by Medicare will continue to be covered for beneficiaries participating in this demonstration. Current claims submission and processing procedures apply to existing medical services delivered to beneficiaries participating in this demonstration (see Section VIII, *Cancer Coverage and Screening Guidelines*). Participation in this demonstration will not change the amount, duration or scope of a beneficiary's fee-for-service Medicare benefits.

Question: Does the statistically significant sample size apply to both Medicare beneficiaries belonging to a defined ethnic or racial minority group who did not have a current diagnosis of cancer prior to enrollment in the demonstration project, as well as to Medicare beneficiaries belonging to a define ethnic or racial minority group who have been diagnosed with cancer prior to enrollment in the demonstration project?

Answer: **(1-25-05)** Yes; statistically significant sample sizes must be provided for both groups so as to support statistically significant results.

Question: If the submitted project and budget were approved, would we be able to count on receiving the budgeted funds in advance to cover costs incurred during the year, or would we have to expend our own funds first to cover project costs and then be reimbursed on a per-patient service provision basis?

Answer: **(1-25-05)** Under the capitation payment system for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities, awardees will be paid a set amount per member for each month that the person is enrolled in the project. Awardees will be paid monthly for these services and will not receive their total funds for the demonstration upfront. The monthly payment will be derived from the overall budget negotiated between CMS and the awardee for delivering cancer screening, diagnosis and treatment facilitation services to a target number of beneficiaries specified by the awardee.

Question: Should applicants include costs for collecting data that will be used in evaluating clinical outcomes, patient satisfaction, and patient quality of life in their overall budget for this demonstration?

Answer: **(1-25-05)** The data that awardees are required to collect will be in connection with the delivery of cancer screening, diagnosis and treatment facilitation services to a target number of beneficiaries specified by the awardee. This data collection activity must be included in the monthly capitation payment rate.

Independent of this solicitation, CMS will contract with an evaluation contractor who will collect separate data to conduct a formal evaluation of the demonstration. The applicant 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.

Question: Will the demonstration organization be at full financial risk for all services covered under the capitation payment?

Answer: **(1-25-05)** Under the capitation payment system for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities, awardees will be paid a set amount per member for each month that the person is enrolled in the project. Awardees will not receive total demonstration funding upfront, but in monthly capitation payments derived from their overall budget. Unlike some of CMS's disease management demonstrations, Medicare will not recover funds from sites that do not meet budget neutrality.

Question: Will randomization be carried out separately for those without and those with a cancer diagnosis at enrollment?

Answer: Yes.
(1-25-05)

Question: Will the demonstration be limited to Medicare beneficiaries age 65 and over or can younger beneficiaries be included?

Answer: The statute defines target individuals as being "entitled to benefits under Part A,
(1-25-05) and enrolled under part B, of title XVIII of the Social Security Act [Medicare]." The legislation does not specify that the beneficiary has to be 65 and over. Medicare coverage for some of the target cancers starts at 40 (mammograms) and 50 (CRC and PSA). Enrollees may be dually enrolled in Medicare and Medicaid, but they cannot be Medicaid recipients only. Any Medicare beneficiary who meets these, as well as the target racial and ethnic population, criteria is eligible for recruitment in this demonstration.

Question: Are the costs associated with attendance at meetings stipulated in the RFP (up to two organization representations for four annual meetings) to be covered by the capitation payment?

Answer: All costs associated with delivering cancer screening, diagnosis and treatment
(1-25-05) facilitation services to the target population as required by the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement must be included in the monthly capitation payment derived from the overall budget specified by the awardee.

Question: Would U.S. residents and citizens who were born in Sub-Saharan Africa qualify for participation in the demonstration project? Could organizations which represent these populations join in collaboration with local health-care provider organizations as co-applicants?

Answer: Yes.
(1-25-05)

Question: Do the rural areas need to match the same standards of statistical significance as the urban areas?

Answer: Yes.
(1-25-05)

Question: Please specify for what purpose the initial $50,000 startup funds are intended.

Answer: **(1-25-05)** CMS is willing to consider requests for assistance with the following kinds of initial implementation costs: modification of existing protocols, services, outreach, educational materials, hiring of personnel, and attendance of awardee representatives at the first annual demonstration meeting. 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.

Question: Are "urban" and "rural" people considered specific target population types?

Answer: **(1-25-05)** No, the legislatively-mandated "rural" and "inner-city" area projects, as well as the Pacific Islands project, are project locations, not target populations. The four legislatively-mandated target populations are American Indians (including Alaskan Natives, Eskimos, and Aleuts), Asian Americans and Pacific Islanders, Blacks, and Hispanics. CMS will determine whether a proposed target population meets the criteria for a "rural" or "inner-city" project.

Question: If an applicant wants to provide services to an urban African American (Black) and a rural African American (Black) population, would that population and service area (urban and rural together) be acceptable in one proposal?

Answer: **(1-25-05)** Yes.

Question: Section I of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement states: "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. Must the applicant address both populations in the proposed project, or is it acceptable to only target ONE population; i.e., a screening project?

Answer: **(2-28-05)** Both types of Medicare beneficiary populations must be addressed. 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) followup of abnormal findings and diagnosis; and (3) improved access to and followup of treatment and adjuvant treatment services. For the second population, the applicant must propose facilitation strategies to improve access to and followup of treatment and adjuvant treatment services for confirmed diagnosis of at least one of the demonstration-specified cancers and/or lung cancer.

Question: Certain requirements of the "CMS Grant Application Information Kit" do not exactly match the application requirements contained in the "Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement." Which requirements should be met for a responsive application package?

Answer: **(2-28-05)** The application requirements in the "Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement" take precedence.

Question: The term "cancer screening assessment" is easily confused with the references to the required facilitation of cancer screening activities throughout the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement. Please clarify.

Answer: **(2-28-05)** After reconsideration of the term "cancer screening assessment," we are changing this term to "**cancer status assessment**" to avoid confusion.

Question: Is a copy of the CMS cancer status assessment instrument available for preview?

Answer: **(2-28-05)** We are working with our independent CPTD implementation contractor to develop the cancer status assessment instrument. The tool will essentially collect patient history information sufficient to determine whether and when a project participant has seen a physician, been screened for the target cancers under this demonstration, and/or been diagnosed with a target cancer prior to demonstration project enrollment. This information will be used by the project site to inform CMS as to whether the participant should be placed on the list of "persons without a current diagnosis of cancer prior to enrollment in the demonstration project" or the list of "persons previously diagnosed with cancer of the breast, cervix, colon and/or rectum, prostate or lung prior to demonstration project enrollment." There will be no collection of risk assessment information or clinical examinations via the cancer status assessment administration.

Question: Please clarify the process timeline in Section I.C.1-5.

Answer: **(2-28-05)** We have provided a demonstration process flowchart via a new link on the CPTD website.

Question: Would the randomization be performed at the level of the applicant organization's study population, or would it be done at the level of the national pool of participants in the demonstration project?

Answer: **(2-28-05)** The randomization will be performed at the level of the applicant organization's study population. (Please refer to the demonstration process flowchart via a new link on the CPTD website.)

Question: Please clarify whether the capitation fee must cover services provided to participants with comorbidities; e.g., a cancer patient with diabetes.

Answer: **(2-28-05)** Persons with comorbidities may participate in the demonstration, but the capitation fee is to only cover facilitation services delivered for the cancer screening, diagnosis and treatment, not for services related to treatment of comorbidities. All Medicare covered clinical services will be reimbursed through the regular Medicare claims processing system.

Question: The RFA requires that each site evaluate interventions to improve outcomes for both individuals at risk, as well as patients diagnosed with cancer. This poses a practical challenge, as only a small proportion of participants in a screening program would be diagnosed with cancer; and the yield would be insufficient for an intervention study that is adequately powered to answer a major research question about patients diagnosed with cancer. Therefore, we have decided to design two separate randomized controlled trials. We would like to confirm that this approach, i.e., two separate studies, both focusing on African Americans in Baltimore, would be responsive to the RFA.

Answer: **(2-28-05)** Your understanding of and approach to the requirements of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement are correct. The "CPTD Process Flowchart" (which can be accessed via a new CPTD website link) indicates that based on the results of the "Cancer Status Assessment," the project site will determine whether the participant should be placed on the list of "persons without a current diagnosis of cancer prior to enrollment in the demonstration project" or the list of "persons previously diagnosed with cancer of the breast, cervix, colon and/or rectum, prostate or lung prior to demonstration project enrollment." A CMS contractor will randomize these two separate lists into a control and intervention group for each population; i.e., a control and intervention group each for "persons without a current diagnosis of cancer prior to enrollment in the demonstration project" and a control and intervention group each for "persons previously diagnosed with cancer of the breast, cervix, colon and/or rectum, prostate or lung prior to demonstration project enrollment."

Question: Has CMS placed a limit on the fee for risk assessment and the capitation rate?

Answer: **(2-28-05)** CMS will negotiate capitation rates with awardees during the waiver cost process period (after site selection by the Administrator). Negotiated rates will be based on information submitted by applicants as required in the CPTD Funding

Opportunity Announcement. All capitation rates will ultimately be contingent upon the overall availability of Medicare trust funds authorized for this demonstration.

Question: Can the project budget include the cost of co-insurance for the screenings that require co-insurance, e.g., screening mammography, sigmoidoscopy, and colonoscopy? Since one of the major barriers for patients undergoing treatment is the coinsurance, can the project budget include funding to help participants pay coinsurance for treatment services?

Answer: **(2-28-05)** A site may choose to waive coinsurance for cancer screening services and pay the difference out of its budget. Applicants choosing to do this should include coinsurance costs in their budget. Coinsurance and facilitation costs should be presented very clearly in the proposed budget to allow CMS to make a decision as to whether funds are available to cover both costs. Ensuring there is enough funding to cover facilitation services is the first priority, as the purpose of this demonstration is to evaluate the impact of these services on reducing disparities in cancer outcomes and not to test the impact of waiving coinsurance for cancer screening.

Question: Section I.C.1. of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities Funding Opportunity Announcement 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. Beta is the probability of a Type II error or the chance of missing a meaningful difference. If you expect 80 percent power, shouldn't beta = 0.20 since Power = 1-beta?

Answer: **(2-28-05)** Yes, beta should equal 0.20.

Question: Does the desired difference of at least 10 percent increase in screening mean 10 percentage points (e.g., 50 percent screened in facilitated screening vs. 40 percent in control) or does it mean 110 percent of the control screening rate (e.g., 40 percent x 110 percent = 44 percent)?

Answer: **(2-28-05)** We are looking for a 10 percent increase in screening rates between the treatment and control group, which would mean 110 percent of the control screening rate. This applies to the group of participants that do not have cancer at the time of entry into this study. The applicant is to propose its sample size estimates for determining the impact of cancer treatment facilitation services for the group that does have cancer at the time of recruitment into the demonstration.

Question: Can an applicant, due to concerns about contamination and community needs, request that CMS conduct their randomization by locality, county, or some other aggregate unit?

Answer: **(3-14-05)** The solicitation indicates that we expect beneficiaries to be randomly assigned. Applicants must present such an approach and be prepared to implement it. The applicant may also discuss an alternative approach, such as by locality, and explain why this design would be more appropriate. CMS will make the decision to accept an alternative randomization procedure.