

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

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Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road, MS-24, Atlanta, GA 30333

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| Item # | Variable Name | Column Length Begin End | | | Codes / Format / Comments | Edit Checks / Skip Patterns |
|---|--|----------------------------|----|----|---|---|
| 1. Client and Record Identification – Complete for each CCDE record | | | | | | |
| 1.1 | Program | 3 | 1 | 3 | State FIPS code or program code assigned to tribal and territorial programs. Right justify and include leading zeroes (i.e. California = 006). | Valid code for your program. |
| 1.2 | Client identifier | 15 | 4 | 18 | If Social Security Number (SSN) is used, it must be encoded. The ID number must be unique for each client and used consistently across all records for an individual client in order to track the client over time. This field should not contain any identifiable information, including partial names or dates. Alphanumeric (no special symbols), left justify Alphabetic characters must be entered consistently in uppercase or lowercase, and include leading zeroes as applicable. | |
| 1.3 | Record identifier | 6 | 19 | 24 | This field will be used to uniquely identify one record among many for a unique Client ID. This can be a visit date or a sequential record number. Numeric, right justify | |
| 2. Demographic Information – Complete for each CCDE record | | | | | | |
| 2.1 | Date of birth | 8 | 25 | 32 | MMDDYYYY <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 1950).</i> | "MMDDYYYY", "MM YYYY" or "YYYY", but not blank. |
| 2.2 | Gender (self-reported) | 1 | 33 | 33 | 1 = Male 2 = Female 9 = Other/unknown | Range check. |
| 2.3 | Hispanic or Latino origin (self-reported) | 1 | 34 | 34 | 1 = Yes 2 = No 9 = Unknown/missing | Range check. |

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| Item # | Variable Name | Column Length | Column Begin End | Codes / Format / Comments | Edit Checks / Skip Patterns | |
|--------|----------------------------------|------------------|------------------------|---------------------------|--|--|
| 2.4.1 | Race 1 (self-reported) | 1 | 35 | 35 | 1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native 9 = Unknown <i>Note: Racial groups are OMB-defined. No primary race is collected. Race 1 has no significance over Race 2-5, and may simply be the first race mentioned.</i> | Range check. This field should be populated first. If a client self-identifies more than one race, then each race identified should be reported in a separate race field. |
| 2.4.2 | Race 2 (self-reported) | 1 | 36 | 36 | 1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native | Range check. Item 2.4.2 should be left blank, unless the client reports more than one race. |
| 2.4.3 | Race 3 (self-reported) | 1 | 37 | 37 | 1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native | Range check. Item 2.4.3 should be left blank, unless the client reports more than two races. |
| 2.4.4 | Race 4 (self-reported) | 1 | 38 | 38 | 1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native | Range check. Item 2.4.4 should be left blank, unless the client reports more than three races. |
| 2.4.5 | Race 5 (self-reported) | 1 | 39 | 39 | 1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native | Range check. Item 2.4.5 should be left blank, unless the client reports more than four races. |
| 2.5 | State of residence | 2 | 40 | 41 | 2-digit FIPS code (If unknown, blank fill) Right justify | Valid FIPS code for state. |
| 2.6 | County of residence | 3 | 42 | 44 | 3-digit FIPS code (If unknown, blank fill) Right justify | Valid FIPS county code for state in 2.5. |

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|---|---|---------------|--------------|------------|----------------------------------|--|
| 3. Screening History – Complete for each CCDE record. <i>This information can be self-reported, or can come from information documented in the client's medical record (preferred).</i> | | | | | | |
| 3.1 | Has client ever had a colorectal screening test? | 1 | 45 | 45 | 1 = Yes 2 = No 9 = Unknown | Range check. A CRC screening test is limited to one of the following: Take-home FOBT Take-home FIT Sigmoidoscopy Colonoscopy DCBE CTC Stool DNA |
| 4. Assessed Risk– Complete for each CCDE record. <i>This information can be self-reported, or can come from information documented in the client's medical record (preferred).</i> | | | | | | |
| 4.1 | Personal history of CRC or precancerous polyps | 1 | 46 | 46 | 1 = Yes 2 = No 9 = Unknown | Range check. If Item 4.1 = 1, then Item 6.0 should <u>not</u> = 1. |
| 4.2 | Family history of CRC | 1 | 47 | 47 | 1 = Yes 2 = No 9 = Unknown | Range check. |
| 4.3 | Currently experiencing CRC symptoms | 1 | 48 | 48 | 1 = Yes 2 = No 9 = Unknown | Range check. Clients currently experiencing CRC symptoms are clinically ineligible for CRCCP funded testing and will need to be referred out of the program for the appropriate medical care or evaluation. Each grantee and their Medical Advisory Board will define their list of symptoms requiring medical evaluation and may include rectal bleeding, lower abdominal pain, bloody stools or marked change in bowel habits such as diarrhea or constipation, and significant unexplained weight loss. |
| 5. Screening Adherence – Complete for each CCDE record | | | | | | |

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|--------|--|---------------|-------|-----|--|---|
| 5.1 | Initial test appointment date, or date fecal kit distributed | 8 | 49 | 56 | MMDDYYYY | |
| 5.2 | Screening adherence | 1 | 57 | 57 | <p>1 = Test performed 2 = Test pending 3 = No test performed, FOBT/FIT card not returned* 4 = No test performed, appointment not kept*</p> <p><i>*Guidelines should be established to determine when a fecal kit is deemed unreturned, or how much time can elapse before a client is considered an appointment no show.</i></p> | <p>Range check.</p> <p>If Item 5.2 = 1, then Section 6 must be completed to report at least one test performed.</p> <p>If Item 5.2 is not = 1, then Sections 6 through 11 should be left blank. Section 12 must be completed for each record.</p> |

6. Screening and Diagnostic Tests Performed – Complete for each CCDE record in which Item 5.2 = 1 (Test performed)

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| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|----------------------------------|---------------|--------------|------------|--|---|
| 6.0 | Indication for test 1 | 1 | 58 | 58 | 1 = Screening 2 = Surveillance 3 = Diagnostic 9 = Unknown | Range check. If 4.1 = 1, then Item 6.0 should not = 1. |
| 6.1.01 | Test 1 performed | 1 | 59 | 59 | 1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other | Range check. If 6.0 = 1 then 6.1.01 should not = 5 (DCBE) If 6.0 = 3 then 6.1.01 should = 4 or 5. |
| 6.1.02 | Test 1 performed – other specify | 40 | 60 | 99 | Free text | If 6.1.01 = 7 (Other), then 6.1.02 should be completed; otherwise, leave blank. |
| 6.1.03 | Date of test 1 | 8 | 100 | 107 | MMDDYYYY If 6.1.01 is 1 or 2, please report the date of the lab result. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010). | "MMDDYYYY", "MM YYYY" or "YYYY", but not blank. |
| 6.1.04 | Provider specialty | 2 | 108 | 109 | 1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 11 = Administrator, if FOBT/FIT mailed by non-clinician 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown Right Justify | Range check. |

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| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|---|---------------|--------------|------------|---|--|
| 6.1.05 | Result of test 1 | 1 | 110 | 110 | 1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown | Range check. If 6.1.01 = 1 or 2 then 6.1.05 must = 5, 6, 7 or 9. If 6.1.01 = 3-5, then 6.1.05 must = 1-4, 7 or 9. If 6.1.01 = 7, then 6.1.05 must be completed as appropriate for test performed. |
| 6.1.06 | Was a biopsy/polypectomy performed during the endoscopy? | 1 | 111 | 111 | 1 = Yes 2 = No 9 = Unknown | Range check. If 6.1.06 = 1, then 7.1 must be completed. Leave blank if 6.1.01 = 1, 2, 5 or 7. |
| 6.1.07 | Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE? | 1 | 112 | 112 | 1 = Yes* 2 = No 9 = Unknown <i>Adequacy will be determined by the clinician performing the test.</i> <i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i> | Range check. If 6.1.01 = 3, 4, 5 or 7, then 6.1.07 must be completed; otherwise leave blank. |
| 6.1.08 | Was the cecum reached during the colonoscopy? | 1 | 113 | 113 | 1 = Yes 2 = No 9 = Unknown | Range check. If 6.1.01 does not = 4, then 6.1.08 should be blank. |

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|--------|--|---------------|--------------|------------|--|--|
| 6.1.09 | Test 1 outcome | 1 | 114 | 114 | 1 = Complete 2 = Incomplete/Inadequate | Range check. If 6.1.05 = 5 or 6, then 6.1.09 should = 1 (Complete). If 6.1.05 = 4, then 6.1.09 should = 2 (Incomplete/Inadequate). If 6.1.07 = 2, then 6.1.09 should = 2 (Incomplete/Inadequate). If 6.1.08 = 2, then 6.1.09 should = 2 (Incomplete/Inadequate). |
| 6.1.10 | Recommended next follow-up procedure within this cycle | 1 | 115 | 115 | 1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete) <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i> | Range check. If 6.1.10 = 4 or 8, then 6.2.01, 6.3.01 and 6.4.01 should = 0 (None). If 6.1.10 = 4, then 8.1 must be completed. |
| 6.1.11 | Other recommended test, specify | 40 | 116 | 155 | Free text | If 6.1.10 = 7 (Other), then 6.1.11 should be completed; otherwise, leave blank. |

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|--------|---|---------------|--------------|------------|---|---|
| 6.2.01 | Test 2 performed | 1 | 156 | 156 | 0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other | Range check. If 6.2.01 = 0 (None), then 6.2.02 through 6.2.11 should be blank. |
| 6.2.02 | Test 2 performed – other specify | 40 | 157 | 196 | Free text | If 6.2.01 = 7 (Other), then 6.2.02 should be completed; otherwise, leave blank. |
| 6.2.03 | Date of test 2 | 8 | 197 | 204 | MMDDYYYY <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i> | "MMDDYYYY", "MM YYYY" or "YYYY", but not blank. |
| 6.2.04 | Provider specialty | 2 | 205 | 206 | 1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown Right justify | Range check. |
| 6.2.05 | Result of test 2 | 1 | 207 | 207 | 1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown | Range check. If 6.2.01 = 3-5, then 6.2.05 must = 1-4, 7 or 9. If 6.2.01 = 7, then 6.2.05 must be completed as appropriate for test performed. |
| 6.2.06 | Was a biopsy/polypectomy performed during the endoscopy? | 1 | 208 | 208 | 1 = Yes 2 = No 9 = Unknown | Range check. If 6.2.06 = 1, then 7.1 must be completed. Leave blank if 6.2.01 = 0, 5 or 7. |

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|--------|--|------------------|------------------------|--|--|
| 6.2.07 | Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE? | 1 | 209 209 | 1 = Yes* 2 = No 9 = Unknown <i>Adequacy will be determined by the clinician performing the test.</i> <i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i> | Range check. If 6.2.01 = 3, 4, 5 or 7, then 6.2.07 must be completed; otherwise leave blank. |
| 6.2.08 | Was the cecum reached during the colonoscopy? | 1 | 210 210 | 1 = Yes 2 = No 9 = Unknown | Range check. If 6.2.01 does not = 4, then 6.2.08 should be blank. |
| 6.2.09 | Test 2 outcome | 1 | 211 211 | 1 = Complete 2 = Incomplete/Inadequate | Range check. If 6.2.05 = 5 or 6, then 6.2.09 should = 1 (Complete). If 6.2.05 = 4, then 6.2.09 should = 2 (Incomplete/Inadequate). If 6.2.07 = 2, then 6.2.09 should = 2 (Incomplete/Inadequate). If 6.2.08 = 2, then 6.2.09 should = 2 (Incomplete/Inadequate). |
| 6.2.10 | Recommended next follow-up procedure within this cycle after test 2 | 1 | 212 212 | 1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete) <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i> | Range check. If 6.2.10 = 4 or 8, then 6.3.01 and 6.4.01 should = 0 (None). If 6.2.10 = 4, then 8.1 must be completed. |
| 6.2.11 | Other recommended test, specify | 40 | 213 252 | Free text | If 6.2.10 = 7 (Other), then 6.2.11 should be completed; otherwise, leave blank. |

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|--------|---------------|------------------|-----------------|---------------|---------------------------|-----------------------------|
|--------|---------------|------------------|-----------------|---------------|---------------------------|-----------------------------|

| | | | | | | |
|--------|----------------------------------|----|-----|-----|--|---|
| 6.3.01 | Test 3 performed | 1 | 253 | 253 | 0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other | Range check. If 6.3.01 = 0 (None), then 6.3.02 through 6.3.11 should be blank. |
| 6.3.02 | Test 3 performed – other specify | 40 | 254 | 293 | Free text | If 6.3.01 = 7 (Other), then 6.3.02 should be completed; otherwise, leave blank. |
| 6.3.03 | Date of test 3 | 8 | 294 | 301 | MMDDYYYY <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i> | "MMDDYYYY", "MM YYYY" or "YYYY", but not blank. |

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| Item # | Variable Name | Column Length | Column Begin End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|--|------------------|------------------------|---|---|
| 6.3.04 | Provider specialty | 2 | 302 303 | <p>1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown</p> <p>Right justify</p> | Range check. |
| 6.3.05 | Result of test 3 | 1 | 304 304 | <p>1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown</p> | Range check. If 6.3.01 = 3-5, then 6.3.05 must = 1-4, 7 or 9. If 6.3.01 = 7, then 6.3.05 must be completed as appropriate for test performed. |
| 6.3.06 | Was a biopsy/polypectomy performed during the endoscopy? | 1 | 305 305 | <p>1 = Yes 2 = No 9 = Unknown</p> | Range check. If 6.3.06 = 1, then 7.1 must be completed. Leave blank if 6.3.01 = 0, 5 or 7. |
| 6.3.07 | Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE? | 1 | 306 306 | <p>1 = Yes* 2 = No 9 = Unknown</p> <p><i>Adequacy will be determined by the clinician performing the test.</i></p> <p><i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i></p> | Range check. If 6.3.01 = 3, 4, 5 or 7, then 6.3.07 must be completed; otherwise leave blank. |

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|--------|---|------------------|------------------------|--|--|
| 6.3.08 | Was the cecum reached during the colonoscopy? | 1 | 307 307 | 1 = Yes 2 = No 9 = Unknown | Range check. If 6.3.01 does not = 4, then 6.3.08 should be blank. |
| 6.3.09 | Test 3 outcome | 1 | 308 308 | 1 = Complete 2 = Incomplete/Inadequate | Range check. If 6.3.05 = 5 or 6, then 6.3.09 should = 1 (Complete). If 6.3.05 = 4, then 6.3.09 should = 2 (Incomplete/Inadequate). If 6.3.07 = 2, then 6.3.09 should = 2 (Incomplete/Inadequate). If 6.3.08 = 2, then 6.3.09 should = 2 (Incomplete/Inadequate). |
| 6.3.10 | Recommended next follow-up procedure within this cycle after test 3 | 1 | 309 309 | 1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete) <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i> | Range check. If 6.3.10 = 4 or 8, then 6.4.01 should = 0 (None). If 6.3.10 = 4, then 8.1 must be completed. |
| 6.3.11 | Other recommended test, specify | 40 | 310 349 | Free text | If 6.3.10 = 7 (Other), then 6.3.11 should be completed; otherwise, leave blank. |

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|--------|---------------|------------------|-----------------|---------------|---------------------------|-----------------------------|
|--------|---------------|------------------|-----------------|---------------|---------------------------|-----------------------------|

| | | | | | | |
|--------|----------------------------------|----|-----|-----|--|---|
| 6.4.01 | Test 4 performed | 1 | 350 | 350 | 0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other | Range check. If 6.4.01 = 0 (None), then 6.4.02 through 6.4.10 should be blank. |
| 6.4.02 | Test 4 performed – other specify | 40 | 351 | 390 | Free text | If 6.4.01 = 7 (Other), then 6.4.02 should be completed; otherwise, leave blank. |
| 6.4.03 | Date of test 4 | 8 | 391 | 398 | MMDDYYYY <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i> | "MMDDYYYY", "MM YYYY" or "YYYY", but not blank. |

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|--------|--|------------------|------------------------|---|---|
| 6.4.04 | Provider specialty | 2 | 399 400 | <p>1 = General practitioner 2 = Internist 3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon 7 = Licensed practical nurse 8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant 12 = Radiologist 13 = Obstetrician / Gynecologist (OB/GYN) 99 = Unknown</p> <p>Right justify</p> | Range check. |
| 6.4.05 | Result of test 4 | 1 | 401 401 | <p>1 = Normal/Negative/Diverticulosis/Hemorrhoids 2 = Other finding not suggestive of cancer or polyp(s) 3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings 5 = FOBT/FIT/Other Test Performed Negative 6 = FOBT/FIT/Other Test Performed Positive 7 = Pending 9 = Unknown</p> | Range check. If 6.4.01 = 3-5, then 6.4.05 must = 1-4, 7 or 9. If 6.4.01 = 7, then 6.4.05 must be completed as appropriate for test performed. |
| 6.4.06 | Was a biopsy/polypectomy performed during the endoscopy? | 1 | 402 402 | <p>1 = Yes 2 = No 9 = Unknown</p> | Range check. If 6.4.06 = 1, then 7.1 must be completed. Leave blank if 6.4.01 = 0, 5 or 7. |
| 6.4.07 | Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE? | 1 | 403 403 | <p>1 = Yes* 2 = No 9 = Unknown</p> <p><i>Adequacy will be determined by the clinician performing the test.</i></p> <p><i>*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown).</i></p> | Range check. If 6.4.01 = 3, 4, 5 or 7, then 6.4.07 must be completed; otherwise leave blank. |

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|---|---|------------------|-----------------|---------------|---|--|
| 6.4.08 | Was the cecum reached during the colonoscopy? | 1 | 404 | 404 | 1 = Yes 2 = No 9 = Unknown | Range check. If 6.4.01 does not = 4, then 6.4.08 should be blank. |
| 6.4.09 | Test 4 outcome | 1 | 405 | 405 | 1 = Complete 2 = Incomplete/Inadequate | Range check. If 6.4.05 = 5 or 6, then 6.4.09 should = 1 (Complete). If 6.4.05 = 4, then 6.4.09 should = 2 (Incomplete/Inadequate). If 6.4.07 = 2, then 6.4.09 should = 2 (Incomplete/Inadequate). If 6.4.08 = 2, then 6.4.09 should = 2 (Incomplete/Inadequate). |
| 6.4.10 | Recommended next follow-up procedure within this cycle after test 4 | 1 | 406 | 406 | 4 = Surgery to complete diagnosis* 8 = None (cycle is complete) <i>* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</i> | Range check. If 6.4.10 = 4, then 8.1 must be completed. |
| 7. Pathology From All Endoscopy Tests Performed - Complete if a biopsy or polypectomy was performed during any of Test 1-4 [if 6.x.06 = 1(Yes)] | | | | | | |

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|--------|---|------------------|-----------------|---------------|--|--|
| 7.1 | Histology of most severe polyp/lesion | 2 | 407 | 408 | <p>1 = Normal or other non-polyp histology 2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.) 3 = Hyperplastic polyp 4 = Adenoma, NOS (no high grade dysplasia noted) 5 = Adenoma, tubular (no high grade dysplasia noted) 6 = Adenoma, mixed tubular villous (no high grade dysplasia noted) 7 = Adenoma, villous (no high grade dysplasia noted) 8 = Adenoma, serrated (no high grade dysplasia noted) 9 = Adenoma with high grade dysplasia (includes in situ carcinoma) 10 = Adenocarcinoma, invasive 11 = Cancer, other 99 = Unknown/other lesions ablated, not retrieved or confirmed</p> <p>Right justify</p> <p><i>Do not include information from surgical resections in this section.</i></p> | <p>Range check.</p> <p>Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.</p> <p>If 7.1 = 4-11, then 7.2 and 7.3 must be completed.</p> |
| 7.2 | Total number of adenomatous polyps/lesions | 2 | 409 | 410 | <p>01 – 96 = Number of adenomatous polyps/lesions removed or biopsied 97 = ≥ 97 adenomatous polyps/lesions removed or biopsied 98 = At least one adenomatous polyp/lesion removed, exact number removed or biopsied not known 99 = Unknown</p> <p><i>Do not include information from surgical resections in this section.</i></p> <p>Right justify</p> | <p>Range Check.</p> <p>If 7.1 = 4-11, then 7.2 must be completed; otherwise, leave blank.</p> |
| 7.3 | Size of largest adenomatous polyp/lesion | 1 | 411 | 411 | <p>1 = < 1 cm 2 = ≥ 1 cm 9 = Unknown</p> <p><i>Do not include information from surgical resections in this section.</i></p> | <p>Range check.</p> <p>If 7.1 = 4-11, then 7.3 must be completed; otherwise, leave blank.</p> |

8. Diagnosis Information for Surgeries Performed to Complete Diagnosis

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|--|---------------|--------------|------------|---|--|
| 8.1 | Histology from surgical resection | 2 | 412 | 413 | <p>0 = Surgery recommended but not performed 1 = Normal or other non-polyp histology 2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.) 3 = Hyperplastic polyp 4 = Adenoma, NOS (no high grade dysplasia noted) 5 = Adenoma, tubular (no high grade dysplasia noted) 6 = Adenoma, mixed tubular/villous (no high grade dysplasia noted) 7 = Adenoma, villous (no high grade dysplasia noted) 8 = Adenoma, serrated (no high grade dysplasia noted) 9 = Adenoma with high grade dysplasia (includes in situ carcinoma) 10 = Adenocarcinoma, invasive 11 = Cancer, other 99 = Unknown/other lesions ablated, not retrieved or confirmed</p> <p><i>Use histology from surgical resection in conjunction with histology of the most severe polyp/lesion reported in Item 7.1, to report the "Final diagnosis" (Item 9.02).</i></p> <p>Right justify</p> | <p>Range check.</p> <p>If 6.1.10, 6.2.10, 6.3.10 or 6.4.10 = 4, then complete 8.2; otherwise leave blank.</p> <p>If surgery was recommended (6.1.10, 6.2.10, 6.3.10 or 6.4.10 = 4) but was not performed, then 8.1 should = 0 (Surgery recommended but not performed).</p> <p>If no surgery was recommended (6.1.10, 6.2.10, 6.3.10 and 6.4.10 not = 4), then leave blank.</p> |
| 8.2 | Date surgery performed | 8 | 414 | 421 | MMDDYYYY <i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i> | <p>"MMDDYYYY", "MM YYYY", or "YYYY".</p> <p>If 8.1 = 1-11, 99, then complete 8.2; otherwise, leave blank.</p> |

9. Final Diagnosis – Complete for all CCDE records with at least one test performed

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|--|---------------|--------------|------------|--|--|
| 9.01 | Status of final diagnosis | 1 | 422 | 422 | <p>1 = Complete (final diagnosis determined) 2 = Pending final diagnosis 3 = Client refused diagnostic follow-up^{1,2} 4 = Client lost to follow-up before final diagnosis was made^{1,2} 5 = Irreconcilable²</p> <p>¹Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up.</p> <p>²These items should have an administrative close-out date reported in 9.03 "Date of final diagnosis".</p> <p>A response of 5 will be used for those records where, after clinical review, it was determined that there was no sufficient way to translate the clinical scenario into the CCDE data record.</p> | <p>Range check.</p> <p>If 5.2 = 1, then complete 9.01; otherwise, leave blank.</p> |
| 9.02 | Final diagnosis | 1 | 423 | 423 | <p>1 = Normal/Negative 2 = Hyperplastic polyps 3 = Adenomatous polyp, no high grade dysplasia 4 = Adenomatous polyp with high grade dysplasia 5 = Cancer</p> <p>Registry Information for Cancer/High Grade Dysplasia section must be completed if 9.02 (Final diagnosis) = 4 or 5.</p> | <p>Range check.</p> <p>If the only test performed in the cycle was either FOBT or FIT, then complete 9.02 as 1 (Normal/Negative).</p> <p>If 9.01 = 1, then complete 9.02; otherwise, leave blank.</p> <p>If 9.02 = 4 or 5, then 11.01 (Registry linkage status) must be completed.</p> |
| 9.03 | Date of final diagnosis | 8 | 424 | 431 | MMDDYYYY | <p>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</p> |
| 9.04 | Recommended screening or surveillance test for next cycle | 1 | 432 | 432 | <p>1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 8 = None 9 = Unknown</p> | <p>Range check.</p> <p>If client is terminally ill or for other reasons no further tests are recommended, then code this as 8 (None).</p> <p>Leave blank if 9.01 does not = 1</p> |

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|---|---------------|--------------|------------|---|---|
| 9.05 | Indication for screening or surveillance test for next cycle | 1 | 433 | 433 | 1 = Screening 2 = Surveillance after a positive colonoscopy and/or surgery | Range check. Leave blank if 9.01 does not = 1 Leave blank if 9.04 = 8, 9 |
| 9.06 | Number of months before screening or surveillance test for next cycle | 3 | 434 | 436 | 12 – 180 = Actual number of months 999 = Unknown Right Justify | Range check. Leave blank if 9.01 does not = 1 Leave blank if 9.04 = 8, 9 |
| 9.07 | Complications (1) of endoscopy or DCBE requiring observation or treatment | 2 | 437 | 438 | 0 = No complications reported 1 = Bleeding requiring transfusion 2 = Bleeding not requiring transfusion 3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc 4 = Complications related to anesthesia 5 = Bowel perforation 6 = Post-polypectomy syndrome/excessive abdominal pain 7 = Death 8 = Other 99 = Unknown Right justify | Range check. If 6.1.01, 6.2.01, 6.3.01 or 6.4.01 = 3, 4, 5 or 7, then 9.07 must be completed; otherwise leave blank. Report the worst of up to 2 distinct serious complications of CRC testing occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death. Report only one complication in each of 9.07 and 9.08. |
| 9.08 | Complications (2) of endoscopy or DCBE requiring observation or treatment | 2 | 439 | 440 | 0 = N/A – no 2nd complication reported 1 = Bleeding requiring transfusion 2 = Bleeding not requiring transfusion 3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc 4 = Complications related to anesthesia 5 = Bowel perforation 6 = Post-polypectomy syndrome/excessive abdominal pain 7 = Death 8 = Other 99 = Unknown Right justify | Range check. If 6.1.01, 6.2.01, 6.3.01 or 6.4.01 = 3, 4, 5 or 7, then 9.08 must be completed; otherwise leave blank. Report the worst of up to 2 distinct serious complications of CRC testing occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death. Report only one complication in each of 9.07 and 9.08. |
| 9.09 | Complications of endoscopy or DCBE – other specify | 40 | 441 | 480 | Free text | If 9.07 or 9.08 = 8, then 9.09 must be completed; otherwise, leave blank. |

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Begin | End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--------|---|------------------|-------|-----|----------------------------------|-----------------------------|
| 9.10 | CRCCP funds used for any screening/diagnostic test? | 1 | 481 | 481 | 1 = Yes 2 = No 9 = Unknown | Range check. |

| | | | | | | |
|---|-------------------|---|-----|-----|--|--|
| 10. Treatment Information - Complete this section when Final Diagnosis (9.02) = 5. This section may be completed when Final Diagnosis (9.02) = 4. | | | | | | |
| 10.1 | Recurrent cancers | 1 | 482 | 482 | 1 = New CRC primary 2 = Recurrent CRC 3 = Non-CRC primary (metastasis from another organ) 9 = Unknown | Range check. If 9.02 = 5, then 10.1 must be completed; otherwise, leave blank. |

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|--|--|---------------|--------------|------------|---|---|
| 10.2 | Status of treatment | 1 | 483 | 483 | <p>1 = Treatment started and/or completed 2 = Treatment pending 3 = Treatment not indicated due to polypectomy² 4 = Treatment not recommended² 5 = Treatment refused^{1,2} 6 = Lost to follow-up^{1,2} 9 = Unknown</p> <p>¹Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up.</p> <p>²These items must have an administrative close-out date reported in 10.3 "Date of treatment".</p> | <p>Range check.</p> <p>If 9.02 = 5, then 10.2 must be completed.</p> <p>If 9.02 = 4, then 10.2 may be completed; however, 10.2 may not = 3, 4 or 9.</p> <p>Leave blank if 9.02 = 1, 2 or 3.</p> |
| 10.3 | Date of treatment | 8 | 484 | 491 | <p>MMDDYYYY</p> <p><i>If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2010).</i></p> | <p>If 10.2 = 1, 3-6, then "MMDDYYYY", "MM YYYY" or "YYYY".</p> <p>If 10.2 = 3-6, then an administrative close-out date is required.</p> <p>Leave blank if 10.2 = 2 or 9.</p> |
| 11. Registry Information for Cancer/High Grade Dysplasia – Complete this section when Final Diagnosis (9.02) = 4 or 5 | | | | | | |
| 11.01 | Registry linkage status <i>Has this record been linked to the state cancer registry?</i> | 1 | 492 | 492 | 1 = Pending linkage 2 = Linked, matched 3 = Linked, not matched | Range check. |
| 11.02 | Registry date of diagnosis <i>[NAACCR data item #390]</i> | 8 | 493 | 500 | MMDDYYYY | <p>Leave blank if 11.01 = 1, 3.</p> <p>If not blank, must be a valid date.</p> |
| 11.03 | Registry histologic type <i>[NAACCR data item #522]</i> | 4 | 501 | 504 | <p>Range: 8000-9989</p> <p><i>A complete list of valid values/labels will be provided for reference in Chapter 3 of the Data User's Manual.</i></p> | <p>Range check.</p> <p>Leave blank if 11.01 = 1, 3.</p> |
| 11.04 | Registry behavior <i>[NAACCR data item #523]</i> | 1 | 505 | 505 | 0 = Benign 1 = Uncertain whether benign or malignant/Borderline malignancy 2 = Carcinoma In Situ 3 = Malignant | <p>Range check.</p> <p>Leave blank if 11.01 = 1, 3.</p> |

**ATTACHMENT 3a. Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Column Begin End | Codes / Format / Comments | Edit Checks / Skip Patterns | |
|--------|---|------------------|------------------------|---------------------------|---|---|
| 11.05 | Registry primary site [NAACCR data item #400] See SEER Program Coding and Staging Manual: http://seer.cancer.gov | 4 | 506 | 509 | C000-C999 <i>NOTE: The 'C' must be included as part of the variable response in the CCDE file. For example Cecum = C180. A complete list of valid values/labels will be provided for reference in the CCDE User's Manual.</i> Alphanumeric, left justify | Range check. Leave blank if 11.01 = 1, 3 |
| 11.06 | Registry CS-derived SS2000 [NAACCR data item #3020] See CS Staging Manual & SEER Summary Staging Manual: http://www.cancerstaging.org http://seer.cancer.gov | 1 | 510 | 510 | 0 = In situ 1 = Localized 2 = Regional, direct extension only 3 = Regional, regional lymph nodes only 4 = Regional, extension and nodes 5 = Regional, NOS 7 = Distant 8 = Not applicable 9 = Unknown/unstaged | Range check. Leave blank if 11.01 = 1, 3 |
| 11.07 | Registry CS-derived AJCC stage group [NAACCR data Item #3000] See CS Staging Manual: http://www.cancerstaging.org | 3 | 511 | 513 | Range: 000-999 <i>A complete list of valid values/labels is available for reference in the CCDE User's Manual.</i> | Range check. Leave blank if 11.01 = 1, 3 |
| 11.08 | Registry CS extension [NAACCR data item #2810] See CS Staging Manual: http://www.cancerstaging.org | 3 | 514 | 516 | Range: 000-999 <i>A complete list of valid values/labels is available for reference in the CCDE User's Manual.</i> | Range check. Leave blank if 11.01 = 1, 3 |
| 11.09 | Registry CS lymph nodes [NAACCR data item #2830] See CS Staging Manual: http://www.cancerstaging.org | 3 | 517 | 519 | Range: 000-999 <i>A complete list of valid values/labels is available for reference in the CCDE User's Manual.</i> | Range check. Leave blank if 11.01 = 1, 3 |

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Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table**

| Item # | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks / Skip Patterns |
|---|---|------------------|-----------------|---------------|--|---|
| 11.10 | Registry CS mets at diagnosis [NAACCR data item #2850] See CS Staging Manual: http://www.cancerstaging.org | 2 | 520 | 521 | Range: 00-99 <i>A complete list of valid values/labels is available for reference in the CCDE User's Manual.</i> | Range check. Leave blank if 11.01 = 1, 3 |
| 11.11 | Registry CS tumor size [NAACCR data item #2800] See CS Staging Manual: http://www.cancerstaging.org | 3 | 522 | 524 | 001-988 Exact size in millimeters 989 = ≥ 989 millimeters 990 = Microscopic focus or foci only; no size of focus is given 991 = Described as less than 1 cm 992 = Described as between 1 cm and 2 cm 993 = Described as between 2 cm and 3 cm 994 = Described as between 3 cm and 4 cm 995 = Described as between 4 cm and 5 cm 998 = Familial/Multiple polyposis 999 = Unknown; size not stated | Range check and skip pattern check. Leave blank if 11.01 = 1, 3. |
| 12. Record Information – Completed for each CCDE record | | | | | | |
| 12.1 | CCDE version | 3 | 525 | 527 | 100 = Data collected beginning 10/01/2009 | Range check. |
| | End of record mark | 1 | 528 | 528 | Character that ends the current record and begins a new line of text. | Example: Carriage Return – Line Feed (CR-LF) |