

**Maryland Department of Health and Mental Hygiene, Center for Cancer Prevention and Control
Guidance for Cancer Client Database (CDB) Form Completion: Prostate Cancer Post-Screening**

PAGE #	SECTION	FIELD	GUIDANCE	REQUIRED FIELD
			<p><i>Data will be entered in the Prostate Post-Screening form for clients who: 1) have had an abnormal DRE or PSA in the program (as part of a physical exam performed in the CRC module of your program) and need to have further evaluation to rule out prostate cancer, or 2) need diagnosis and/or treatment but were screened outside of the program .</i></p>	
1	Program Eligibility	Is client eligible for additional CRF diagnosis, treatment, or case management services?	<p>Eligible for diagnostic, treatment, and/or case management services in CRF Program, when indicated (e.g., surgery, chemotherapy, additional procedures, etc.). Your response to this field will determine how the rest of this form is completed.</p> <p>- If you check either of the "Yes" choices, the CDB will take you directly to page 2 of this form. If you select "No" or "Unknown" you will be able to enter data into the "Ineligible Client" fields on page 1. Once complete, you will then be positioned at the Cycle Closure page without every going to page 2.</p> <p>Yes, funds available: Client needs more care and: 1) Client meets income, insurance, and residence eligibility of Program, 2) Client has signed "long form" consent, and 3) CRF funds are available and being used to pay part or all of the medical care. (This may include clients who have no coverage, or those, for example, who get Medical Assistance but on whom you are spending CRF funds for services not covered by MA or other insurance.)</p> <hr/> <p>Yes, but funds NOT available: Client needs more care and: 1) Client meets income, insurance, and residence eligibility of Program, 2) Client has signed "long form" consent, and 3) CRF funds are NOT available to pay for any part of their medical care so you have linked the client to another payment source, e.g. Medical Assistance (MA), Maryland Cancer Fund (MCF), Maryland Health Insurance Plan (MHIP), Charity Care or some other source of funding so cover the expenses incurred for diagnosis and/or treatment.</p> <p>Checking "Yes, but funds not available" will allow you to reflect your case management required to link a client to care and guide them through the process and to document the findings and outcomes on clients you case manage (e.g., stage, type of treatment).</p>	Yes

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1	Program Eligibility	Is client eligible for additional CRF diagnosis, treatment, or case management services?	<p>No: 1) Client needs more care; and 2) Client does not meet income, insurance, age, or residence eligibility of Program.</p> <p>For example, if your program does not require written documentation of eligibility for screening and upon request for that documentation to determine eligibility for treatment you discover that the client is over-income and therefore not eligible for treatment funds then client should be entered as "No."</p> <hr/> <p>Unknown: Client declines to provide the Program with the information necessary to determine eligibility. Program is unable to obtain necessary eligibility information, e.g., client is lost to follow-up before eligibility is determined.</p>	Yes
	Ineligible Client	Reason for Ineligibility	<p>Check all that apply:</p> <hr/> <p><i>Age:</i> Client does not fall in the specified age range for diagnosis or treatment as specified by the Program.</p> <hr/> <p><i>Income:</i> Client's income is too high to meet the eligibility criteria.</p> <hr/> <p><i>Health Insurance:</i> Client had health insurance when first enrolled in the Program (e.g., private, Medicaid, Medicare, military) that will cover the costs associated with the needed diagnostic and/or treatment procedures. As noted above, if the client obtained insurance through linkage by your program for diagnostic and/or treatment services, the client should not be considered ineligible in this cycle due to insurance.</p> <hr/> <p><i>Residency:</i> Client does not meet residency criteria as specified by the Program (e.g., does not live in Maryland or has moved out of state before initiating additional procedures or treatments).</p> <hr/> <p><i>Other, specify:</i> Check "other" and enter reason if not covered above.</p>	No

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1	Ineligible Client	Was ineligible client referred elsewhere for diagnosis/treatment?	All ineligible clients who need further evaluation for abnormal findings should be referred. This can be a referral to a specific health care provider (HCP)/physician/practice OR can be a recommendation in writing, that the client seek out a urologist for further evaluation or at least contact his own primary care physician to seek out further diagnostic or treatment options. If the client refused a referral or was lost to follow-up before a referral could be made, please note this in the "Comments" section.	Yes
		Ineligible Client Outcome	<p>- Choose only one:</p> <p>- In order to complete this section, you will need to contact the client to see if the client was seen by the HCP to which he/she was referred for follow-up. It is important to do this so you can document the outcome of that follow-up effort.</p> <p>Per latest Standards of Care for Case Management, you should make at least one contact after referring the client to determine the outcome of the referral and to make sure the client has followed through with the provider for care; if not reached or if client has not followed through, send the client the recommendations by certified letter.</p> <hr/> <p>- Choose only one.</p> <p><i>Client consulted/scheduled appt./saw HCP:</i> Check this one if the client tells you he/she has consulted with, scheduled an appointment with, or has seen an HCP regarding the positive findings, even if it is not the specific HCP to whom you referred the client.</p> <hr/> <p><i>Client declined to see HCP:</i> Check this one if the client tells you he/she is not planning on consulting or seeing an HCP for the positive findings.</p> <hr/> <p><i>Client plans to see HCP:</i> Check this one if the client tells you he/she has not yet contacted an HCP regarding the positive findings, but is planning to do so. If you call the client at a later date and the client has contacted or seen the HCP, you can change this to the first choice.</p> <hr/> <p><i>Client lost to follow-up:</i> If you are unable to locate the client to find out if the client did see an HCP, then you should choose this option. Please document in "Comments" what efforts were made to contact the client.</p>	Yes
		Final disposition of ineligible clients who contacted an HCP	<p>- Choose only one.</p> <p>- You will only be able to enter a final disposition if you have selected "Client consulted/scheduled appt./saw HCP" from above.</p> <p>- The information for this section may be provided by the client, a family member, or the HCP who saw the client. Please specify in "Comments" the source of the information as this will affect the cycle closure.</p>	Yes

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1	Ineligible Client	Final disposition of ineligible clients who contacted an HCP	<p><i>Not Cancer:</i> If client, family member, or HCP reports that the client saw a HCP who made some decision on whether or not the client was believed to have cancer.</p> <ul style="list-style-type: none"> - If the DRE was abnormal on screening, but felt to be normal at re-examination, that would meet the criteria for "Not Cancer." - If the client had an elevated PSA, had a course of antibiotics for possible prostatitis, and a repeat PSA was normal and no further work-up was recommended, this would qualify as "Not Cancer". - A prostate needle biopsy that was negative for cancer would qualify as "Not Cancer." <p><i>Refused:</i> If you cannot get the outcome of the HCP visit because the client, family member or doctor does not want to provide you with this information, choose this option.</p> <p><i>Unknown:</i> If you cannot reach the client to find out the outcome of the visit, or if the client does not know the results of the procedure, then choose this option and document in "Comments" what efforts were made to contact the client.</p> <p><i>Other, specify:</i> If the client, family member, or HCP says tests were not done to rule out cancer, then choose "Other" and specify why the tests were not done or why they were inconclusive.</p> <p><i>Cancer, specify type:</i> If the client, family member, or HCP says that prostate cancer was found, specify the type here (e.g. prostate cancer or adenocarcinoma). If another type of cancer was found, check Other, specify (above), do not check Cancer here, and note more in Comments.</p> <p><i>Specify treatment status:</i></p> <ul style="list-style-type: none"> - If treatment was recommended and the client did undergo the treatment, select "started treatment." This could include any therapy, even Watchful Waiting. Please specify in comments they type of treatment the client received, if known. - If treatment was required but the client refused, select "refused treatment." - If Prostate Cancer was identified, treatment recommended but the client was lost to follow-up and you are not sure what the treatment status is or if the client has moved out of the area, select the appropriate box: "lost to follow-up" or "moved", respectively. - If none of these options apply, select "other" and then specify what "other" means. 	Yes
		Comments:	Enter any comments pertinent to the diagnosis. Please indicate what efforts were made to contact the client if you were unsuccessful in your attempts. If you were successful, please indicate the source of information for the follow-up outcome.	No

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1	Cycle Closure (for Ineligible Clients or Clients with Unknown Eligibility)	Date Cycle Closed	You should close the cycle when: - 1) you have successfully contacted the client and the client has completed all recommended screening and all the results that are available to you have been obtained and documented; - 2) the client has refused further follow up for screening, diagnosis, or treatment; - 3) the client, family member, or HCP has refused to provide information regarding the follow-up outcome; or - 4) you have exhausted your efforts to contact the client to determine the outcome.	Yes
		Date Cycle Closed	- Client, family member, or HCP has refused to provide information regarding the follow-up outcome. - You are unable to contact the client after several attempts per program policy.	Yes
		Cycle Outcome	Choose one option: Cancer detected: If the patient, a family member, or the HCP reports to you that prostate cancer was detected, choose this outcome. No cancer detected: If you have a copy of the report from the prostate screening or if you have a verbal report from the doctor's office that a screening was performed that did not find cancer or that a biopsy was done and that biopsy was negative, choose this outcome. No cancer suspected: If the client reports to you that further examination or testing was done and no cancer was found or suspected, but you have no confirmation of this from the doctor's office, choose this outcome. Abnormal, cancer status unknown: Choose this outcome if: 1) the client refused follow-up, or the necessary diagnostic tests were not done for any other reason, e.g., client could not be medically cleared for biopsy or surgery, or 2) you do not know the outcome of the follow-up because the client refused to tell you or you were not able to reach the client to find out.	Yes
		Screening Recall	- The recall should be determined by the provider who performed the procedure and should be included in a written summary note. - If the recall is changed after you have entered it in the CDB, put a note in the Recall and/or Closure Comments explaining why; you will have to change the date in the Recall Table as this section will now be locked for editing. - If the client is eligible for some screening services in your program but not all, you can enter a recall for a procedure for which the client is eligible in your program. - If you want to just contact the client at a future date to reassess eligibility, you can enter a recall for "other" and specify a phone call to remind the client to get screened and/or to re-assess eligibility. - If the client is not eligible for further screening in your program you do not need to enter a recall; you can discharge the client.	Yes
		Cycle Closure Comments:	You can enter here any comments about the cycle that you have not previously noted.	No

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1	Eligible Client	Diagnosis/ Treatment Payer	Multiple boxes may be selected: mark all payers that will be contributing to coverage for diagnosis and treatment. It is important that you document all payers who covered expenses related to the prostate cancer diagnosis and/or treatment procedures required.	Yes
		Was eligible client referred for consultation and/or biopsy?	This field should be marked "Yes" for all clients who are referred for any procedures or treatments beyond the initial prostate screening. Include the name of the HCP or practice to which the client is referred and the date of the appointment. If the client is not referred, please indicate why in the "explain" field.	Yes
2	Consultation, Laboratory, and/or Biopsy Results	Additional Laboratory Tests	<p>These fields (up to three) should be used to indicate any additional tests (e.g., blood tests) that were performed during the post-screening consultation. (The results of Trans Rectal Ultrasounds (TRUS) and TRUS guided biopsies are entered in the procedure section below.) These procedures will automatically be listed as procedures in the "Additional Procedures" section along with the appropriate information.</p> <p>Scheduled: Enter the date the test is scheduled to be done.</p> <p>Date Rescheduled: If the test was rescheduled, the new date may be entered for each test.</p> <p>Date: The actual date the test was performed must be entered.</p> <p>Test: Select the type of test that was performed from the drop down list. Other, specify: If "other" test is chosen, enter a brief description of the test.</p> <p>Lab/Provider: Select the name from the drop down box or add a new provider to the drop down; or specify provider in "Other Provider" box.</p> <p>Date Results Received by Program: Enter the date that your program received the results from the Lab/Provider.</p> <p>Results: Enter the results of the test that was performed.</p> <p>Comments: Any additional comments regarding the tests should be entered here.</p>	Yes
		Examination	<p>This section records the date, provider, and results of a consultation with a urologist and possible physical examination findings. Once this section is completed, it will be listed in the "Additional Procedures" section as a Consult-procedure.</p> <p>Date Exam Scheduled: Enter the date the examination is scheduled to be done. Date</p> <p>Exam Rescheduled: If the examination was rescheduled, enter the new date. Date of</p> <p>Exam: The date the exam was performed is required.</p> <p>Provider: Select the name from the drop down box or add a new provider to the drop down; or specify provider in "Other Provider" box.</p> <p>Date Results Received by Program: Enter the date your program received the results from the provider.</p> <p>Examination Results: These results are required, and must be entered as text.</p>	Yes

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2	Consultation, Laboratory, and/or Biopsy Results	Procedure- Check all that apply	<p>None: This box is the default and therefore is checked when no other box is checked.</p> <p>TRUS only: Date Scheduled: Enter the date the TRUS is scheduled to be done. Date Rescheduled: If the examination was rescheduled, enter the new date. Date: The date that the TRUS was performed must be entered here. Date Results Received by Program: Enter the date your program received the results from the provider. Results: This is a text field for entry of TRUS results.</p> <p>TRUS-Guided biopsy: Date Scheduled: Enter the date the TRUS is scheduled to be done. Date Rescheduled: If the examination was rescheduled, enter the new date. Date: The date that the TRUS-Guided biopsy was performed must be entered here. Pathology Lab: Select the name from the drop down box or add a new provider to the drop down; or specify provider in "Other Provider" box. Date Results Received by Program: Enter the date your program received the results from the provider. Results: Check the appropriate box. Provide the Gleason score and clinical stage. Other, specify procedure: If another procedure was performed, indicate the name of the procedure along with the date and the results. Date Scheduled: Enter the date the procedure is scheduled to be done. Date Rescheduled: If the examination was rescheduled, enter the new date. Date: The date that the procedure was performed must be entered here. Pathology Lab: Select the name from the drop down box or add a new provider to the drop down; or specify provider in "Other Provider" box. Date Results Received by Program: Enter the date your program received the results from the provider. Results: This is a text field for entry of procedure results. <i>Note: Any additional procedures, including diagnostic PSA's or DRE's, should be entered under Additional Procedures.</i></p>	Yes
		Impression	Enter the impression that was given by the provider who performed the consultation and the procedure(s).	Yes
3	Summary of Diagnostic Work Up and Treatment	Recommendations at Completion of Diagnostic Work-up	<p>Check all that apply: Recall for routine screening. Exam in ____ months. Date of re-exam: _____ (If a provider has indicated that the client should be re-examined within a specific timeframe, enter the number of months and the date.) Refer for consultation, further evaluation, treatment, etc. (If this option is selected, also enter who the Other, specify (Choose this option if none of the other options listed above apply, and specify the recommendation.)</p>	Yes

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3	Summary of Diagnostic Work Up and Treatment	Diagnosis Status	<p>Select one of the following choices:</p> <p>Complete-Work-up has been completed and prostate cancer was found or prostate cancer was ruled out by biopsy or was no longer suspected after consultation.</p> <p>Refused-Client refused one or more of the recommended procedures or consults needed to complete the work-up.</p> <p>Moved-Client moved out of the jurisdiction before the work-up could be completed.</p> <p>Deceased-Client died before the work-up could be completed.</p> <p>Lost to follow-up-Client was lost to follow-up before the work-up could be completed. Client is determined to be lost to follow-up when a letter is returned indicating the client is no longer at the address and the given phone number is not in service or the client is no longer at that number.</p> <p>Pending final diagnosis-Diagnostic work-up is not completed by the time the cycle is closed but is still in progress, e.g., more tests or procedures are needed to complete the diagnosis but it has been a year since the cycle start date so a new cycle must be started.</p> <p>Chose other provider-Client has chosen to complete his/her diagnostic work-up with a provider not covered by the program and the results of that work-up are not available to the program.</p> <p>Treatment only-Client was diagnosed with prostate cancer prior to starting the cycle and enrolled for treatment only.</p> <p>Unknown-The diagnostic status is unknown for a reason other than any of the above. Please note in the comments section why the diagnostic status is unknown.</p>	Yes
		Date of Diagnosis	<p>If Diagnosis Status = Complete: Enter the date of the procedure/visit that verified the finding of prostate cancer or the date of the procedure/visit that ruled out prostate cancer. If it was a biopsy procedure then it will be the date of the biopsy. If a biopsy was not done but the diagnostic status is complete, enter the date of the visit to the doctor at which this determination was made.</p> <p>If Diagnosis Status = Refused, Moved, Deceased, Lost to follow-up, Pending final diagnosis, Chose other provider, or Unknown: Enter an administrative close-out date as the date of diagnosis.</p>	Yes
		Comments	Enter any comments pertinent to the diagnosis.	No
		Final Diagnosis	<p>Select one from the following options:</p> <p>Normal/Negative for cancer - No evidence of cancer or other diagnosis.</p> <p>Other diagnosis, not cancer, specify - Include prostatic intraepithelial neoplasia (PIN), benign prostatic hypertrophy (BPH), prostatitis, etc.</p> <p>Possible cancer, work-up incomplete - Client has not completed work-up.</p> <p>Cancer, or carcinoma in situ - If cancer, select type-either adenocarcinoma or other, specify.</p>	Yes

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3	Summary of Diagnostic Work Up and Treatment	Cancer Treatment Plan	Select all that apply: Indicate the treatment type(s) that client has begun/will undergo (NOT what was recommended if different from what client received. If some type of treatment was recommended and client refused , please note this in Comments). <ul style="list-style-type: none"> - Surgery - Radiation - Hormonal Treatment - Chemotherapy - Watchful Waiting - Unknown - Other, specify Any procedures that are performed as part of treatment (e.g., surgery, RT, chemo, etc.) should be entered as "Other" procedures in "Additional Procedures."	Yes
		Date of first treatment began	Enter the date the client began their first form of treatment. If the client chooses watchful waiting, enter the date the decision was made, if known.	Yes
		Comments	Enter any comments that your program has with regards to treatment.	No
		Gleason Score on Prostatectomy	If a prostatectomy was performed, enter the Gleason Score from the pathology report for the prostatectomy. If client did not undergo prostatectomy, please leave blank.	No
			All staging information, tumor, nodes, metastases and stage, should be obtained from the surgical pathology reports and treatment providers. If no surgery has been done you may have to rely on clinical staging from the oncologist. If you are unable to obtain staging information, the staging field(s) should be coded as "unknown."	
		Stage Tumor	This refers to the depth of the tumor for the procedure in which the cancer was diagnosed according to the American Joint Committee on Cancer (AJCC): T1-Clinically inapparent tumor not palpable nor visible by imaging; T2-Tumor confined within prostate; T3-Tumor extends through the prostate capsule; T4- Tumor is fixed or invades adjacent structures other than seminal vesicles: bladder neck, external sphincter, rectum, levator muscles, and/or pelvic wall. Tumor stage may be unknown if the information is not available.	Yes
		Stage Nodes	Lymph node staging can be obtained in two ways: 1) Lymph nodes can be removed during surgical resection. "N0" means lymph nodes were removed at surgery and examined, and no cancer was found in any regional lymph nodes. "N1" means prostate cancer was found in regional lymph node(s). 2) In the client who does not have a surgical resection, lymph nodes can be evaluated with radiologic examinations. Lymph nodes that are thought to be enlarged can be assumed to have prostate cancer present, especially if they later shrink with therapy. "NX" means regional lymph nodes were not assessed and no information is available. In the CDB, select whether the nodes were negative (no prostate cancer present), positive (prostate cancer present), or unknown.	Yes

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3	Summary of Diagnostic Work Up and Treatment	Stage Metastases	This refers to organ metastases, not lymph node involvement. "M0" means <u>no</u> distant metastasis and "M1" means distant metastasis. "MX" means it is unknown whether or not there are distant metastases. In the CDB, select whether the metastases were negative (no evidence of distant prostate cancer), positive (there is evidence of distant prostate cancer) or unknown. Metastases may be apparent on radiologic examination, such as bone scans, in which case they are considered to be "M1" or positive.	Yes
		Stage	This requires evaluation of tumor depth, node involvement, and presence or absence of metastases. In the CDB, select the staging by choosing either I, II, III, or IV. Stage may be unknown or not determined if complete information on tumor, nodes, or metastases is unavailable.	Yes
		Treatment Status	This field marks the status of treatment after diagnosis; choose one: -Started/completed – Client began or completed treatment--Check here even if Cancer Treatment Plan was for "Watchful Waiting". -Deceased – Client died prior to treatment. -Lost to follow-up – Treatment was not begun and client could not be located. -Refused – Client refused treatment after diagnosis. -Unknown – Information could not be obtained or is not known regarding treatment status. -Moved – Client changed address prior to treatment.	Yes
		Hospitalized	All clients who undergo surgery are generally hospitalized, so this should be "Yes" for all clients who are admitted for any diagnostic or treatment procedures. When you check "Yes" in this section, the program automatically creates a "hospitalization" procedure which you can modify by using the "Additional Procedures" part of the CDB. Please do not create a second Hospitalization procedure in "Additional Procedures." You should not enter any "pathology findings" in the hospitalization section itself. You should, however, <i>note the date of first admission</i> and any complications that may have occurred during the hospitalization. There is also a space for comments.	Yes
		Hospice	Check "Yes" if the client is referred to hospice for home or in-house hospice care. Checking "Yes" in this section will automatically create a "Hospice" procedure (similar to the automatic creation of a "Hospitalization" procedure). Please do not create a second Hospice procedure. You are able to modify the Hospice entry by using the "Additional Procedures" part of the CDB.	Yes
	Cycle Closure (for Eligible Clients)	Date Cycle Closed	Enter the date you closed the cycle. Program staff should close a cycle when: 1) the client has completed all screening, diagnosis, and treatment procedures indicated/recommended for that cycle; 2) the client has refused further screening, diagnosis, or treatment; 3) the client is lost to follow-up; 4) the client is ineligible for further screening, diagnosis, or treatment; 5) the client has chosen or been linked to another provider; or 6) the client dies. How long you wait to determine, for example, that the client is lost to follow-up before closing the cycle is a local decision (refer to local policies/procedures). When you close a cycle, consider whether the client needs to be discharged from the Prostate module or from the program entirely (e.g., when a client is lost to follow-up or is deceased). You can continue to add additional procedures after the cycle is closed.	Yes

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3	Cycle Closure (for Eligible Clients)	Cycle Outcome	<p>Please note that the choices for Cycle Outcome on each hard copy form do not include all the options for Cycle Outcome that you will see on the screen. More detailed information on the definitions of cycle outcome is included on the Help menu.</p> <p>Cancer detected-Cancer detected and confirmed through a biopsy or during surgery. No cancer detected-A biopsy was done for abnormal screening results and no cancer was found. No cancer suspected:</p> <ul style="list-style-type: none"> - DRE exam normal or abnormal but not suggestive of cancer and PSA not elevated. - PSA not elevated and DRE not performed. - DRE exam normal or abnormal but not suggestive of cancer and PSA not done. <p>Abnormal, cancer status unknown:</p> <ul style="list-style-type: none"> - The program was unable to notify the client of an abnormal result following the initial screening. Client had an elevated PSA or DRE that was suggestive of cancer and the program has no more information on diagnosis/treatment. - Ineligible clients with an abnormal finding on initial screening, for whom no final diagnosis is available. This includes those entered with "client declined to see HCP," and "client lost to follow-up.". It would also include clients whose Final Disposition (after contacting an HCP) is "refused," "unknown," or "other." - Among eligible clients, those who had abnormal screening and further testing is incomplete or has not been conducted because client is lost to follow-up, refused biopsy/work-up, moved, chose other provider, or other reason. <p>No screening done, cancer treatment only-Men who came into the program after screening to have diagnosis and/or treatment paid for by the program OR men who have already been diagnosed with cancer and are now undergoing further treatment in subsequent cycles. No screening done, cancer status unknown-No screening test (PSA or DRE) performed.</p>	Yes

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3	Cycle Closure (for Eligible Clients)	Screening Recall	<p>- The recall should be determined by the provider who performed the procedure and should be included in a written summary note.</p> <p>- If the recall is changed after you have entered it in the CDB, put a note in the Recall and/or Closure Comments explaining why; you will have to change the date in the recall table as this section will now be blocked for editing.</p> <p>- If the client is eligible for some screening services in your program but not all, you can enter a recall for a procedure for which the client is eligible in your program. This includes surveillance screening after cancer is diagnosed.</p> <p>If you want to just contact the client at a future date to reassess eligibility you can enter a recall for "other" and specify a phone call to remind the client to get screened and/or to re-assess eligibility.</p> <p>- If the client is not eligible for further screening in your program you do not need to enter a recall, you can discharge the client.</p> <p>- If the client has a diagnosis of cancer and will be returning for follow-up of future PSAs, enter visits in the recall table, and start a new cycle for each year of follow-up surveillance</p>	Yes
		Comments	Enter any additional comments that your program may have.	No