Colorectal Cancer Clinical Data Elements

Version 1.0

Data User’s Manual

March 31, 2010
Colorectal Cancer Clinical Data Elements (CCDE)

DATA USER'S MANUAL

for the

Colorectal Cancer Control Program (CRCCP)

CCDE Version 1.00
March 2010

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control

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Introduction

This manual was written by the Centers for Disease Control and Prevention (CDC) to centralize the information needed to produce data for the Colorectal Cancer Control Program (CRCCP). One goal of the manual is to provide the technical information necessary for the grantees to produce the Colorectal Cancer Clinical Data Elements (CCDEs). Another goal is to highlight the technical assistance provided to the grantees by the CDC and the clinical data contractor, Information Management Services, Inc. (IMS). A common goal of the CDC and the grantees is to produce data that are timely, complete, and of high quality so that we can better serve the clients targeted by the program.

The intended audience for this manual is the grantee staff responsible for the collection and aggregation of the CCDE data. It is divided into 2 chapters as follows:

Chapter 1  Colorectal Cancer Clinical Data Elements (CCDEs)
This chapter includes a general introduction to the CCDEs and detailed information about each CCDE data item.

Chapter 2  Appendices
This chapter contains the appendices to the manual including the CCDE Submission Narrative Guidelines, the CDC Race and Ethnicity Code Set, the CCDE Data Definition Table, and a Glossary of Terms.
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CHAPTER 1

Colorectal Cancer Clinical Data Elements (CCDEs)
Introduction to the CCDE Chapter

The purpose of this chapter is to provide the grantees with the information necessary to collect the CCDE data.

- **Understanding the CCDE data**
  This section of the chapter provides information regarding the structure of the CCDEs, the definition of a screening cycle, information about collecting and reporting Race and Hispanic Origin data, creating a unique client identification number, and details regarding data conventions used in reporting CCDE items.

- **CCDE Field Descriptions**
  This section provides a detailed description of each CCDE data item. This is the format that must be followed for the CCDE data submissions submitted to CDC.

Note: CDC distributed a draft of the CCDE data set to grantees on 10/30/2009. The final version of the CCDE data set to be used by grantees was subsequently distributed on 12/02/2009. The CCDE Field Descriptions in this User's Manual reflect the final CCDE data set.
Understanding the CCDE Data
Colorectal Cancer Clinical Data Elements

The Colorectal Cancer Clinical Data Elements (CCDEs) are a set of standardized data elements developed to ensure that consistent and complete information on client demographic characteristics, screening history, risk factors, screening and diagnostic tests, diagnosis, staging and treatment are collected on clients screened or diagnosed with program funds. These are the data items that are necessary for the grantees and the CDC to manage and evaluate the clinical component of the Colorectal Cancer Control Program. Grantees may collect additional data for local use (not to be reported to the CDC) if they choose. The CCDEs are collected for each screening event for each client, then computerized, converted into a standardized format, and transmitted to IMS.

CCDE Cycle Definition

A CCDE cycle is reported in one CCDE record. For clients that adhere to testing, a CCDE cycle begins with an initial colorectal cancer screening test and continues through any additional tests or procedures required for diagnostic evaluation following an abnormal or incomplete test, and ends when a final diagnosis is determined and treatment is initiated, if indicated.

Tracking Screening Adherence

Non-adherent clients that did not participate in screening are also reported in the CCDEs to track screening adherence across the program, which is a high priority for CDC. Non-adherent clients are those who initiated testing by receiving a fecal kit or appointment for a procedure, but did not follow through with testing. Each grantee program develops a policy and procedure to determine the timeframe and criteria to administratively close out a record as non-adherent. Refer to Data Items 5.1 and 5.2.

Structure of the CCDEs

The CCDEs consist of twelve sections. Each section contains specific variables to provide the CDC with detailed information about the client’s screening cycle.

**Section 1: Client and Record Identification**
This section identifies your Program and contains client IDs (to uniquely identify and track clients) and record IDs (to identify one record among many for a unique client ID). It must be completed for each client and each CCDE record for that client.

**Section 2: Demographic Information**
This section contains demographic information about clients. The information collected in this section must be self-reported by the clients. This information must be completed for each client and each CCDE record for that client.
Section 3: Screening History
This section contains information regarding previous colorectal screening tests. The information collected in this section can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred if available. This information must be completed for each client and each CCDE record for that client.

Section 4: Assessed Risk
This section contains risk factor information, such as previous diagnoses of precancerous polyps or colorectal cancer. It also captures information about family history of colorectal cancer and current symptoms experienced by the client. The information collected in this section can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred if available. This information must be completed for each client and each CCDE record for that client.

Section 5: Screening Adherence
This section contains information on the client’s adherence to screening once initiated with an appointment made or a fecal kit provided. Information is collected about the initial test appointment date and whether or not the test was performed. It includes information about fecal kit distribution and return. This section must be completed for each client and each CCDE record for that client.

Section 6: Screening and Diagnostic Tests Performed
This section contains information about the types of screening or diagnostic tests received by a client within each screening cycle. This information must be completed for each CCDE record where Section 5 (Screening Adherence) indicates "Test Performed".

Section 7: Pathology from all Endoscopy Tests Performed
This section contains data regarding histology of any polyps or lesions discovered during the screening cycle, along with number and size of any adenomatous polyps or lesions. This section must be completed anytime the client had a biopsy or polypectomy performed during one of the tests in Section 6.

Section 8: Diagnosis Information for Surgeries Performed to Complete Diagnosis
This section contains data regarding the date of surgery and histology from the surgical resection. This section should be completed anytime the client has “surgery recommended to complete the final diagnosis” after one of the tests in Section 6.

Section 9: Final Diagnosis
This section contains data regarding the final diagnosis for a screening cycle, any complications of endoscopy or DCBE experienced by the client, and the recommended test to begin the next cycle. This section should be completed for each CCDE record with at least one test performed (Section 6).

Section 10: Treatment Information
This section collects treatment information for clients with a final diagnosis of cancer.
Data Conventions

These are the general data conventions that apply to the CCDE data. However, the specific information on each field should be followed for a CCDE submission.

**Dates:** All dates are entered in the form MMDDYYYY. For example, January 6, 1942 should be reported as 01061942. If any part of the date is unknown, blank fill just that part. For example, if the month and year are known, but the day is not, blank fill just the day (e.g., 01 1942). Date fields may not be missing the year value.

**Alphanumeric Fields:** Alphanumeric or character data must be left-justified. In a left-justified field, the field value is placed so that the first character of the value is in the first position of the field. For example, Item 1.2 (Client Identifier) is left-justified in the CCDE file. The starting and ending positions are columns 4 through 18. If the Client Identifier is 1234, then “1234” should be placed in columns 4 through 18 and columns 5 through 18 would be filled with blanks as shown here: “1234 ”.

**Numeric Fields:** Numeric fields are right-justified. In a right-justified field, the field value is placed so that the last character of the value is in the last position of the field. For example, Item 1.3 (Record Identifier) is a 6-digit numeric code and it is right justified. The starting and ending positions are 19 through 24. If the record identifier is 1, then “1” should be placed in column 24 and columns 19 through 23 should be blank, as shown here: “   1”. Numeric fields may also be reported using leading zeroes, as shown here: “000001”. Grantees are asked to be consistent in how numeric values are placed.

**Blank Filled Fields:** A blank filled field is filled with blank characters. If the field has a length of six and it is appropriate to blank fill the field, then it should contain six blank characters. It is only appropriate to blank fill a field when it is indicated in the item description. A blank field should not be used as a substitute for an "unknown" response if a valid "unknown" code exists.
CCDE Field Descriptions
ITEM NO / NAME: 1.1: Program

PURPOSE: To indicate the unique identifier for the grantee program.

LENGTH: 3

FIELD LOCATION: 1-3

TYPE: Numeric – right justify. Include leading zeroes.

SKIP PATTERN: This field should always be completed.

CONTENTS: 001 = Alabama (AL)  
004 = Arizona (AZ)  
006 = California (CA)  
008 = Colorado (CO)  
009 = Connecticut (CT)  
010 = Delaware (DE)  
012 = Florida (FL)  
019 = Iowa (IA)  
023 = Maine (ME)  
024 = Maryland (MD)  
025 = Massachusetts (MA)  
027 = Minnesota (MN)  
030 = Montana (MT)  
031 = Nebraska (NE)  
033 = New Hampshire (NH)  
035 = New Mexico (NM)  
036 = New York (NY)  
041 = Oregon (OR)  
042 = Pennsylvania (PA)  
046 = South Dakota (SD)  
049 = Utah (UT)  
053 = Washington (WA)

Tribal Program Codes
090 = Arctic Slope (AC)  
092 = Southcentral Foundation (SO)  
098 = South Puget Intertribal Planning Agency (SP)  
099 = Alaska Native Tribal Health Consortium (AN)

EXPLANATION: The state FIPS codes are the Federal Information Processing Standard codes developed by the National Bureau of Standards. The tribal program codes are codes assigned by the CDC to be used by the tribal programs in lieu of state FIPS codes.

EXAMPLE: For Arizona: 004
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ITEM NO / NAME: **1.2: Client identifier**

PURPOSE: To indicate a system-generated identification number for each client that will be consistent for the client throughout the database.

LENGTH: 15

FIELD LOCATION: 4-18

TYPE: Alphanumeric (no special symbols) – left justify, case sensitive.

SKIP PATTERN: This field should always be completed.

CONTENTS: A fifteen-digit alphanumeric code. The client identifier must be unique and constant for each client in your database in order to track each client over time. A client identifier that is unique only to a specific clinic or location is not acceptable because it cannot track the client between locations. Completely numeric client identifiers are preferred; however, the CCDEs allow the use of alphanumeric client identifiers if you find it necessary. If alphabetic characters are included in the Client identifier field, they must be entered consistently in uppercase or lowercase for all records for each client.

Confidentiality is of the utmost importance. The CDC does not want a client identifier that could be used to link CCDE records to other databases. Certain identification numbers such as Social Security Numbers lack this privacy. If Social Security Numbers are used, or any other number which has linking capabilities, then the client identifier must be encoded. The CDC does not want to know the encoding scheme used by your program. However, your program should derive an encoding scheme which you can decode to the original client identifier in the event that a problem is found. The use of partial names and/or dates is also not recommended.

We provide the following suggestions and an example encoding procedure which we hope you will find helpful. Digit rotation and nines-complement are two methods which, when combined, can be used as an effective encoding scheme. Digit rotation is simply rotating a set of digits either left or right. The nines-complement of a number is nine minus the number, i.e. the nines-complement of 2 is 7, the nines-complement of 5 is 4 and the nines-complement of 0 is 9. An example of an encoding procedure for the Social Security Number, 123-45-6789 is as follows:
## Section 1 – Client and Record Identification

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<th>Procedure</th>
<th>Before/After</th>
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<tr>
<td>Nines-complement of digits 2,4,8,9</td>
<td>123-45-6789 / 173-55-6710</td>
</tr>
<tr>
<td>Rotate left - digits 1,3,5,6</td>
<td>173-55-6710 / 375-56-1710</td>
</tr>
<tr>
<td>Rotate right - digits 2,3,8,9</td>
<td>375-56-1710 / 307-66-1751</td>
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</table>

**EXAMPLE:**
Client identifier is 001000002357901: 001000002357901

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ITEM NO / NAME: **1.3: Record identifier**

PURPOSE: To identify one record among many for a client.

LENGTH: 6

FIELD LOCATION: 19-24

TYPE: Numeric – right justify

SKIP PATTERN: This field should always be completed.

CONTENTS: A six-digit numeric code. This field will be used to identify one unique record among many for a client. For example, the record identifier can be a visit date or a sequential record number.

EXPLANATION: A screening cycle begins with either an initial colorectal cancer test or the distribution of a fecal kit, continues through any additional tests required for diagnostic evaluation following an abnormal or incomplete test, and ends when a final diagnosis is reached and treatment is initiated, when required.

Each CCDE record identifies a unique screening cycle for a client. A client can have multiple screening cycles reported in the CCDE file. The record identifier helps to differentiate one screening cycle among many for a client. The record identifier could be the date of cycle initiation (e.g. FOBT date), or it could simply be a sequential number (e.g. 1 = first cycle, 2 = second cycle, etc).

Grantees are asked to be consistent in the method used for creating a record identifier.

EXAMPLE: Using a date of 4/1/2010: **040110**

Using a cycle number of 1: **000001** or **1**

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ITEM NO / NAME: 2.1: Date of birth

PURPOSE: To specify the date of birth self-reported by a client.

LENGTH: 8

FIELD LOCATION: 25-32

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of birth from 01 to 12, DD is the day of birth from 01 to 31, and YYYY is the year of birth, including the century. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01 1955). At a minimum, the year of birth must be reported.

EXPLANATION: Date of birth must be self-reported by the client. This field is used to compute age values and is vital to various analyses. It is, therefore, important to provide as complete a date as possible.

EXAMPLE: For a client born on May 1, 1953: 05011953

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ITEM NO / NAME: 2.2: Gender

PURPOSE: To specify the gender self-reported by a client.

LENGTH: 1

FIELD LOCATION: 33

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Male
          2 = Female
          9 = Other/unknown

EXPLANATION: Gender must be self-reported by the client. A response of 9 (Other/unknown) in the context of this question could mean that the client was not asked, the client’s answer was not recorded, the client self-identified with a gender other than male or female, or the client refused to answer the question.

EXAMPLE: Client is female: 2

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ITEM NO / NAME: **2.3 Hispanic or Latino origin**

PURPOSE: To indicate the self-reported Hispanic or Latino Origin of a client.

LENGTH: 1

FIELD LOCATION: 34

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes
2 = No
9 = Unknown/missing

EXPLANATION: The method of identifying Hispanic or Latino Origin must be self-identification by the client. Consider placing this field prior to race on the data form for better completion of the race/ethnicity data.

Hispanic Origin or Latino should be collected as a separate data field from race. If Hispanic or Latino Origin is not collected separately from race on your forms and a client reports race as Hispanic, then Item 2.3 (Hispanic or Latino origin) should be reported as 1 (Yes) and Item 2.4.1 (Race 1) should be reported as 9 (Unknown). If Hispanic or Latino Origin is not collected separately and a client reports race as something other than “Hispanic” or “Latino”, then Item 2.3 (Hispanic or Latino origin) should be reported as 9 (Unknown/missing). If Hispanic or Latino Origin is not asked of the client, the answer is not recorded, the client doesn’t know or the client refuses to answer, then report 9 (Unknown/missing).

EXAMPLE: For a self-reported Hispanic or Latino client: 1

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ITEM NO / NAME: 2.4.1: Race 1

PURPOSE: To indicate the first race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 35

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = White
2 = Black or African American
3 = Asian
4 = Native Hawaiian or Other Pacific Islander
5 = American Indian or Alaska Native
9 = Unknown

EXPLANATION: The method of identifying race must be self-identification by the client. If a client reports more than one race category, then this field should be populated first; and Item 2.4.2 “Race 2” through Item 2.4.5 “Race 5” should be used sequentially, as needed, to report additional race categories. No primary race is collected. The Race 1 field has no significance over Race 2-5, and may simply be the first race that is mentioned or recorded by the client.

If Item 2.3 (Hispanic or Latino origin) is not collected separately from race, and race is reported as “Hispanic”, then race should be reported to the CDC as 9 (Unknown) and Item 2.3 (Hispanic or Latino Origin) should be reported to the CDC as 1 (Yes).

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at http://www.whitehouse.gov/omb/fedreg/1997standards.html.

A Race and Ethnicity Code Set is provided at the end of this chapter (Chapter 2) in Appendix B. The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.
EXAMPLE: If a client self-identifies as Asian: 3

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ITEM NO / NAME: 2.4.2: Race 2

PURPOSE: To indicate the second race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 36

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than one race is self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White  
2 = Black or African American  
3 = Asian  
4 = Native Hawaiian or Other Pacific Islander  
5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than one race. No primary race is collected. The Race 1 field has no significance over Race 2, and Race 2 has no significance over the Race 3-5 fields. It may simply be the second race mentioned by a client. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at [http://www.whitehouse.gov/omb/fedreg/1997standards.html](http://www.whitehouse.gov/omb/fedreg/1997standards.html).

A Race and Ethnicity Code Set is provided at the end of this chapter in Appendix B. The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian and White: Race 1 = 3 and Race 2 = 1

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ITEM NO / NAME: **2.4.3: Race 3**

**PURPOSE:** To indicate the third race that is self-reported by a client.

**LENGTH:** 1

**FIELD LOCATION:** 37

**TYPE:** Numeric

**SKIP PATTERN:** This field should be completed when more than two races are self-reported by a client; otherwise, leave blank.

**CONTENTS:**

1 = White
2 = Black or African American
3 = Asian
4 = Native Hawaiian or Other Pacific Islander
5 = American Indian or Alaska Native

**EXPLANATION:**

The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than two races. No primary race is collected. The Race 1-2 fields have no significance over the Race 3-5 fields. It may simply be the third race mentioned by a client. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at [http://www.whitehouse.gov/omb/fedreg/1997standards.html](http://www.whitehouse.gov/omb/fedreg/1997standards.html).

A Race and Ethnicity Code Set is provided at the end of this chapter in **Appendix B**. The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

**EXAMPLE:** If a client identifies as Asian, White and African American: Race 1 = 3; Race 2 = 1; and Race 3 = 2

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ITEM NO / NAME: 2.4.4: Race 4

PURPOSE: To indicate the fourth race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 38

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than three races are self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White
2 = Black or African American
3 = Asian
4 = Native Hawaiian or Other Pacific Islander
5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than three races. No primary race is collected. The Race 1-3 fields have no significance over the Race 4-5 fields. It may simply be the fourth race mentioned by a client. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at http://www.whitehouse.gov/omb/fedreg/1997standards.html.

A Race and Ethnicity Code Set is provided at the end of this chapter in Appendix B. The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian, White, African American and Alaska Native: Race 1 = 3; Race 2 = 1; Race 3 = 2; and Race 4 = 5

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ITEM NO / NAME: 2.4.5: Race 5

PURPOSE: To indicate the fifth race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 39

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than four races are self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White
2 = Black or African American
3 = Asian
4 = Native Hawaiian or Other Pacific Islander
5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than four races. No primary race is collected. The Race 1-4 fields have no significance over the Race 5 field. It may simply be the fifth race mentioned by a client. No more than five races will be reported for a client in any CCDE record. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at http://www.whitehouse.gov/omb/fedreg/1997standards.html.

A Race and Ethnicity Code Set is provided at the end of this chapter in Appendix B. The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian, White, African American, Alaskan Native and Hawaiian: Race 1 = 3; Race 2 = 1; Race 3 = 2; Race 4 = 5; and Race 5 = 4

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ITEM NO / NAME: 2.5: State of residence

PURPOSE: To indicate the FIPS code for a client’s state of residence.

LENGTH: 2

FIELD LOCATION: 40-41

TYPE: Numeric - right justify

SKIP PATTERN: If known, this field should be completed; otherwise, leave blank.

CONTENTS: A 2-digit numeric code.

EXPLANATION: State of residence must be self-reported by the client. The state Federal Information Processing Standard (FIPS) codes are developed by the National Institute of Standards and Technology (NIST) and are available at http://www.itl.nist.gov/fipspubs/fip5-2.htm. There is a code for each state and territory.

EXAMPLE: Client’s state of residence is Maryland: 24

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ITEM NO / NAME: **2.6 County of residence**

PURPOSE: To indicate the FIPS code for a client's county of residence.

LENGTH: 3

FIELD LOCATION: 42-44

TYPE: Numeric - right justify

SKIP PATTERN: If known, this field should be completed; otherwise, leave blank.

CONTENTS: A 3-digit numeric code relevant to the State of residence reported in Item 2.5.

EXPLANATION: County of residence must be self-reported by the client. The county FIPS codes are the Federal Information Processing Standard codes developed by the National Institute of Standards and Technology (NIST) and are available at [http://www.itl.nist.gov/fipspubs/co-codes/states.htm](http://www.itl.nist.gov/fipspubs/co-codes/states.htm). There is a 3-digit code for each county in a state or territory. If the state or territory where the client lives does not have counties, enter 999.

EXAMPLE: Client's county of residence is Frontier, Nebraska: **063**

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ITEM NO / NAME: 3.1: Has client ever had a colorectal screening test?

PURPOSE: To indicate if a client has previously received any of the following colorectal screening tests: take-home FOBT, take-home FIT, sigmoidoscopy, colonoscopy, DCBE, CTC (virtual colonoscopy) or stool DNA.

LENGTH: 1

FIELD LOCATION: 45

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This information can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available. Fecal tests done by a provider in an office are not acceptable and should not be recorded in this field.

If the client has had any of the above noted colorectal screening tests in the past, then complete this field as 1 (Yes). If the client has never had a colorectal screening test prior to the visit, then complete this field as 2 (No). If the client has had a previous colorectal screening test within the program (as part of a separate screening cycle), complete this field as 1 (Yes).

A response of 9 (Unknown) in the context of this question may mean that the client was not asked, the answer was not recorded, the client was unsure, or the client refused to answer the question.

EXAMPLE: If a client has previously had a take-home FOBT or FIT: 1

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ITEM NO / NAME: 4.1: Personal history of CRC (colorectal cancer) or precancerous polyps

PURPOSE: To indicate if a client has ever been diagnosed with colorectal cancer or adenomatous/pre-cancerous polyps.

LENGTH: 1

FIELD LOCATION: 46

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

If Item 4.1 (Personal history of CRC (colorectal cancer) or precancerous polyps) = 1 (Yes), then Item 6.0 (Indication for test 1) should not = 1 (Screening).

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client has ever been diagnosed with colorectal cancer, which is cancer of the colon or rectum. Other possible terms for CRC include colon cancer, rectal cancer, cancer of the large intestine, cancer of the large bowel, and bowel cancer. Anal cancer, or cancer of the anus, should not be reported in this field.

It should also be used to indicate if the client has ever been diagnosed with a precancerous polyp or pre-malignant polyp. A precancerous/pre-malignant polyp would include any adenomatous polyps. A response of 1 (Yes) will indicate that the client is at increased risk for CRC, and Item 6.0 (Indication for test 1) cannot be reported as 1 (Screening).

This information can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available. If the client indicates that he/she has been previously diagnosed with CRC or had a precancerous polyp, then this field should be completed as 1 (Yes). If the client has never been diagnosed with CRC or a precancerous polyp prior to the visit, then complete this field as 2 (No).

A response of 9 (Unknown) in the context of this question may mean that the client was not asked, the answer was not recorded, the client was unsure, or the client refused to answer the question.
EXAMPLE: A client indicates he/she was diagnosed with CRC previously: 1

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ITEM NO / NAME: 4.2: Family history of CRC

PURPOSE: To indicate if the client has a family history of colorectal cancer.

LENGTH: 1

FIELD LOCATION: 47

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This information should be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available.

The information reported in this field may include family history of either CRC or adenomatous polyps.

Each grantee, in conjunction with the Medical Advisory Board, will determine criteria and type of screening test offered for clients at increased risk for CRC due to family history of CRC or adenomatous polyps. These criteria should be consistent with available guidelines.

EXAMPLE: A client’s father was diagnosed with CRC: 1

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ITEM NO / NAME: 4.3: Currently experiencing CRC symptoms

PURPOSE: To indicate if the client is currently experiencing colorectal cancer symptoms.

LENGTH: 1

FIELD LOCATION: 48

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes  
2 = No  
9 = Unknown

EXPLANATION: This information can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available.

Each grantee should work with its Medical Advisory Board to define a list of symptoms requiring medical evaluation. The list may include, but may not be limited to:

- Rectal bleeding, bloody diarrhea, or blood in the stool within the past 6 months (bleeding that is known or suspected to be due to hemorrhoids after clinical evaluation would not prevent a client from receiving CRC screening services).

- Prolonged change in bowel habits (e.g., diarrhea or constipation for more than two weeks that has not been clinically evaluated).

- Persistent abdominal pain.

- Symptoms of bowel obstruction (e.g., abdominal distension, nausea, vomiting, severe constipation).

- Significant unintentional weight loss of 10% or more of starting body weight.

If the response is 1 (Yes), then the client is clinically ineligible for CRCCP funded testing, and will need to be referred out of the program for the appropriate medical care or evaluation.
If a clinically ineligible client is subsequently evaluated and cleared for screening, they may be enrolled for CRCCP funded testing with Item 4.3 updated from 1 (Yes) to 2 (No).

EXAMPLE: The client is not currently experiencing any CRC symptoms: 2

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ITEM NO / NAME: 5.1: Initial test appointment date, or date fecal kit distributed

PURPOSE: To indicate the date testing was initiated for a client based on date of FOBT/FIT kit distribution or the initial appointment date for the first test recommended within this cycle.

LENGTH: 8

FIELD LOCATION: 49 - 56

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is a value from 01 to 12, DD is a value from 01 to 31, and YYYY is the year, including the century. No part of this date field may be left blank.

If a month or day is unknown, then that part of the date should be completed using a valid default value. Each grantee should decide upon the default values to be used for unknown month and/or day, and should apply them consistently. For example, your Program may choose to use “06” for unknown month and “15” for unknown day. Do not use “99” to report unknown month or day values.

EXPLANATION: If the initial test was a take-home FOBT or take-home FIT, then indicate the date that the fecal kit was distributed to the client. Otherwise, indicate the initial appointment date scheduled for the first test.

EXAMPLE: If an FOBT kit was mailed to the client on 3/5/2010: 03052010

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ITEM NO / NAME: 5.2: Screening adherence

PURPOSE: To indicate if the client received the initial test recommended.

LENGTH: 1

FIELD LOCATION: 57

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

If Item 5.2 (Screening adherence) = 1 (Test Performed), then Section 6 must be completed to report at least one test performed.

If Item 5.2 (Screening adherence) is not = 1 (Test Performed), then Sections 6 through 11 should be left blank. Section 12 must be completed for each record.

CONTENTS: 1 = Test Performed
2 = Test Pending
3 = No test performed, FOBT/FIT card not returned
4 = No test performed, appointment not kept

EXPLANATION: Each grantee will need to establish guidelines to determine when a fecal kit is considered unreturned, how much time can elapse or the number of appointments rescheduled before a client is considered an appointment no show.

If the client returns the fecal kit, or receives the initial test within the timeline established by the grantee, indicate 1 (Test performed).

If at the time of CCDE data submission, the client has not returned the fecal kit or received an initial test, but the timeframe established has not expired, indicate 2 (Test pending).

If the established timeframe has been reached, and the fecal kit has not been returned, indicate 3 (No test performed, FOBT/FIT card not returned). The CCDE cycle should be considered closed. In the event that an alternative test, such as a colonoscopy, is provided to the client, the colonoscopy should be recorded in a new CCDE cycle as the initial test.

If, once the established timeframe has been reached, and the appointment for the initial test has not been kept, indicate 4 (No test performed, appointment not kept). The CCDE cycle should be
considered closed. This does not mean that attempts to get the client in for testing should stop. If the client does return for an initial test, a new CCDE cycle should be created.

EXAMPLE: If the client returns their FOBT kit: 1

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**ITEM NO / NAME:** 6.0: **Indication for test 1**

**PURPOSE:** To report the indication or purpose for the first test provided to the client, reported in Item 6.1.01 (Test 1 performed).

**LENGTH:** 1

**FIELD LOCATION:** 58

**TYPE:** Numeric

**SKIP PATTERN:** This field should be completed when 5.2 (Screening Adherence = 1) (Test Performed).

If Item 4.1 (Personal history of CRC (colorectal cancer) or precancerous polyps) = 1 (Yes), then Item 6.0 (Indication for test 1) should not = 1 (Screening).

**CONTENTS:**
- 1 = Screening
- 2 = Surveillance
- 3 = Diagnostic
- 9 = Unknown

**EXPLANATION:**
A screening test (1) is a test provided for a client who has no colorectal cancer symptoms, may have never been screened for colorectal cancer, or may have had a previous screening test without significant findings and is due for routine rescreening.

A surveillance test (2) is a test (typically a colonoscopy) done at more frequent intervals than screening to evaluate a client who has a known history of colorectal polyps or colorectal cancer, to look for recurrence of these. The appropriate intervals for surveillance tests can be found in published guidelines.

A diagnostic test (3) is a test (typically a DCBE or colonoscopy) performed to evaluate signs or symptoms or to follow-up an abnormal screening test. An indication of 3 (Diagnostic) should occur infrequently, and should be monitored by grantees.

If the first test to be provided is a take-home fecal kit (FOBT or FIT), then the Indication for test 1 should not = 3 (Diagnostic). If the first test to be provided is a DCBE, then the Indication for test 1 should not = 1 (Screening).

**EXAMPLE:** If the purpose of the first test provided is for screening: 1
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ITEM NO / NAME: **6.1.01: Test 1 performed**

PURPOSE: To indicate the first test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 59

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

If Item 6.0 (Indication for test 1) = 1 (Screening), then Item 6.1.01 should not = 5 (DCBE).

If Item 6.0 (Indication for test 1) = 3 (Diagnostic), then Item 6.1.01 should only = 4 or 5.

CONTENTS: 1 = Take-home Fecal Occult Blood Test (FOBT)
2 = Take-home Fecal Immunochemical Test (FIT)
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the first test received by the client within the current cycle.

EXAMPLE: If the first test provided to the client is a sigmoidoscopy: 3

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ITEM NO / NAME: 6.1.02: Test 1 performed – Other specify

PURPOSE: To specify the type of “other” test indicated in Item 6.1.01 (Test 1 performed).

LENGTH: 40

FIELD LOCATION: 60 - 99

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.1.01 (Test 1 performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.1.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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ITEM NO / NAME: 6.1.03: Date of test 1

PURPOSE: To specify the date of the first test.

LENGTH: 8

FIELD LOCATION: 100 - 107

TYPE: Date

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. 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. 08 2010). This field should not be left completely blank if a first test was performed.

EXPLANATION: This field captures the date that test 1 is performed. If the test is a take-home FOBT or FIT, then report the date that the kit was processed.

If a test was recommended, but the appointment was not kept, or the FOBT/FIT kit was not returned, then this information should be reported in Item 5.1 (Initial test appointment date, or date fecal kit distributed) and Item 5.2 (Screening adherence). Items in Section 6 (Screening and Diagnostic Tests Performed) are limited to reporting data on tests that were completed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

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ITEM NO / NAME: **6.1.04: Provider specialty**

PURPOSE: To report the specialty of the clinician providing the first test.

LENGTH: 2

FIELD LOCATION: 108 - 109

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS:  
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

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.1.01.

If the first test is an FOBT/FIT, capture the specialty of the individual that made the assessment that a FOBT/FIT should be provided to the client.

A response of 11 (Administrator, if FOBT/FIT mailed by non-clinician) should be used only when an administrator, not a clinician, makes the assessment that a FOBT/FIT kit should be provided to the client.

EXAMPLE: If the provider specialty for the first test is a general surgeon: 5
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ITEM NO / NAME: 6.1.05: Result of test 1  
PURPOSE: To specify the result of test 1.  
LENGTH: 1  
FIELD LOCATION: 110  
TYPE: Numeric  
SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

If Item 6.1.01 (Test 1 performed) = 1 (Take-home FOBT) or 2 (Take-home FIT), then Item 6.1.05 must = 5, 6, 7 or 9.

If Item 6.1.01 (Test 1 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.1.05 must = 1-4, 7 or 9.

If Item 6.1.01 (Test 1 performed) = 7 (Other), then Item 6.1.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.1.02 (Test 1 performed – other specify).

CONTENTS:  
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  

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

For take-home FOBT, take-home FIT or other similar stool tests, if the medical chart records any gradation of positive (e.g. “weakly positive” or “slightly positive”), then Item 6.1.05 should be recorded as 6 (FOBT/FIT/Other Test Performed Positive).

A response of 2 (Other finding not suggestive of cancer or polyp(s) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp. Examples of Other findings may include:

- Colitis (inflammation of the bowel wall)  
- Arteriovenous malformation
- Ulcerative colitis
- Crohn’s colitis

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.

When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the take-home FOBT is positive: 6

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ITEM NO / NAME: 6.1.06: Was a biopsy/polypectomy performed during the endoscopy?

PURPOSE: To indicate if a biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 111

TYPE: Numeric

SKIP PATTERN: If Item 6.1.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if Item 6.1.01 (Test 1 performed) = 1 (Take-home FOBT), 2 (Take-home FIT), 5 (DCBE) or 7 (Other).

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the first test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

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ITEM NO / NAME: 6.1.07: Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 112

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 (Test 1 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 1 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.1.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate). The standardized colonoscopy reporting and data system (CO-RADs) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

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ITEM NO / NAME: 6.1.08: Was the cecum reached during the colonoscopy?

PURPOSE: To indicate whether or not the procedure report notes that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 113

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 (Test 1 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If the 6.1.08 = 2 (No), then 6.1.09 (Outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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ITEM NO / NAME: **6.1.09: Test 1 outcome**

PURPOSE: To indicate if the test reported in Item 6.1.01 was complete.

LENGTH: 1

FIELD LOCATION: 114

TYPE: Numeric

SKIP PATTERN: If Item 6.1.05 (Result of test 1) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.1.09 should = 1 (Complete).

If Item 6.1.05 (Result of test 1) = 4 (Inadequate/Incomplete test with no findings), then Item 6.1.09 should = 2 (Incomplete/Inadequate).

If Item 6.1.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.1.09 should = 2 (Incomplete/Inadequate).

If Item 6.1.08 (Cecum reached) = 2 (No), then Item 6.1.09 should = 2 (Incomplete/Inadequate).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.1.05 (Result of test 1). If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached during colonoscopy, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

If the provider recommends an immediate repeat exam (or additional tests needed to come to a Final Diagnosis) due to the incomplete, or non-removal of a significant polyp, then report 2 (Incomplete/Inadequate). Report the repeat exam (or additional tests needed) as Test 2.
EXAMPLE: If the colonoscopy is considered complete:

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ITEM NO / NAME: **6.1.10: Recommended next follow-up procedure within this cycle.**

PURPOSE: To indicate the next recommended procedure following the completion of Test 1 needed to complete this cycle. (This should not be confused with Item 9.04 to report the next test recommended for re-screening or surveillance.)

LENGTH: 1

FIELD LOCATION: 115

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence = 1 (Test Performed).

CONTENTS: 1 = Sigmoidoscopy
2 = Colonoscopy
3 = DCBE
4 = Surgery to complete diagnosis
7 = Other
8 = None (cycle is complete)

EXPLANATION: Once test 1 is completed, the next recommended procedure within the screening cycle should be reported. The next recommended test within the screening cycle should either be a diagnostic test to follow-up a positive initial screening test or another screening test where the first screening test was incomplete or inconclusive.

If the next recommended follow-up procedure within the cycle is 4 (surgery to completed diagnosis) or 8 (none), then Items (6.2.01, 6.3.01 or 6.4.01, Tests2-4 performed) should be coded with 0 (None).

In the rare event that surgery is needed to complete diagnosis, Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable.

There may be rare instances in which it is appropriate for an FOBT or FIT to be recommended as a follow-up procedure within the cycle and reported as Test 2. In these instances Item 6.1.10 should be reported as 7 (Other). Item 6.1.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

- The initial FOBT or FIT card could not be read by the lab
• Client did not perform the initial FOBT or FIT correctly

• An FOBT or FIT is recommended as follow-up to an incomplete or inconclusive colonoscopy that cannot be repeated

EXAMPLE: If a DCBE is recommended as the next procedure within this client’s “cycle”: 3

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ITEM NO / NAME: **6.1.11: Other recommended test, specify**

PURPOSE: To specify the Other test recommended in Item 6.1.10.

LENGTH: 40

FIELD LOCATION: 116 - 155

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.1.10 (Recommended next follow-up procedure within this cycle) is reported as 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.1.10. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: virtual colonoscopy

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ITEM NO / NAME: 6.2.01: Test 2 performed

PURPOSE: To indicate the second test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 156

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the second test received by the client within the current cycle.

EXAMPLE: If the second test provided to the client is a DCBE: 5

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ITEM NO / NAME: 6.2.02: Test 2 performed – Other specify

PURPOSE: To specify the type of “other” test indicated in Item 6.2.01 (Test 2 performed).

LENGTH: 40

FIELD LOCATION: 157 - 196

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.2.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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ITEM NO / NAME: 6.2.03: Date of Test 2

PURPOSE: To specify the date of the second test.

LENGTH: 8

FIELD LOCATION: 197 - 204

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. 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. 08 2010). This field should not be left completely blank if a second test was performed.

EXPLANATION: This field captures the date that Test 2 is performed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

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ITEM NO / NAME: 6.2.04: Provider specialty

PURPOSE: To report the specialty of the clinician providing the second test.

LENGTH: 2

FIELD LOCATION: 205 - 206

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

CONTENTS:
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

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.2.01.

EXAMPLE: If the provider specialty for the second test is a general surgeon: 5

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ITEM NO / NAME: 6.2.05: Result of Test 2

PURPOSE: To specify the results of Test 2.

LENGTH: 1

FIELD LOCATION: 207

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

If Item 6.2.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.2.05 must = 1 - 4, 7 or 9.

If Item 6.2.01 = 7 (Other), then Item 6.2.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.2.02

CONTENTS: 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

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

A response of 2 (Other finding not suggestive of cancer or polyp(s) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp.

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.
When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the colonoscopy is normal: 1

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ITEM NO / NAME: 6.2.06: Was a biopsy/polypectomy performed during the endoscopy?

PURPOSE: To indicate if a biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 208

TYPE: Numeric

SKIP PATTERN: If Item 6.2.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if Item 6.2.01 = 0, 5 or 7.

CONTENT: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the second test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

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ITEM NO / NAME: 6.2.07: Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 209

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 (Test 2 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 2 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.2.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate). The standardized colonoscopy reporting and data system (CO-RADs) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

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ITEM NO / NAME: **6.2.08: Was the cecum reached during the colonoscopy?**

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 210

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 (Test 2 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.2.08 is 2 (No), then Item 6.2.09 (Test 2 outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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ITEM NO / NAME:  **6.2.09: Test 2 outcome**

PURPOSE:  To indicate if the test reported in Item 6.2.01 was complete.

LENGTH:  1

FIELD LOCATION:  211

TYPE:  Numeric

SKIP PATTERN:  This field should be completed when Item 6.2.01 (Test 2 performed) is not 0 = (None).

If Item 6.2.05 (Result of Test 2) = 4 (Inadequate/Incomplete test with no findings), then Item 6.2.09 should = 2 (Incomplete).

If Item 6.2.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.2.09 should = 1 (Complete).

If Item 6.2.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.2.09 should = 2 (Incomplete).

If Item 6.2.08 (Cecum reached) = 2 (No), then Item 6.2.09 should = 2 (Incomplete).

CONTENTS:  1 = Complete  
           2 = Incomplete/Inadequate

EXPLANATION:  Each test provided should have a specific result that is reported in Item 6.2.05.  If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps.  In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

If the provider recommends an immediate repeat exam (or additional tests needed to come to a Final Diagnosis) due to the
incomplete, or non-removal of a significant polyp, then report 2 (Incomplete/Inadequate). Report the repeat exam (or additional tests needed) as Test 3.

EXAMPLE: If the colonoscopy is considered complete: 1

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ITEM NO / NAME: 6.2.10: Recommended next follow-up procedure within this cycle after test 2.

PURPOSE: To indicate the next recommended procedure following the completion of Test 2.

LENGTH: 1

FIELD LOCATION: 212

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

CONTENTS: 1 = Sigmoidoscopy
2 = Colonoscopy
3 = DCBE
4 = Surgery to complete diagnosis
7 = Other
8 = None (cycle is complete)

EXPLANATION: Once Test 2 is completed, the next recommended procedure within the screening cycle should be reported. The next recommended test within the screening cycle should either be a diagnostic test to follow-up a positive initial screening test or another screening test where the first and second screening tests were incomplete or inconclusive.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable. No further procedures (Items 6.3.01 or 6.4.01) should be reported. Items 6.3.01 and 6.4.01 should be completed with 0 (None).

If Test 2 is normal and the recommended screening or surveillance test for the next cycle is FOBT or FIT, then indicate 8 (None). The screening cycle should be considered complete and the next FOBT or FIT should begin a new CCDE record. Items 6.3.01 and 6.4.01 should be completed with 0 (None).
Section 6 – Screening and Diagnostic Tests Performed

There may be rare instances in which it is appropriate for an FOBT or FIT to be reported as Test 3. In these instances Item 6.2.10 should be reported as 7 (Other). Item 6.2.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

- FOBT or FIT card could not be read by the lab
- Client did not perform FOBT or FIT correctly
- An FOBT or FIT is recommended as follow-up to an incomplete or inconclusive colonoscopy that cannot be repeated

EXAMPLE: If a DCBE is recommended as the next procedure within this client’s “cycle”: 3

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ITEM NO / NAME: 6.2.11: Other recommended test, specify

PURPOSE: To specify the Other test recommended in Item 6.2.10.

LENGTH: 40

FIELD LOCATION: 213 - 252

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.2.10 is reported as 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.2.10. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: virtual colonoscopy

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ITEM NO / NAME: 6.3.01: Test 3 performed

PURPOSE: To indicate the third test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 253

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the third test received by the client within the current cycle.

EXAMPLE: If the third test provided to the client is a DCBE: 5

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ITEM NO / NAME: 6.3.02: Test 3 performed – Other specify

PURPOSE: To specify the type of “other” test indicated in Item 6.3.01 (Test 3).

LENGTH: 40

FIELD LOCATION: 254 - 293

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.3.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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ITEM NO / NAME: **6.3.03: Date of Test 3**

PURPOSE: To specify the date of the third test.

LENGTH: 8

FIELD LOCATION: 294 - 301

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. 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. 08 2010). This field should not be left completely blank if a second test was performed.

EXPLANATION: This field captures the date that Test 3 is performed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: **08012010**

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ITEM NO / NAME: 6.3.04: Provider specialty

PURPOSE: To report the specialty of the clinician providing the third test.

LENGTH: 2

FIELD LOCATION: 302 - 303

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

CONTENTS: 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

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.3.01.

EXAMPLE: If the provider specialty for the third test is a general surgeon: 5

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ITEM NO / NAME: 6.3.05: Result of Test 3

PURPOSE: To specify the results of Test 3.

LENGTH: 1

FIELD LOCATION: 304

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

If Item 6.3.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.3.05 must = 1 - 4, 7 or 9.

If Item 6.3.01 = 7 (Other), then Item 6.3.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.3.02.

CONTENTS: 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

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

A response of 2 (Other finding not suggestive of cancer or polyp(s)) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp.

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.
When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the colonoscopy is normal: 1

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ITEM NO / NAME: 6.3.06: Was a biopsy/polypectomy performed during the endoscopy?

PURPOSE: To indicate if a biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 305

TYPE: Numeric

SKIP PATTERN: If Item 6.3.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if 6.3.01 = 0, 5 or 7.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the third test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

REVISION HISTORY:

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</table>
ITEM NO / NAME: 6.3.07: Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 306

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 (Test 3 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes 2 = No 9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 3 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.3.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate). The standardized colonoscopy reporting and data system (CO-RADS) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

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</table>
ITEM NO / NAME: 6.3.08: Was the cecum reached during the colonoscopy?

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 307

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 (Test 3 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.3.08 is 2 (No), then Item 6.3.09 (Test 3 outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

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</table>
ITEM NO / NAME: 6.3.09: Test 3 outcome

PURPOSE: To indicate if the third test was complete.

LENGTH: 1

FIELD LOCATION: 308

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

If Item 6.3.05 (Result of Test 3) = 4 (Inadequate/Incomplete test with no findings), then Item 6.3.09 should = 2 (Incomplete).

If Item 6.3.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.3.09 should = 1 (Complete).

If Item 6.3.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.3.09 should = 2 (Incomplete).

If Item 6.3.08 (Cecum reached) = 2 (No), then Item 6.3.09 should = 2 (Incomplete).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.3.05. If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

If the provider recommends an immediate repeat exam (or additional tests needed to come to a Final Diagnosis) due to the
incomplete, or non-removal of a significant polyp, then report 2 (Incomplete/Inadequate). Report the repeat exam (or additional tests needed) as Test 4.

EXAMPLE: If the colonoscopy is considered complete: 1

REVISION HISTORY:

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</table>
ITEM NO / NAME: 6.3.10: Recommended next follow-up procedure within this cycle after test 3.

PURPOSE: To indicate the next recommended procedure following the completion of Test 3.

LENGTH: 1

FIELD LOCATION: 309

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

CONTENTS: 1 = Sigmoidoscopy
2 = Colonoscopy
3 = DCBE
4 = Surgery to complete diagnosis
7 = Other
8 = None (cycle is complete)

EXPLANATION: Once Test 3 is completed, the next recommended procedure within the screening cycle should be reported. The next recommended test within the screening cycle would either be a diagnostic test to follow-up a positive initial screening test or another screening test where Test 1 through Test 3 screening tests were incomplete or inconclusive.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable. No further procedures (Item 6.4.01) should be reported. Item 6.4.01 will be completed with 0 (None).

If Test 3 is normal and the recommended screening or surveillance test for the next cycle is FOBT or FIT, then indicate 8 (None). The screening cycle should be considered complete and the next FOBT or FIT should begin a new CCDE record. Item 6.4.01 should be completed with 0 (None).
There may be rare instances in which it is appropriate for an FOBT or FIT to be reported as Test 4. In these instances Item 6.3.10 should be reported as 7 (Other). Item 6.3.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

- FOBT or FIT card could not be read by the lab
- Client did not perform FOBT or FIT correctly
- An FOBT or FIT is recommended as follow-up to an incomplete or inconclusive colonoscopy that cannot be repeated

EXAMPLE: If a DCBE is recommended as the next procedure within this clients “cycle”: 3

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</tbody>
</table>
ITEM NO / NAME: 6.3.11: Other recommended test, specify

PURPOSE: To specify the Other test recommended in Item 6.3.10.

LENGTH: 40

FIELD LOCATION: 310 - 349

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.3.10 is reported as 7 (Other). Otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.3.10. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: virtual colonoscopy

REVISION HISTORY:

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</table>
ITEM NO / NAME: **6.4.01: Test 4 performed**

PURPOSE: To indicate the fourth test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 350

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 0 = None  
3 = Sigmoidoscopy  
4 = Colonoscopy  
5 = Double-contrast Barium Enema (DCBE)  
7 = Other

EXPLANATION: This field should be reported with the fourth test received by the client within the current cycle.

EXAMPLE: If the fourth test provided to the client is a DCBE: 5

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</table>
ITEM NO / NAME: 6.4.02: Test 4 performed – Other specify

PURPOSE: To specify the type of “other” test indicated in Item 6.4.01 (Test 4).

LENGTH: 40

FIELD LOCATION: 351 - 390

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) = 7 (Other). Otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.4.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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</tbody>
</table>
ITEM NO / NAME: 6.4.03: Date of Test 4

PURPOSE: To specify the date of the fourth test.

LENGTH: 8

FIELD LOCATION: 391 - 398

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. 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. 08 2010). This field should not be left completely blank if a second test was performed.

EXPLANATION: This field captures the date that Test 4 is performed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

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</table>
ITEM NO / NAME: 6.4.04: Provider specialty

PURPOSE: To report the specialty of the clinician providing the fourth test.

LENGTH: 2

FIELD LOCATION: 399 - 400

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

CONTENTS: 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

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.4.01.

EXAMPLE: If the provider specialty for the fourth test is a general surgeon: 5

REVISION HISTORY:

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</table>
ITEM NO / NAME: 6.4.05: Result of Test 4

PURPOSE: To specify the results of Test 4.

LENGTH: 1

FIELD LOCATION: 401

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

If Item 6.4.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.4.05 must = 1 - 4, 7 or 9.

If Item 6.4.01 = 7 (Other), then Item 6.4.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.4.02.

.contents:
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

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

A response of 2 (Other finding not suggestive of cancer or polyp(s)) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp.

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.
When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the colonoscopy is normal: 1

REVISION HISTORY:

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</table>
ITEM NO / NAME: 6.4.06: Was a biopsy/polypectomy performed during the endoscopy?

PURPOSE: To indicate if biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 402

TYPE: Numeric

SKIP PATTERN: If Item 6.4.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

   Leave blank if 6.4.01 = 0, 5 or 7.

CONTENTS: 1 = Yes
           2 = No
           9 = Unknown

EXPLANATION: This field should only be completed if the fourth test provided is either a colonoscopy or sigmoidoscopy.

   If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

REVISION HISTORY:

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<td>1.00</td>
<td>12/02/2009</td>
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</table>
ITEM NO / NAME: 6.4.07: Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 403

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 (Test 4 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes  
2 = No  
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 1 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.4.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate). The standardized colonoscopy reporting and data system (CO-RADS) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

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</table>
ITEM NO / NAME: **6.4.08: Was the cecum reached during the colonoscopy?**

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 404

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 (Test 4 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.4.08 is 2 (No), then Item 6.4.09 (Test 4 outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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</table>
ITEM NO / NAME: **6.4.09: Test 4 outcome**

PURPOSE: To indicate if the fourth test was complete.

LENGTH: 1

FIELD LOCATION: 405

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

If Item 6.4.05 (Result of Test 4) = 4 (Inadequate/Incomplete test with no findings), then Item 6.4.09 should = 2 (Incomplete).

If Item 6.4.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.4.09 should = 1 (Complete).

If Item 6.4.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.4.09 should = 2 (Incomplete).

If Item 6.4.08 (Cecum reached) = 2 (No), then Item 6.4.09 should = 2 (Incomplete).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.4.05. If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).
EXAMPLE: If the colonoscopy is considered complete: 1

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</table>
ITEM NO / NAME: 6.4.10: Recommended next follow-up procedure within this cycle after test 4.

PURPOSE: To indicate the next recommended procedure following the completion of Test 4.

LENGTH: 1

FIELD LOCATION: 406

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

CONTENTS: 4 = Surgery to complete diagnosis
8 = None (cycle is complete)

EXPLANATION: Once Test 4 is completed, the next recommended procedure within the screening cycle should be reported.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable.

If Test 4 was normal and the next test recommended is a screening exam (FOBT or FIT), indicate 8 (None). The screening cycle would be completed and the new screening test will begin a new CCDE record.

EXAMPLE: If no further tests are recommended within this clients “cycle”: 8

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</table>
### ITEM NO / NAME: 7.1: Histology of the most severe polyp or lesion

**PURPOSE:** Report the worst histology of all biopsies and polypectomies performed during this cycle.

**LENGTH:** 2

**FIELD LOCATION:** 407 - 408

**TYPE:** Numeric - right justify

**SKIP PATTERN:** This field should be completed if a biopsy or polypectomy was performed during any of Test 1 – 4 [Item 6.x.06 = 1 (Yes)].

**CONTENTS:**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Normal or other non-polyp histology</td>
</tr>
<tr>
<td>2</td>
<td>Non-adenomatous polyp (inflammatory, hamartomatous, etc.)</td>
</tr>
<tr>
<td>3</td>
<td>Hyperplastic polyp</td>
</tr>
<tr>
<td>4</td>
<td>Adenoma, NOS (no high grade dysplasia noted)</td>
</tr>
<tr>
<td>5</td>
<td>Adenoma, tubular (no high grade dysplasia noted)</td>
</tr>
<tr>
<td>6</td>
<td>Adenoma, mixed tubular villous (no high grade dysplasia noted)</td>
</tr>
<tr>
<td>7</td>
<td>Adenoma, villous (no high grade dysplasia noted)</td>
</tr>
<tr>
<td>8</td>
<td>Adenoma, serrated (no high grade dysplasia noted)</td>
</tr>
<tr>
<td>9</td>
<td>Adenoma with high grade dysplasia (includes in situ carcinoma)</td>
</tr>
<tr>
<td>10</td>
<td>Adenocarcinoma, invasive</td>
</tr>
<tr>
<td>11</td>
<td>Cancer, other</td>
</tr>
<tr>
<td>99</td>
<td>Unknown/other lesions ablated, not retrieved or confirmed</td>
</tr>
</tbody>
</table>

**EXPLANATION:** Report the most severe histology result found across all pathology for Test 1 through Test 4 when a biopsy or polypectomy was performed during endoscopy. Do not include histology results from surgical resection. Histology from surgical resection should be reported in Item 8.1.

Do not update or change the histology reported for this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

If the worst histology includes any of the adenoma diagnoses (4-11), then Items 7.2 and 7.3 must be completed.

**EXAMPLE:** If the histology for the polyp/lesion removed is carcinoma: 11
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</table>
The following table was designed to assist grantees in mapping specific ICD-O morphology codes to the CCDE Histology categories.

<table>
<thead>
<tr>
<th>CCDE Colorectal Histology Categories</th>
<th>International Classification of Disease for Oncology, 3rd Edition, Acceptable Morphology Codes and Terminology from Common Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1=Normal or other non-polyp histology</td>
<td>n/a</td>
</tr>
<tr>
<td>2=Non-adenomatous polyp (inflammatory, hamartomatous, etc.)</td>
<td>n/a</td>
</tr>
<tr>
<td>3=Hyperplastic polyp</td>
<td>n/a</td>
</tr>
<tr>
<td>4=Adenoma, NOS (no high-grade dysplasia noted)</td>
<td>8140-8147, 8160-8162, 8180-8210, 8212, 8214-8221, 8250-8260, 8262, 8264-8506, 8520-8550, 8560, 8570-8573, 8940-8941 (with behavior codes of /0)</td>
</tr>
<tr>
<td></td>
<td>8140/0 Adenoma, NOS</td>
</tr>
<tr>
<td></td>
<td>8210/0 Adenomatous polyp, NOS</td>
</tr>
<tr>
<td></td>
<td>8212/0 Flat adenoma</td>
</tr>
<tr>
<td></td>
<td>8220/0 Adenomatous polyposis coli</td>
</tr>
<tr>
<td></td>
<td>8221/0 Multiple adenomatous polyps</td>
</tr>
<tr>
<td>5=Adenoma, tubular (no high-grade dysplasia noted)</td>
<td>8211 (with behavior code of /0)</td>
</tr>
<tr>
<td></td>
<td>8211/0 Tubular adenoma, NOS</td>
</tr>
<tr>
<td>6=Adenoma, mixed tubular villous (no high-grade dysplasia noted)</td>
<td>8263 (with behavior code of /0)</td>
</tr>
<tr>
<td></td>
<td>8263/0 Tubulovillous adenoma, NOS</td>
</tr>
<tr>
<td>7=Adenoma, villous (no high-grade dysplasia noted)</td>
<td>8261 (with behavior code of /0)</td>
</tr>
<tr>
<td></td>
<td>8261/0 Villous adenoma, NOS</td>
</tr>
<tr>
<td>8=Adenoma, serrated (no high-grade dysplasia noted)</td>
<td>8213 (with behavior code of /0)</td>
</tr>
<tr>
<td></td>
<td>8213/0 Serrated adenoma</td>
</tr>
<tr>
<td>9=Adenoma with high-grade dysplasia (includes in situ carcinoma)</td>
<td>8140-8147, 8160-8162, 8180-8221, 8250-8506, 8520-8550, 8560, 8570-8573, 8940-8941 (with behavior codes of /2)</td>
</tr>
<tr>
<td></td>
<td>8140/2 Adenocarcinoma in situ, NOS</td>
</tr>
<tr>
<td></td>
<td>8210/2 Adenocarcinoma in situ in adenomatous polyp</td>
</tr>
<tr>
<td></td>
<td>8261/2 Adenocarcinoma in situ in villous adenoma</td>
</tr>
<tr>
<td></td>
<td>8263/2 Adenocarcinoma in situ in tubulovillous adenoma</td>
</tr>
<tr>
<td>10=Adenocarcinoma, invasive</td>
<td>8140-8147, 8160-8162, 8180-8221, 8250-8506, 8510, 8520-8550, 8560, 8570-8573, 8940-8941 (with behavior codes of /3)</td>
</tr>
<tr>
<td></td>
<td>8140/3 Adenocarcinoma, NOS</td>
</tr>
<tr>
<td></td>
<td>8141/3 Scirrhous adenocarcinoma</td>
</tr>
<tr>
<td></td>
<td>8210/3 Adenocarcinoma in adenomatous polyp</td>
</tr>
<tr>
<td>CCDE Colorectal Histology Categories</td>
<td>International Classification of Disease for Oncology, 3rd Edition, Acceptable Morphology Codes and Terminology from Common Codes</td>
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| 10=Adenocarcinoma, invasive (continued) | 8211/3 Tubular adenocarcinoma  
8214/3 Parietal cell carcinoma  
8220/3 Adenocarcinoma in adenomatous polyposis coli  
8221/3 Adenocarcinoma in multiple adenomatous polyps  
8260/3 Papillary adenocarcinoma, NOS  
8261/3 Adenocarcinoma in villous adenoma  
8262/3 Villous adenocarcinoma  
8263/3 Adenocarcinoma in tubulovillous adenoma  
8470/3 Mucinous cystadenocarcinoma, NOS  
8480/3 Mucinous adenocarcinoma  
8481/3 Mucin-producing adenocarcinoma  
8490/3 Signet ring cell carcinoma  
8560/3 Adenosquamous carcinoma  
8570/3 Adenocarcinoma with squamous metaplasia  
8571/3 Adenocarcinoma with cartilaginous and osseous metaplasia  
8940/3 Mixed tumor, malignant, NOS  
8941/3 Carcinoma in pleomorphic adenoma |
| 11=Cancer, other | 8000-8139, 8148-8159, 8163-8179, 8222-8249, 8507-8509, 8511-8519, 8551-8559, 8561-8569, 8574-8939, 8942-9989 (with behavior codes of /3) |
|                          | 8001/3 Tumor cells, malignant  
8002/3 Malignant tumor, small cell type  
8004/3 Malignant tumor, spindle cell type  
8005/3 Malignant tumor, clear cell type  
8050/3 Papillary carcinoma, NOS  
8070/3 Squamous cell carcinoma, NOS.  
8240/3 Carcinoid tumor, NOS  
8249/3 Atypical carcinoid tumor |
ITEM NO / NAME: 7.2: Total number of adenomatous polyps/lesions

PURPOSE: To indicate the total number of adenomatous polyps/lesions removed or biopsied through all endoscopy procedures during the client’s “cycle”. Do not report specimens from surgical resections.

LENGTH: 2

FIELD LOCATION: 409 - 410

TYPE: Numeric - right justify

SKIP PATTERN: If Item 7.1 (Histology of most severe polyp/lesion) is an adenoma or cancer (4-11), then Item 7.2 should be completed; otherwise, leave blank.

CONTENTS: 01 = One adenomatous polyp/lesion removed or biopsied
02 = Two adenomatous polyps/lesions removed or biopsied
...
97 = ≥ Ninety-seven adenomatous polyps/lesions removed or biopsied
98 = At least one adenomatous polyp/lesion removed or biopsied, exact number not known
99 = Unknown

EXPLANATION: The actual number of adenomatous polyps or lesions removed should be acquired for each test provided. In the case of a large cancer or lesion which cannot be removed during endoscopy, the endoscopist may biopsy the area to obtain a specimen for pathology. Include these specimens when counting the total number of all adenomatous polyps or lesions removed or biopsied and report in Item 7.2.

When more than 97 adenomatous polyps or lesions are removed or biopsied during endoscopy, report 97 (≥ 97 polyps/lesions).

If the report indicates adenomatous polyps or lesions were removed or biopsied, but no definite account of the number removed is available, indicate 98 (At least one polyp/lesion, exact number not known).

If it is unknown whether any adenomatous polyps or lesions were removed or biopsied, code 99 (Unknown).
EXAMPLE: If 8 adenomatous polyps/lesions are noted: 08

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ITEM NO / NAME:  7.3: Size of largest adenomatous polyp/lesion

PURPOSE:  To report the size of the largest adenomatous polyp or lesion reported across all endoscopy procedures performed within the cycle. Do not report specimens from surgical resections.

LENGTH:  1

FIELD LOCATION:  411

TYPE:  Numeric – right justify

SKIP PATTERN:  If Item 7.1 (Histology of most severe polyp/lesion) is an adenoma or cancer (4-11), then Item 7.3 should be completed; otherwise, leave blank.

CONTENTS:  1 = < 1 cm  
2 = ≥ 1 cm  
9 = Unknown

EXPLANATION:  Report the diameter of the polyp/lesion in centimeters (cm) or the longest dimension of the polyp/lesion. This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology. Do not include information from any surgical resection.

There may be instances when a lesion is biopsied, but not removed during endoscopy. The size of such lesions should also be taken into consideration when reporting the size of the largest adenomatous polyp or lesion.

Size may be found on both the endoscopy and pathology reports, but size from the endoscopy report is preferred. If the specimen is not intact when sent to the pathology lab, do not report specimen size from the pathology report.

EXAMPLE:  If the size of the lesion is 2 cm:  2

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ITEM NO / NAME: 8.1: Histology from surgical resection

PURPOSE: To report the worst histopathology from the surgical resection reported in Item 6.x.10 (where x is either the 1st, 2nd, 3rd or 4th test reported in Section 6) if the client underwent surgery to complete the diagnosis.

LENGTH: 2

FIELD LOCATION: 412 - 413

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.10 is 4 (Surgery to complete diagnosis), then this field should be completed; otherwise, leave blank.

CONTENTS: 
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

NOTE: For guidance on converting ICD-O morphology to CCDE histology from surgical resection, refer to the table following Item 7.1 (Histology of most severe polyp/lesion).

EXPLANATION: Most often, if a polyp is detected during endoscopy, it can be removed during the endoscopy and the client will not need surgery to complete the diagnosis. On some occasions, if the polyp is large or the lesion is suspicious for cancer, a biopsy will be taken, but the lesion will not be removed in its entirety during the endoscopy. Instead, it will be removed during a subsequent surgery to complete the diagnosis.

Report the worst histopathological diagnosis made from surgical resection. The response options are listed in general order of severity. If more than one surgical resection was performed to obtain a final diagnosis, all of the resections performed should be
considered when determining the worst histopathological diagnosis.

If surgery was recommended in Item 6.x.10 (Recommended next follow-up procedure within the cycle), but was not performed, code 0 (Surgery recommended but not performed). If no surgery was recommended in Item 6.x.10, then Item 8.1 should be left blank.

If the histology from surgical resection is not found in the pathology report, indicate 99 (Unknown).

Use the histology from surgical resection in conjunction with Item 7.1 (Histology of most severe polyp/lesion) when reporting the final diagnosis (Item 9.02).

EXAMPLE: If the histology for the polyp/lesion removed is cancer, other: _11_

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ITEM NO / NAME: 8.2: Date surgery performed

PURPOSE: To indicate the date of the surgical resection to complete the diagnosis.

LENGTH: 8

FIELD LOCATION: 414 - 421

TYPE: Date

SKIP PATTERN: If 8.1 = 1-11, 99 then complete this field; otherwise, leave blank.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of surgery from 01 to 12, DD is the day of surgery from 01 to 31, and YYYY is the year of the surgery, including the century. 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. 08 2010).

EXPLANATION: This field captures the date that the surgery to complete diagnosis was performed. If more than one surgical resection was performed to obtain a final diagnosis, then report the date of the surgery which provided the final diagnosis (Item 9.02).

Frequently, the screening cycle will conclude with endoscopy and surgery will not be required to complete the diagnosis. Surgery to complete the final diagnosis will only be performed if a suspicious polyp or lesion could not be completely removed during endoscopy.

If Item 8.1 = 0 (Surgery recommended but not performed), then this field should be left blank.

EXAMPLE: If a surgery was performed on August 1, 2010: 08012010

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ITEM NO / NAME: 9.01: Status of final diagnosis

PURPOSE: To specify the status of final diagnosis for a cycle after all screening and diagnostic tests are performed/offered to the client.

LENGTH: 1

FIELD LOCATION: 422

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening adherence) is reported as 1 (performed); otherwise, leave blank.

CONTENTS: 1 = Complete (final diagnosis determined)
2 = Pending final diagnosis
3 = Client refused diagnostic follow-up
4 = Client lost to follow-up before final diagnosis was made
5 = Irreconcilable.

EXPLANATION: Report the status of the client’s care after all screening and diagnostic tests are performed/offered to the client.

If a client receives a single screening test, and that test is normal/negative, then complete this field as 1 (Complete).

A status of 2 (Pending final diagnosis) indicates that not all of the planned tests have been completed and therefore a final diagnosis has not yet been determined. A record should not be pending for more than one year. Such records should be monitored so that as a client’s tests are completed, and a final diagnosis is made, this field may be updated to the appropriate status of final diagnosis.

A status of 3 (Client refused diagnostic follow-up) should be reported if a client severs his or her relationship with the Program. For example, a client may decline the recommended tests, or may choose to have the tests performed by a provider outside of the Program. While such cases are simply reported to the CDC as 3 (Refused) in the CCDE file, Grantees should track more detailed information about each “refused” case.

A status of 4 (Client lost to follow-up) should be reported if prior to the completion of all recommended tests, a client moves to a location beyond the Program’s range of service delivery, or the client can no longer be located by the grantee. A status of 4 (Lost to Follow-up) should also be reported if a client dies prior to the
completion of all recommended tests. Lost to follow-up should be reported when tracking efforts have been attempted in accordance with the grantee’s written protocol, but were unsuccessful. Again, while such cases are simply reported to the CDC as 4 (Lost to Follow-up) in the CCDE file, grantees should track more detailed information about each “lost” case.

All grantees must have a policy in place to define how much time can elapse before the client is considered 3 (Refused) or 4 (Lost to follow-up). The CDC realizes that in many cases attempts to contact a client occur well beyond the closure of a record as lost to follow-up or refused. In the event that these efforts are successful and the client returns to the Program after the record was closed as lost to follow-up or refused, the grantee should consult with the client’s clinician and its Medical Advisory Board to determine if the client's previous cycle of care should resume, or if a new cycle of care should begin.

A status of 5 (Irreconcilable) should be used for records which after clinical review, it was determined that there was no sufficient way to translate the clinical scenario into the CCDE data record. For example, a clinician might refer a client for a short-term recall instead of following the clinical guidelines for immediate diagnostic work-up. In such cases, enter “5” to indicate a cycle that has been reviewed and subsequently closed with an irreconcilable status.

It is recommended that grantees do not include irreconcilable status of final diagnosis on their CCDE data collection forms for providers to select. The intent of irreconcilable status of final diagnosis is for administrative use at your Program’s central data location, and not at the provider level. Its intended use is to help grantees manage the records in the Feedback Reports that need to be reviewed and reconciled. However, records closed using an irreconcilable status of final diagnosis will still be regarded as records with incomplete follow-up in analyses of completeness.

EXAMPLE: If status of client’s care for the current CCDE record is complete:

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ITEM NO / NAME:  **9.02: Final diagnosis**

PURPOSE:  To specify the final diagnosis after all tests have been completed.

LENGTH:  1

FIELD LOCATION:  423

TYPE:  Numeric

SKIP PATTERN:  If Item 9.01 (Status of final diagnosis) is 1 (Complete), then this field should be completed; otherwise, leave blank.

CONTENTS:  1 = Normal/Negative  
2 = Hyperplastic polyps  
3 = Adenomatous polyp, no high grade dysplasia  
4 = Adenomatous polyp with high grade dysplasia  
5 = Cancer

EXPLANATION:  After all screening and diagnostic tests are performed or offered to the client, report the final diagnosis that the clinician will use to determine the re-screening or surveillance test recommendation. In some cases, polyps or lesions may be removed during differing procedures, with each procedure resulting in a different histology. Report the worst diagnosis (among all procedures performed) as the final diagnosis.

If the only test performed in the screening cycle (Item 6.1.01) was an FOBT or FIT that was negative, and Item 9.01 (Status of final diagnosis) = 1 (complete), then complete this field as 1 (Normal/Negative).

Section 10 (Treatment Information) should be completed if Item 9.02 (Final Diagnosis) = 5 (Cancer). Treatment information may be completed if Item 9.02 = 4 (Adenomatous Polyp with high grade dysplasia) and treatment was recommended by the clinician.

Section 11 (Registry Information for Cancer/High Grade Dysplasia) should be completed if Item 9.02 (Final Diagnosis) = 4 (Adenomatous polyp with high grade dysplasia) or 5 (Cancer).

EXAMPLE:  If the final diagnosis is Normal: 1
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ITEM NO / NAME: **9.03: Date of final diagnosis**

**PURPOSE:** To specify the date of final diagnosis.

**LENGTH:** 8

**FIELD LOCATION:** 424 - 431

**TYPE:** Date

**SKIP PATTERN:** This field should be completed if Item 9.01 (Status of final diagnosis) is 1 (Complete), 3 (Refused), 4 (Lost to follow-up) or 5 (Irreconcilable); otherwise, it should be blank.

**CONTENTS:** An 8-digit date field of the form MMDDYYYY, where MM is the month of diagnosis from 01 to 12, DD is the day of diagnosis from 01 to 31, and YYYY is the year of diagnosis. If any part of the date is unknown, blank-fill only that part. For example, if the month and year of diagnosis are known, but the day is not, then blank-fill the day (e.g. **08 2010**).

**EXPLANATION:** This field should indicate the date of the procedure that provided the final diagnosis (which may include the date of the “normal” screening test). If more than one procedure was performed to obtain a final diagnosis, report the date of the procedure which provided the worst histologic diagnosis. In some cases the first of multiple tests may provide the date of final diagnosis.

If the client refused tests, or was determined to be lost to follow-up, then an administrative close-out date should be reported as the date of final diagnosis. If the client moved before all tests were completed and a final diagnosis could not be obtained, then an administrative close-out date should be reported as the date of final diagnosis.

**EXAMPLE:** If the date of the final pathology report is July 15, 2010: **07152010**

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ITEM NO / NAME: **9.04: Recommended screening or surveillance test for next cycle**

PURPOSE: To indicate the next recommended test for the client at the end of the “cycle”.

LENGTH: 1

FIELD LOCATION: 432

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 9.01 does not = 1.

CONTENTS:  
1 = Take-home FOBT  
2 = Take-home FIT  
3 = Sigmoidoscopy  
4 = Colonoscopy  
5 = DCBE  
8 = None  
9 = Unknown

EXPLANATION: Report the next screening or surveillance test recommended to the client at the end of the cycle. Examples include a surveillance colonoscopy following a previous abnormal colonoscopy and/or surgery, or the next screening test recommended to the client following a normal/negative test.

If client is terminally ill, or for other reasons no further tests are recommended by the clinician, then code this item as 8 (None).

EXAMPLE: If a FOBT is recommended as the test to begin the next cycle: 1

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ITEM NO / NAME: **9.05: Indication for screening or surveillance test for next cycle**

PURPOSE: To report the indication for the next test recommended to the client.

LENGTH: 1

FIELD LOCATION: 433

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 9.01 (Status of final diagnosis) does not =1 (Complete).

Leave blank if Item 9.04 (Recommended screening or surveillance test for next cycle) = 8 (None) or 9 (Unknown).

CONTENTS: 1 = Screening

2 = Surveillance after a positive colonoscopy and/or surgery

EXPLANATION: If a test was recommended in Item 9.04, then the indication for the test (screening vs. surveillance) should be reported.

Grantees should encourage their providers to make re-screening and surveillance frequency recommendations based on published guidelines, when available.

EXAMPLE: If the next recommended test is a screening test: 1

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ITEM NO / NAME: 9.06: Number of months before screening or surveillance test for next cycle.

PURPOSE: To indicate the recommended interval between Item 9.03 (Date of final diagnosis) and the next recommended screening/surveillance test.

LENGTH: 3

FIELD LOCATION: 434 - 436

TYPE: Numeric - right justify

SKIP PATTERN: Leave blank if Item 9.01 does not = 1 (Complete).

Leave blank if Item 9.04 (Recommended screening or surveillance test for next cycle) = 8 (None) or 9 (Unknown).

CONTENTS: 12 = Twelve months
13 = Thirteen months

…
180 = One hundred eighty months
999 = Unknown

EXPLANATION: If a test was recommended in Item 9.04, then the report the interval between the final diagnosis and the next test date. If Item 9.04 is reported as 8 (None) or 9 (Unknown), this field should be left blank.

EXAMPLE: If the recommended interval before the next test is two years: 24

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ITEM NO / NAME: **9.07: Complications (1) of endoscopy or DCBE requiring observation or treatment**

PURPOSE: To indicate if there was a complication that occurred due to a DCBE or endoscopy procedure.

LENGTH: 2

FIELD LOCATION: 437 - 438

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.01 (Test Performed) was 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other) then this field should be completed; otherwise, leave blank.

CONTENTS: 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

EXPLANATION: Grantees may report the worst of up to two distinct serious complications occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death. One complication should be reported in Item 9.07, and the other in Item 9.08.

If there were no complications reported by the client or clinician, report 0 (No complications reported) in both Items 9.07 and 9.08. If the client only experienced one complication, report that complication in Item 9.07 and then report 0 (No complications reported) in Item 9.08.

If Item 9.07 = 8 (Other), then Item 9.09 (Complications of endoscopy or DCBE - other specify) should be completed.

EXAMPLE: If the client experienced bleeding, but did not require a transfusion: 2
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ITEM NO / NAME: 9.08: Complications (2) of endoscopy or DCBE requiring observation or treatment

PURPOSE: To indicate a second complication that occurred due to a DCBE or endoscopy procedure.

LENGTH: 2

FIELD LOCATION: 439 - 440

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.01 (Test Performed) was 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other) then this field should be completed. Otherwise, leave blank.

CONTENTS:
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

EXPLANATION: Grantees may report the worst of up to two distinct serious complications occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death. One complication should be reported in Item 9.07, and the other in Item 9.08.

If there were no complications reported by the client or clinician, report 0 (No complications reported) in both Items 9.07 and 9.08. If the client only experienced one complication, report that complication in Item 9.07 and then report 0 (No complications reported) in Item 9.08.

If Item 9.08 = 8 (Other), then Item 9.09 (Complications of endoscopy or DCBE - other specify) should be completed.

EXAMPLE: If the client experienced bleeding, but did not require a transfusion: 2
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ITEM NO / NAME: 9.09: Complications of endoscopy or DCBE – Other specify

PURPOSE: To specify the type of “other” complication reported in Item 9.07 or Item 9.08.

LENGTH: 40

FIELD LOCATION: 441 - 480

TYPE: Free text

SKIP PATTERN: If Item 9.07 or Item 9.08 = 8 (Other), then this field should be completed; otherwise, leave blank.

EXPLANATION: This field captures the type of “other” complication indicated in Item 9.07 and/or Item 9.08. Try to use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data. Acceptable other complications would include infection (bacteremia or abscess) or allergic reaction to sedative.

This field should not be used to report a third complication. It is appropriate for each grantee to collect as much information as possible about all complications experienced; however, it is only necessary to report the two worst complications to the CDC.

EXAMPLE: If the client experienced an infection: Infection

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ITEM NO / NAME: 9.10: CRCCP funds used for any screening/diagnostic test?

PURPOSE: To indicate if CRCCP funds were used to pay for any of the screening or diagnostic tests reported in 6.x.01.

LENGTH: 1

FIELD LOCATION: 481

TYPE: Numeric

SKIP PATTERN: If at least one test was completed, then this field should be completed; otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: If the funding source for the screening or diagnostic test is documented, then a response of 1 (Yes) or 2 (No) should be reported. If the funding source cannot be determined, then a response of 3 (Unknown) should be reported.

EXAMPLE: If the client had an FOBT that was paid for with CRCCP funds: 1

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TEM NO / NAME: **10.1: Recurrent cancers**

PURPOSE: Indicate if the cancer reported in Item 9.02 (Final Diagnosis) is a new primary, a recurrent cancer, or a non-CRC primary cancer.

LENGTH: 1

FIELD LOCATION: 482

TYPE: Numeric

SKIP PATTERN: If Item 9.02 (Final Diagnosis) is 5 (Cancer), then this field should be completed; otherwise, leave blank.

CONTENTS: 1 = New CRC primary  
2 = Recurrent CRC  
3 = Non-CRC primary (metastasis from another organ)  
9 = Unknown

EXPLANATION: If the cancer reported in Item 9.02 is a new primary colorectal cancer, report 1 (New CRC primary). If the cancer is a metastasis of a non-colorectal primary, then report it as 3 (Non-CRC primary).

An example of when 9 (Unknown) might be reported is if cells are so poorly differentiated that the organ of origin cannot be identified. This should occur rarely.

Grantees will need to work with their Cancer Registry to determine if a cancer is a new CRC primary, a non-CRC primary or a recurrent CRC cancer.

EXAMPLE: If the cancer found is a recurrent CRC cancer: 2

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ITEM NO / NAME: 10.2: Status of treatment

PURPOSE: To specify the status of standard treatment for any cancer diagnosed.

LENGTH: 1

FIELD LOCATION: 483

TYPE: Numeric

SKIP PATTERN: If Item 9.02 (Final Diagnosis) = 5 (Cancer), then this field should be completed.

If Item 9.02 = 4 (Adenomatous polyp with high grade dysplasia), then this field may be completed; however, Item 10.2 may not = 3 (Treatment not indicated due to polypectomy), 4 (Treatment not recommended) or 9 (Unknown).

Leave blank if Item 9.02 = 1 (Normal/Negative), 2 (Hyperplastic polyps) or 3 (Adenomatous polyp, no high grade dysplasia).

CONTENTS: 1 = Treatment started and/or completed
2 = Treatment pending
3 = Treatment not indicated due to polypectomy
4 = Treatment not recommended
5 = Treatment refused
6 = Lost to follow-up
9 = Unknown

EXPLANATION: For the purpose of this program, the CDC requires the reporting of standard or conventional treatments. Non-standard or alternative treatments should not be reported as 1 (Treatment Started). In the event that the client chooses a form of non-standard or alternative treatment, this field should be coded as 5 (Treatment refused).

NOTE: Experimental drugs, such as those used in clinical trials, may be reported as 1 (Treatment started).

The fact that a client is referred for standard treatment is NOT sufficient confirmation that treatment has been started. A client should be classified as having started treatment only when the grantee has confirmed that a plan for standard treatment has been developed and actually started. The date when standard treatment began refers to the client’s actual start of therapy.

Endoscopy can often achieve screening and treatment simultaneously, by detecting and removing a polyp. A complete polypectomy would be considered both diagnostic and the only
required treatment. In this case, the procedure should be reported in the Screening and Diagnostic Tests Performed section (Item 6.x.01). Treatment should be reported as 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the polypectomy. In this instance, Item 9.03 (Date of final diagnosis) and Item 10.3 (Date of treatment) would be the same.

In the circumstance that surgical removal of a polyp or cancer (to complete a diagnosis) is complete, with no evidence of spreading, the surgery would also be considered both diagnostic and the only required treatment. In this case, the date of surgery should be reported in Item 8.2 (Date of Surgery), Treatment should be 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the surgery.

If any additional treatment beyond a polypectomy or surgery is required because of local or distant spread of a cancer (e.g. chemotherapy or radiation therapy), the Status of Treatment and Date of Treatment need to be determined by the start of the standard or conventional treatment beyond that of the polypectomy or surgery.

Each grantee must have a policy in place to define how much time can elapse before the client is considered 5 (Treatment refused) or 6 (Lost to follow-up).

**EXAMPLE:**

If client refused treatment: 5

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ITEM NO / NAME: 10.3: Date of treatment

PURPOSE: To report the date treatment began.

LENGTH: 8

FIELD LOCATION: 484 - 491

TYPE: Date

SKIP PATTERN: If Item 10.2 (Status of treatment) = 2 (Treatment pending) or 9 (Unknown), this field must be blank; otherwise it must be completed.

If Item 10.2 (Status of treatment) = 1 (Treatment started and/or completed), 3 (Treatment not indicated due to polypectomy), 4 (Treatment not recommended), 5 (Treatment refused) or 6 (Lost to follow-up), then this item should be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of treatment from 01 to 12, DD is the day of treatment from 01 to 31, and YYYY is the year of treatment, including the century. If any part of the date is unknown, blank-fill only that part. For example, if the month and year of treatment are known, but the day is not, then blank-fill the day (e.g. 08 2010).

EXPLANATION: If Item 10.2 (Status of Treatment) is 1 (Started), then complete with the date the treatment began.

The fact that a client is referred for standard treatment is not sufficient confirmation that treatment has been started. A client should be classified as having started treatment only when the grantee has confirmed that a plan for standard treatment has been developed and actually started. The date when standard treatment began refers to the client’s actual start of therapy.

Endoscopy can often achieve screening and treatment simultaneously, by detecting and removing a polyp. A complete polypectomy would be considered both diagnostic and the only required treatment. In this case, the procedure should be reported in the Screening and Diagnostic Tests Performed section (6.x.01), Treatment should be reported as 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the polypectomy. In this instance, Item 9.03 (Date of final diagnosis) and Item 10.3 (Date of Treatment) would be the same.

In the circumstance that surgical removal of a polyp or cancer (to complete a diagnosis) is complete, with no evidence of spread, the surgery would also be considered both diagnostic and the only
required treatment. In this case, the date of surgery should be reported in Item 8.2 (Date of Surgery). Treatment should be 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the surgery.

If any additional treatment beyond a polypectomy or surgery to complete diagnosis is required because of local or distant spread of a cancer (e.g. chemotherapy or radiation therapy), the Status of Treatment and Date of Treatment need to be determined by the start of the standard or conventional treatment beyond that of the polypectomy or surgery to complete diagnosis.

Each grantee must have a policy in place to define how much time can elapse before the client is considered 5 (Treatment refused) or 6 (Lost to follow-up).

Each grantee must have a policy in place to define how much time can elapse before the client is considered to be “Refused” or “Lost to follow-up”

EXAMPLE: Client began chemotherapy on December 15, 2010: 12152010

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ITEM NO / NAME: **11.01: Registry linkage status**

**PURPOSE:** To indicate if the record for the client reported in Item 9.02 (Final Diagnosis) has been linked to the state/central cancer registry.

**LENGTH:** 1

**FIELD LOCATION:** 492

**TYPE:** Numeric

**SKIP PATTERN:** This field should only be completed if Item 9.02 (Final Diagnosis) was reported as 4 (Adenomatous Polyp with high grade dysplasia) or 5 (Cancer); otherwise, leave blank.

**CONTENTS:**
- 1 = Pending linkage
- 2 = Linked, matched
- 3 = Linked, not matched

**EXPLANATION:** At the time of each CCDE submission, this field should be updated to indicate if the record has been linked to the state/central cancer registry or not.

If your Program has not linked a record with the Cancer Registry at the time of the CCDE submission, report this item as 1 (Pending linkage).

If your Program has successfully matched a record with the Cancer Registry at the time of the CCDE submission, report this item as 2 (Linked, matched).

If during the linkage process a record in the CCDEs is NOT identified in the state/central cancer registry (based on matching algorithm guidelines developed by CDC using a combination of client identifiers such as name and date of birth), indicate 3 (Linked, not matched).

**EXAMPLE:** If the case is matched with a record in the state/central cancer registry: 2

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ITEM NO / NAME:  **11.02: Registry Date of Diagnosis**

PURPOSE: To report the date of diagnosis obtained from the state/central cancer registry.

LENGTH: 8

FIELD LOCATION: 493 - 500

TYPE: Date - MMDDYYYY format

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: An 8-digit date item of the form MMDDYYYY, where MM (month) is the month of diagnosis from 01 to 12, DD (day) is the day of diagnosis from 01 to 31, and YYYY is the year of the diagnosis, including the century. If any part of the date is unknown, 9-fill or blank-fill only that part. For example, if the month and year of diagnosis are known, but the day is not, then blank fill the day (e.g. 08/2010).

EXPLANATION: This item should indicate the date of diagnosis [NAACCR data item # 390] obtained from the state/central cancer registry.

Please note that Item 9.03 (the Date of Final Diagnosis) and Item 11.02 may differ in many instances.

EXAMPLE: If the Registry Date of Diagnosis is 08/28/2010: 08282010.

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ITEM NO / NAME: 11.03: Registry Histologic Type

PURPOSE: To report the histologic type obtained from the state/central cancer registry.

LENGTH: 4

FIELD LOCATION: 501 - 504

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Values for Item 11.03 (Registry Histologic Type) fall within the range of 8000 to 9989.

NOTE: See Chapter 3 (Registry Linkage) for a list of the most common histology/behavior codes and their definitions as reported in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the Registry Histologic Type [NAACCR data item # 522] obtained from the state/central cancer registry database.

EXAMPLE: If the Registry Histologic Type is 8070: 8070.

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ITEM NO / NAME: 11.04: Registry Behavior

PURPOSE: To indicate the behavior code obtained from the state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 505

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 0 = Benign
1 = Uncertain whether benign or malignant/Borderline malignancy
2 = Carcinoma, In Situ
3 = Malignant

**NOTE:** See Chapter 3 (Registry Linkage) for a list of the most common histology/behavior codes and their definitions as reported in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the Registry Behavior type [NAACCR data item # 523] obtained from the state/central cancer registry database.

EXAMPLE: If the Registry Behavior indicates “Malignant”: 3

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ITEM NO / NAME: **11.05: Registry primary site**

PURPOSE: To report the primary site obtained from the state/central cancer registry.

LENGTH: 4

FIELD LOCATION: 506 - 509

TYPE: Alphanumeric - left justify

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: C000 through C999. The “C” must be included as part of the variable response.

Chapter 3 (Registry Linkage) contains documentation which provides a table of available primary site codes as listed in the topography section of the *International Classification of Diseases for Oncology*, Third Edition (ICD-O-3).

EXPLANATION: If Item 11.1 (Registry linkage status) is reported as 2 (Linked, matched), the primary site [NAACCR data item #400] obtained from the cancer registry should be reported.

EXAMPLE: If the primary site is cecum: **C180**

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ITEM NO / NAME: 11.06: Registry CS-derived SS2000

PURPOSE: To report the derived summary stage obtained from the state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 510

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 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

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS)-derived summary stage 2001 [NAACCR data item #3020] obtained from the cancer registry database. Please refer to the Web site www.cancerstaging.org for general instructions provided to cancer registry sites on reporting this information.

Chapter 3 (Registry Linkage) has additional information for this item.

EXAMPLE: If the registry CS-derived stage is localized: 1

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ITEM NO / NAME: 11.07: Registry CS-derived AJCC stage group

PURPOSE: To report the CS-derived AJCC stage group as indicated by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 511 – 513

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).


NOTE: See Chapter 3 (Registry Linkage) for a complete list of all available codes and their definitions as reported in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS)-derived AJCC stage [NAACCR data item #3000] obtained from the cancer registry database.

EXAMPLE: If polyp was diagnosed as a Stage II: 300

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ITEM NO / NAME: 11.08: Registry CS extension

PURPOSE: To indicate the extension of disease, as reported by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 514 – 516

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS extension include: 000, 050, 100, 110, 120, 130, 140, 150, 160, 170, 200, 300, 400, 410, 420, 450, 460, 490, 500, 550, 560, 570, 600, 650, 660, 700, 750, 800, 850, 900, 950, 999.

NOTE: See Chapter 3 (Registry Linkage) for a complete list of all available codes and their definitions as reported in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS)-derived extension [NAACCR data item #2810] obtained from the cancer registry database.

EXAMPLE: If the CS reported extension for Colon is “Localized, NOS”: 300

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ITEM NO / NAME: **11.09: Registry CS lymph nodes**

PURPOSE: To indicate the lymph node involvement, as reported by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 517 – 519

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS lymph nodes are 000, 050, 100, 200, 300, 400, 410, 420, 450, 460, 470, 800, 999.

**NOTE:** See Chapter 3 (Registry Linkage) for a complete list of all available codes and their definitions as reported in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS) lymph node involvement [NAACCR data item #2830] obtained from the cancer registry database.

EXAMPLE: If the primary site is colon, and the lymph nodes involvement reported is “Regional lymph node(s) for ascending colon: **200**

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ITEM NO / NAME: 11.10: Registry CS mets at diagnosis

PURPOSE: To indicate any distant metastases at the time of diagnosis, as reported by the state/central cancer registry.

LENGTH: 2

FIELD LOCATION: 520 – 521

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 00, 05, 08, 15, 20, 22, 25, 27, 30, 35, 38, 45, 60, 99.

10, 11, 12, 40 and 50 are valid but obsolete codes and should be used infrequently.

NOTE: See Chapter 3 (Registry Linkage) for a complete list of all available codes and their definitions as reported in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the CS mets at diagnosis [NAACCR data item #2850] obtained from the cancer registry database.

EXAMPLE: If the mets at diagnosis are reported as “None”: 00

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ITEM NO / NAME: 11.11: Registry Collaborative Stage (CS) – Tumor Size

PURPOSE: To report the tumor size as indicated by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 522 – 524

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 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

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the Collaborative Stage (CS) Tumor Size [NAACCR data item # 2800] obtained from the state/central cancer registry database.

Not all cancer registries collect this information. If this field is blank in the Cancer Registry, report 999 (Unknown).

EXAMPLE: If CS-Tumor Size was described as between 3 cm and 4 cm: 994

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ITEM NO / NAME: **12.1: CCDE version**

PURPOSE: To report the CCDE version that the current record was collected in.

LENGTH: 3

FIELD LOCATION: 525 – 527

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 100 = All data currently being collected/reported.

EXPLANATION: As the program begins to evaluate data collected, some variables may be dropped, new variables may be added, or additional options may be added to variable responses. As these changes occur, the CCDE version number will change.

EXAMPLE: Clinical data for a client was collected in March 2010: 100.

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CHAPTER 2

Appendices
APPENDIX A

CDC RACE AND ETHNICITY CODE SET
<table>
<thead>
<tr>
<th>CCDE Category</th>
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</table>
| 1. White      | **EUROPEAN** (which may include:)
  | Armenian |
  | English |
  | French |
  | German |
  | Irish |
  | Italian |
  | Polish |
  | Scottish |
  | **MIDDLE EASTERN OR NORTH AFRICAN** (which may include:)
  | Assyrian |
  | Egyptian |
  | Iranian |
  | Iraqi |
  | Lebanese |
  | Palestinian |
  | Syrian |
  | Afghanistani |
  | Israeli |
| 2. Black or African American | **BLACK**
  | **AFRICAN AMERICAN**
  | **AFRICAN** (which may include:)
<p>| Botswanaan |
| Ethiopian |
| Liberian |
| Namibian |
| Nigerian |
| Zairian |
| Bahamian |
| Barbadian |
| Dominican |
| Dominican Islander |
| Haitian |
| Jamaican |</p>
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<tr>
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<tbody>
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<td>Trinidadian</td>
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<td>West Indian</td>
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<td>3. Asian</td>
<td>Asian Indian</td>
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<td>Maldivian</td>
</tr>
<tr>
<td></td>
<td>Nepalese</td>
</tr>
<tr>
<td></td>
<td>Singaporean</td>
</tr>
<tr>
<td></td>
<td>Maldivian</td>
</tr>
<tr>
<td></td>
<td>Micronesian</td>
</tr>
<tr>
<td></td>
<td>Micronesian</td>
</tr>
<tr>
<td></td>
<td>Polynesian (which may include:)</td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian</td>
</tr>
<tr>
<td></td>
<td>Samoan</td>
</tr>
<tr>
<td></td>
<td>Tahitian</td>
</tr>
<tr>
<td></td>
<td>Tongan</td>
</tr>
<tr>
<td></td>
<td>Tokelauan</td>
</tr>
<tr>
<td></td>
<td>Micronesian (which may include:)</td>
</tr>
<tr>
<td></td>
<td>Guamanian</td>
</tr>
<tr>
<td></td>
<td>Chamorro</td>
</tr>
<tr>
<td></td>
<td>Mariana Islander</td>
</tr>
<tr>
<td></td>
<td>Marshallese</td>
</tr>
<tr>
<td>CCDE CATEGORY</td>
<td>CONCEPT</td>
</tr>
<tr>
<td>------------------------------------------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>4. Native Hawaiian or Other Pacific Islander (Cont’d)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Palauan</td>
</tr>
<tr>
<td></td>
<td>Carolinian</td>
</tr>
<tr>
<td></td>
<td>Kosraean</td>
</tr>
<tr>
<td></td>
<td>Pohnpeian</td>
</tr>
<tr>
<td></td>
<td>Yapese</td>
</tr>
<tr>
<td></td>
<td>Saipanese</td>
</tr>
<tr>
<td></td>
<td>Kiribati</td>
</tr>
<tr>
<td></td>
<td>Chuukese</td>
</tr>
<tr>
<td></td>
<td><strong>MELANESIAN (which may include:)</strong></td>
</tr>
<tr>
<td></td>
<td>Fijian</td>
</tr>
<tr>
<td></td>
<td>Papua New Guinean</td>
</tr>
<tr>
<td></td>
<td>Solomon Islander</td>
</tr>
<tr>
<td></td>
<td>New Hebrides</td>
</tr>
<tr>
<td></td>
<td><strong>OTHER PACIFIC ISLANDER</strong></td>
</tr>
<tr>
<td>5. American Indian or Alaskan Native</td>
<td><strong>AMERICAN INDIAN</strong></td>
</tr>
<tr>
<td></td>
<td><strong>CANADIAN AND LATIN AMERICAN INDIAN (which may include:)</strong></td>
</tr>
<tr>
<td></td>
<td>Canadian Indian</td>
</tr>
<tr>
<td></td>
<td>Central American Indian</td>
</tr>
<tr>
<td></td>
<td>French American Indian</td>
</tr>
<tr>
<td></td>
<td>Mexican American Indian</td>
</tr>
<tr>
<td></td>
<td>South American Indian</td>
</tr>
<tr>
<td></td>
<td>Spanish American Indian</td>
</tr>
<tr>
<td></td>
<td><strong>ALASKAN NATIVE (which may include:)</strong></td>
</tr>
<tr>
<td></td>
<td>Alaskan Indian</td>
</tr>
<tr>
<td></td>
<td>Inuit</td>
</tr>
<tr>
<td></td>
<td>Aleut</td>
</tr>
</tbody>
</table>
### TABLE 2 – ETHNICITY CONCEPTS AND CODES

<table>
<thead>
<tr>
<th>CCDE CATEGORY</th>
<th>CONCEPT</th>
</tr>
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<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>Spaniard</td>
</tr>
<tr>
<td></td>
<td>Mexican</td>
</tr>
<tr>
<td></td>
<td>Central American</td>
</tr>
<tr>
<td></td>
<td>South American</td>
</tr>
<tr>
<td></td>
<td>Latin American</td>
</tr>
<tr>
<td></td>
<td>Puerto Rican</td>
</tr>
<tr>
<td></td>
<td>Cuban</td>
</tr>
<tr>
<td></td>
<td>Dominican</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B

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
### Colorectal Cancer Control Program (CRCCP)
### Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Begin</th>
<th>End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Program</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>State FIPS code or program code assigned to tribal and territorial programs. Right justify and include leading zeroes (i.e. California = 006).</td>
<td>Valid code for your program.</td>
</tr>
<tr>
<td>1.2</td>
<td>Client identifier</td>
<td>15</td>
<td>4</td>
<td>18</td>
<td>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. <em>Alphabetic characters must be entered consistently in uppercase or lowercase, and include leading zeroes as applicable.</em></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Record identifier</td>
<td>6</td>
<td>19</td>
<td>24</td>
<td>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. <em>Numeric, right justify</em></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Date of birth</td>
<td>8</td>
<td>25</td>
<td>32</td>
<td>MMDDYYYY <em>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).</em></td>
<td>“MMDDYYYY”, “MM YYYYY” or “YYYY”, but not blank.</td>
</tr>
<tr>
<td>2.2</td>
<td>Gender</td>
<td>1</td>
<td>33</td>
<td>33</td>
<td>1 = Male 2 = Female 9 = Other/unknown</td>
<td>Range check.</td>
</tr>
<tr>
<td>2.3</td>
<td>Hispanic or Latino origin</td>
<td>1</td>
<td>34</td>
<td>34</td>
<td>1 = Yes 2 = No 9 = Unknown/missing</td>
<td>Range check.</td>
</tr>
</tbody>
</table>

---

Alphabetic characters must be entered consistently in uppercase or lowercase, and include leading zeroes as applicable.
<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Begin</th>
<th>End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
</table>
| 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  
**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. | 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. |
<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Length</th>
<th>Begin</th>
<th>End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Has client ever had a colorectal screening test?</td>
<td>1</td>
<td>45</td>
<td>45</td>
<td>1 = Yes  2 = No  9 = Unknown</td>
<td>Range check.</td>
</tr>
</tbody>
</table>
|        |               |        |      |     |                           | A CRC screening test is limited to one of the following:  
|        |               |        |      |     |                           | Take-home FOBT  
|        |               |        |      |     |                           | Take-home FIT  
|        |               |        |      |     |                           | Sigmoidoscopy  
|        |               |        |      |     |                           | Colonoscopy  
|        |               |        |      |     |                           | DCBE  
|        |               |        |      |     |                           | CTC  
|        |               |        |      |     |                           | Stool DNA  
| 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 not = 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. |
## Colorectal Cancer Control Program (CRCCP)
### Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Length</td>
<td>Begin</td>
<td>End</td>
</tr>
<tr>
<td>5.</td>
<td>Screening Adherence – Complete for each CCDE record</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td>Initial test appointment date, or date fecal kit distributed</td>
<td>8</td>
<td>49</td>
<td>56</td>
</tr>
<tr>
<td>5.2</td>
<td>Screening adherence</td>
<td>1</td>
<td>57</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Item #</td>
<td>Variable Name</td>
<td>Column Length</td>
<td>End</td>
<td>Codes / Format / Comments</td>
</tr>
<tr>
<td>--------</td>
<td>---------------</td>
<td>---------------</td>
<td>-----</td>
<td>---------------------------</td>
</tr>
</tbody>
</table>
| 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. |
Right Justify |
<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
</table>
| 6.1.05 | Result of test 1                                  | 1 110  110 | 1 = Normal/Negative/Diverticulosis/Hemorrhoids<br>2 = Other finding not suggestive of cancer or polyp(s)<br>3 = Polyp(s), or Lesion(s) suspicious for cancer<br>4 = Inadequate/Incomplete test with no findings<br>5 = FOBT/FIT/Other Test Performed Negative<br>6 = FOBT/FIT/Other Test Performed Positive<br>7 = Pending<br>9 = Unknown | Range check.<br>  
If 6.1.01 = 1 or 2 then 6.1.05 must = 5, 6, 7 or 9.<br>  
If 6.1.01 = 3-5, then 6.1.05 must = 1-4, 7 or 9.<br>  
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<br>2 = No<br>9 = Unknown | Range check.<br>  
If 6.1.06 = 1, then 7.1 must be completed.<br>  
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*<br>2 = No<br>9 = Unknown<br>  
*Adequacy will be determined by the clinician performing the test.  
Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown). | Range check.<br>  
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<br>2 = No<br>9 = Unknown | Range check.<br>  
If 6.1.01 does not = 4, then 6.1.08 should be blank. |
## Colorectal Cancer Control Program (CRCCP)
### Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1.09</td>
<td><strong>Test 1 outcome</strong></td>
<td>1 114 114</td>
<td>1 = Complete</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = Incomplete/Inadequate</td>
<td>If 6.1.05 = 5 or 6, then 6.1.09 should = 1 (Complete).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If 6.1.05 = 4, then 6.1.09 should = 2 (Incomplete/Inadequate).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If 6.1.07 = 2, then 6.1.09 should = 2 (Incomplete/Inadequate).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If 6.1.08 = 2, then 6.1.09 should = 2 (Incomplete/Inadequate).</td>
</tr>
<tr>
<td>6.1.10</td>
<td><strong>Recommended next follow-up procedure within this cycle</strong></td>
<td>1 115 115</td>
<td>1 = Sigmoidoscopy</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = Colonoscopy</td>
<td>If 6.1.10 = 4 or 8, then 6.2.01, 6.3.01 and 6.4.01 should = 0 (None).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 = DCBE</td>
<td>If 6.1.10 = 4, then 8.1 must be completed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 = Surgery to complete diagnosis*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7 = Other</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8 = None (cycle is complete)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended.</strong></td>
<td></td>
</tr>
<tr>
<td>6.1.11</td>
<td><strong>Other recommended test, specify</strong></td>
<td>40 116 155</td>
<td>Free text</td>
<td>If 6.1.10 = 7 (Other), then 6.1.11 should be completed; otherwise, leave blank.</td>
</tr>
<tr>
<td>Item #</td>
<td>Variable Name</td>
<td>Column begin</td>
<td>Column end</td>
<td>Codes / Format / Comments</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------</td>
<td>--------------</td>
<td>------------</td>
<td>------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>6.2.01</td>
<td>Test 2 performed</td>
<td>156</td>
<td>156</td>
<td>0 = None&lt;br&gt;3 = Sigmoidoscopy&lt;br&gt;4 = Colonoscopy&lt;br&gt;5 = DCBE&lt;br&gt;7 = Other&lt;br&gt;0 = None</td>
</tr>
<tr>
<td>6.2.02</td>
<td>Test 2 performed – other specify</td>
<td>157</td>
<td>196</td>
<td>Free text</td>
</tr>
<tr>
<td>6.2.03</td>
<td>Date of test 2</td>
<td>197</td>
<td>204</td>
<td>MMDDYYYY&lt;br&gt;“MMDDYYYY”, “MM YYYY” or “YYYY”, but not blank.</td>
</tr>
<tr>
<td>6.2.04</td>
<td>Provider specialty</td>
<td>205</td>
<td>206</td>
<td>1 = General practitioner&lt;br&gt;2 = Internist&lt;br&gt;3 = Family practitioner&lt;br&gt;4 = Gastroenterologist&lt;br&gt;5 = General surgeon&lt;br&gt;6 = Colorectal surgeon&lt;br&gt;7 = Licensed practical nurse&lt;br&gt;8 = Registered nurse&lt;br&gt;9 = Nurse practitioner&lt;br&gt;10 = Physician assistant&lt;br&gt;12 = Radiologist&lt;br&gt;13 = Obstetrician / Gynecologist (OB/GYN)&lt;br&gt;99 = Unknown&lt;br&gt;Right justify</td>
</tr>
<tr>
<td>6.2.05</td>
<td>Result of test 2</td>
<td>207</td>
<td>207</td>
<td>1 = Normal/Negative/Diverticulosis/Hemorrhoids&lt;br&gt;2 = Other finding not suggestive of cancer or polyp(s)&lt;br&gt;3 = Polyp(s), or Lesion(s) suspicious for cancer&lt;br&gt;4 = Inadequate/Incomplete test with no findings&lt;br&gt;5 = FOBT/FIT/Other Test Performed Negative&lt;br&gt;6 = FOBT/FIT/Other Test Performed Positive&lt;br&gt;7 = Pending&lt;br&gt;9 = Unknown</td>
</tr>
<tr>
<td>Item #</td>
<td>Variable Name</td>
<td>Column</td>
<td>Length</td>
<td>Begin</td>
</tr>
<tr>
<td>-------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------</td>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td>6.2.06</td>
<td>Was a biopsy/polypectomy performed during the endoscopy?</td>
<td>1</td>
<td>208</td>
<td>208</td>
</tr>
<tr>
<td>6.2.07</td>
<td>Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?</td>
<td>1</td>
<td>209</td>
<td>209</td>
</tr>
<tr>
<td>6.2.08</td>
<td>Was the cecum reached during the colonoscopy?</td>
<td>1</td>
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<td>6.2.09</td>
<td>Test 2 outcome</td>
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<td>6.2.10</td>
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<td>212</td>
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<td>6.2.11</td>
<td>Other recommended test, specify</td>
<td>40</td>
<td>213</td>
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<td>Variable Name</td>
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<td>6.3.01</td>
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<td>253 253</td>
<td>Range check.</td>
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<tr>
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<td>0 = None</td>
<td>If 6.3.01 = 0 (None), then 6.3.02 through 6.3.11 should be blank.</td>
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<tr>
<td></td>
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<td>3 = Sigmoidoscopy</td>
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<td></td>
<td>5 = DCBE</td>
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<td></td>
<td></td>
<td>7 = Other</td>
<td></td>
</tr>
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<td>6.3.02</td>
<td>Test 3 performed – other specify</td>
<td>40</td>
<td>254 293</td>
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<td>Free text</td>
<td>If 6.3.01 = 7 (Other), then 6.3.02 should be completed; otherwise, leave blank.</td>
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<tr>
<td>6.3.03</td>
<td>Date of test 3</td>
<td>8</td>
<td>294 301</td>
<td>“MMDDYYYY”, “MM YYYY” or “YYYY”, but not blank.</td>
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<td>MMDDYYYY</td>
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<td>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).</td>
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<td>6.3.04</td>
<td>Provider specialty</td>
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<td>302 303</td>
<td>Range check.</td>
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<td>1 = General practitioner</td>
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<td></td>
<td>2 = Internist</td>
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<td></td>
<td></td>
<td>3 = Family practitioner</td>
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<td></td>
<td>4 = Gastroenterologist</td>
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<td></td>
<td>5 = General surgeon</td>
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<td>6 = Colorectal surgeon</td>
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<td>7 = Licensed practical nurse</td>
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<td>8 = Registered nurse</td>
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<td>9 = Nurse practitioner</td>
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<td>10 = Physician assistant</td>
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<td></td>
<td>12 = Radiologist</td>
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<td></td>
<td>13 = Obstetrician / Gynecologist (OB/GYN)</td>
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<td></td>
<td></td>
<td></td>
<td>99 = Unknown</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Right justify</td>
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</tr>
<tr>
<td>6.3.05</td>
<td>Result of test 3</td>
<td>1</td>
<td>304 304</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 = Normal/Negative/Diverticulosis/Hemorrhoids</td>
<td>If 6.3.01 = 3-5, then 6.3.05 must be 1-4, 7 or 9.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = Other finding not suggestive of cancer or polyp(s)</td>
<td>If 6.3.01 = 7, then 6.3.05 must be completed as appropriate for test performed.</td>
</tr>
</tbody>
</table>
### Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item #</th>
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<th>Column Length</th>
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<tr>
<td>6.3.06</td>
<td>Was a biopsy/polypectomy performed during the endoscopy?</td>
<td>1  305  305</td>
<td>1 = Yes, 2 = No, 9 = Unknown</td>
<td>Range check. If 6.3.06 = 1, then 7.1 must be completed. Leave blank if 6.3.01 = 0, 5, or 7.</td>
</tr>
<tr>
<td>6.3.07</td>
<td>Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?</td>
<td>1  306  306</td>
<td>1 = Yes*, 2 = No, 9 = Unknown. *Adequacy will be determined by the clinician performing the test.</td>
<td>Range check. If 6.3.01 = 3, 4, 5 or 7, then 6.3.07 must be completed; otherwise leave blank.</td>
</tr>
<tr>
<td>6.3.08</td>
<td>Was the cecum reached during the colonoscopy?</td>
<td>1  307  307</td>
<td>1 = Yes, 2 = No, 9 = Unknown</td>
<td>Range check. If 6.3.01 does not = 4, then 6.3.08 should be blank.</td>
</tr>
<tr>
<td>6.3.09</td>
<td>Test 3 outcome</td>
<td>1  308  308</td>
<td>1 = Complete, 2 = Incomplete/Inadequate</td>
<td>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).</td>
</tr>
<tr>
<td>Item #</td>
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</tr>
<tr>
<td>6.3.10</td>
<td>Recommended next follow-up procedure within this cycle after test 3</td>
<td>1 309 309</td>
<td>1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 7 = Other 8 = None (cycle is complete)</td>
<td>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.</td>
</tr>
<tr>
<td>6.3.11</td>
<td>Other recommended test, specify</td>
<td>40 310 349</td>
<td>Free text</td>
<td>If 6.3.10 = 7 (Other), then 6.3.11 should be completed; otherwise, leave blank.</td>
</tr>
<tr>
<td>Item #</td>
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<td>Column</td>
<td>Codes / Format / Comments</td>
<td>Edit Checks / Skip Patterns</td>
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<td>---------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>6.4.01</td>
<td>Test 4 performed</td>
<td>1</td>
<td>350 350</td>
<td>0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 7 = Other</td>
</tr>
<tr>
<td>6.4.02</td>
<td>Test 4 performed – other specify</td>
<td>40</td>
<td>351 390</td>
<td>Free text</td>
</tr>
<tr>
<td>6.4.03</td>
<td>Date of test 4</td>
<td>8</td>
<td>391 398</td>
<td>MMDDYYYY</td>
</tr>
<tr>
<td>6.4.04</td>
<td>Provider specialty</td>
<td>2</td>
<td>399 400</td>
<td>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</td>
</tr>
<tr>
<td>6.4.05</td>
<td>Result of test 4</td>
<td>1</td>
<td>401 401</td>
<td>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</td>
</tr>
</tbody>
</table>
### Colorectal Cancer Control Program (CRCCP)
### Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
</table>
| 6.4.06 | Was a biopsy/polypectomy performed during the endoscopy?                       | 1 402 402 | 1 = Yes  
2 = No  
9 = Unknown                                                                 | 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 | 1 = Yes*  
2 = No  
9 = Unknown                                                                 | Adequacy will be determined by the clinician performing the test.  
*Procedure report must explicitly state that the bowel prep was adequate; otherwise, report 9 (Unknown). |
| 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)                                                                 | Range check.  
If 6.4.10 = 4, then 8.1 must be completed.  
* Diagnosis Information for Surgeries Performed to Complete Diagnosis section must be completed if surgery is recommended. |
<table>
<thead>
<tr>
<th>Item #</th>
<th>Variable Name</th>
<th>Column</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
</tr>
</thead>
</table>
| 7.1   | Histology of most severe polyp/lesion| 2 407 408 | 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 | Right justify  
Do not include information from surgical resections in this section. | Range check.  
Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.  
If 7.1 = 4-11, then 7.2 and 7.3 must be completed. |
| 7.2   | Total number of adenomatous polyps/lesions | 2 409 410 | 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  
Do not include information from surgical resections in this section. | Right justify  
Do not include information from surgical resections in this section. | Range Check.  
If 7.1 = 4-11, then 7.2 must be completed; otherwise, leave blank. |
| 7.3   | Size of largest adenomatous polyp/lesion | 1 411 411 | 1 = < 1 cm  
2 = ≥ 1 cm  
9 = Unknown  
Do not include information from surgical resections in this section. | Range check.  
If 7.1 = 4-11, then 7.3 must be completed; otherwise, leave blank. |
## Colorectal Cancer Control Program (CRCCP)
### Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
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<th>Item #</th>
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<tr>
<td></td>
<td><strong>8. Diagnosis Information for Surgeries Performed to Complete Diagnosis</strong></td>
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<td></td>
<td></td>
<td></td>
<td><strong>8.1 Histology from surgical resection</strong> 2 412 413 0 = Surgery recommended but not performed</td>
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</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>1 = Normal or other non-polyp histology</td>
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<td></td>
<td></td>
<td>2</td>
<td>2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>3 = Hyperplastic polyp</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>4 = Adenoma, NOS (no high grade dysplasia noted)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>5 = Adenoma, tubular (no high grade dysplasia noted)</td>
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<td></td>
<td></td>
<td>6</td>
<td>6 = Adenoma, mixed tubular villous (no high grade dysplasia noted)</td>
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<td></td>
<td></td>
<td></td>
<td>7</td>
<td>7 = Adenoma, villous (no high grade dysplasia noted)</td>
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<td></td>
<td>8</td>
<td>8 = Adenoma, serrated (no high grade dysplasia noted)</td>
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<td>9</td>
<td>9 = Adenoma with high grade dysplasia (includes in situ carcinoma)</td>
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<td></td>
<td>10</td>
<td>10 = Adenocarcinoma, invasive</td>
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<td></td>
<td></td>
<td></td>
<td>11</td>
<td>11 = Cancer, other</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>99</td>
<td>99 = Unknown/other lesions ablated, not retrieved or confirmed</td>
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<tr>
<td>8.1</td>
<td><strong>Histology from surgical resection</strong></td>
<td>2</td>
<td>412</td>
<td>412</td>
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<td>Use histology from surgical resection in conjunction with histology of the most severe polyp/lesion reported in Item 7.1, to report the &quot;Final diagnosis&quot; (Item 9.02).</td>
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</tr>
<tr>
<td>8.2</td>
<td><strong>Date surgery performed</strong></td>
<td>8</td>
<td>414</td>
<td>421</td>
<td></td>
<td>Use histology from surgical resection in conjunction with histology of the most severe polyp/lesion reported in Item 7.1, to report the &quot;Final diagnosis&quot; (Item 9.02).</td>
<td></td>
</tr>
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<td>Item #</td>
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</tr>
</tbody>
</table>
| 9.01   | Status of final diagnosis | 1             | 422          | 422        | 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 = Irreconcilable\(^2\)  
\(^1\)Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up.  
\(^2\)These items should have an administrative close-out date reported in 9.03 “Date of final diagnosis”.  
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. | Range check.  
If 5.2 = 1, then complete 9.01; otherwise, leave blank. |
| 9.02   | Final diagnosis         | 1             | 423          | 423        | 1 = Normal/Negative  
2 = Hyperplastic polyps  
3 = Adenomatous polyp, no high grade dysplasia  
4 = Adenomatous polyp with high grade dysplasia  
5 = Cancer  
**Registry Information for Cancer/High Grade Dysplasia** section must be completed if 9.02 (Final diagnosis) = 4 or 5. | Range check.  
If the only test performed in the cycle was either FOBT or FIT, then complete 9.02 as 1 (Normal/Negative).  
If 9.01 = 1, then complete 9.02; otherwise, leave blank.  
If 9.02 = 4 or 5, then 11.01 (Registry linkage status) must be completed. |
| 9.03   | Date of final diagnosis | 8             | 424          | 431        | MMDDYYYY  
*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).*  
If 9.01 = 1, 3, 4 or 5, then “MMDDYYYY”, “MM YYYY” or “YYYY”.  
If 9.01 = 3, 4 or 5, then an administrative close-out date will be necessary.  
Leave blank if 9.01 = 2 |
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<th>Item #</th>
<th>Variable Name</th>
<th>Column</th>
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<td>9.04</td>
<td>Recommended screening or surveillance test for next cycle</td>
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<td>1 = Take-home FOBT</td>
<td>Range check.</td>
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<td>2 = Take-home FIT</td>
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<td>3 = Sigmoidoscopy</td>
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<td>4 = Colonoscopy</td>
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<td>5 = DCBE</td>
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<td></td>
<td>8 = None</td>
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<td></td>
<td>9 = Unknown</td>
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<td></td>
<td>Range check.</td>
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<td></td>
<td>If client is terminally ill or for other reasons no further tests are recommended, then code this as 8 (None).</td>
<td></td>
</tr>
<tr>
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<td></td>
<td>Leave blank if 9.01 does not = 1</td>
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</tr>
<tr>
<td>9.05</td>
<td>Indication for screening or surveillance test for next cycle</td>
<td>433</td>
<td>1</td>
<td>433</td>
<td></td>
<td>1 = Screening</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>2 = Surveillance after a positive colonoscopy and/or surgery</td>
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<td>Leave blank if 9.04 = 8, 9</td>
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<tr>
<td>9.06</td>
<td>Number of months before screening or surveillance test for next cycle</td>
<td>434</td>
<td>3</td>
<td>434</td>
<td>436</td>
<td>12 – 180 = Actual number of months</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
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<td>999 = Unknown</td>
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<td>Leave blank if 9.01 does not = 1</td>
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<td>9.07</td>
<td>Complications (1) of endoscopy or DCBE requiring observation or treatment</td>
<td>437</td>
<td>2</td>
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<td>438</td>
<td>0 = No complications reported</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>1 = Bleeding requiring transfusion</td>
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<td></td>
<td></td>
<td></td>
<td>2 = Bleeding not requiring transfusion</td>
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<td></td>
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<td></td>
<td>3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc)</td>
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<td>4 = Complications related to anesthesia</td>
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<td></td>
<td>5 = Bowel perforation</td>
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<td></td>
<td>6 = Post-polypectomy syndrome/excessive abdominal pain</td>
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<td>7 = Death</td>
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<td></td>
<td>8 = Other</td>
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<td></td>
<td>99 = Unknown</td>
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<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>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.</td>
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<tr>
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<td>Report only one complication in each of 9.07 and 9.08.</td>
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</tr>
<tr>
<td>9.08</td>
<td>Complications (2) of endoscopy or DCBE requiring observation or treatment</td>
<td>2</td>
<td>439</td>
<td>440</td>
<td>0 = N/A – no 2nd complication reported</td>
<td>Range check.</td>
<td></td>
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<tr>
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<td></td>
<td>1 = Bleeding requiring transfusion</td>
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<td>2 = Bleeding not requiring transfusion</td>
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<td>3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc)</td>
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<td>4 = Complications related to anesthesia</td>
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<td>5 = Bowel perforation</td>
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<td>6 = Post-polypectomy syndrome/excessive abdominal pain</td>
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<td>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</td>
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<td>completed; otherwise leave blank.</td>
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<td>Report the worst of up to 2 distinct serious complications of CRC testing occurring</td>
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<td>within 30 days of the test date and resulting in an emergency room visit, hospitalization</td>
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<td>or death.</td>
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<td></td>
<td>Report only one complication in each of 9.07 and 9.08.</td>
<td></td>
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</tr>
<tr>
<td>9.09</td>
<td>Complications of endoscopy or DCBE – other specify</td>
<td>40</td>
<td>441</td>
<td>480</td>
<td>Free text</td>
<td>If 9.07 or 9.08 = 8, then 9.09 must be completed; otherwise, leave blank.</td>
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<tr>
<td>9.10</td>
<td>CRCCP funds used for any screening/diagnostic test?</td>
<td>1</td>
<td>481</td>
<td>481</td>
<td>1 = Yes</td>
<td>Range check.</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>2 = No</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>9 = Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>Variable Name</td>
<td>Column</td>
<td>Codes / Format / Comments</td>
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</tr>
<tr>
<td>10.1</td>
<td>Recurrent cancers</td>
<td>1</td>
<td>1 = New CRC primary&lt;br&gt;2 = Recurrent CRC&lt;br&gt;3 = Non-CRC primary (metastasis from another organ)&lt;br&gt;9 = Unknown</td>
<td>Range check.&lt;br&gt;If 9.02 = 5, then 10.1 must be completed; otherwise, leave blank.</td>
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</tr>
<tr>
<td>10.2</td>
<td>Status of treatment</td>
<td>1</td>
<td>1 = Treatment started and/or completed&lt;br&gt;2 = Treatment pending&lt;br&gt;3 = Treatment not indicated due to polypectomy&lt;br&gt;4 = Treatment not recommended&lt;br&gt;5 = Treatment refused&lt;br&gt;6 = Lost to follow-up&lt;br&gt;9 = Unknown</td>
<td>Range check.&lt;br&gt;If 9.02 = 5, then 10.2 must be completed.&lt;br&gt;If 9.02 = 4, then 10.2 may be completed; however, 10.2 may not = 3, 4 or 9.&lt;br&gt;Leave blank if 9.02 = 1, 2 or 3.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>10.3</td>
<td>Date of treatment</td>
<td>8</td>
<td>MMDDYYYY&lt;br&gt;<strong>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).</strong></td>
<td>If 10.2 = 1, 3-6, then “MMDDYYYY”, “MM YYYY” or “YYYY”.&lt;br&gt;If 10.2 = 3-6, then an administrative close-out date is required.&lt;br&gt;Leave blank if 10.2 = 2 or 9.</td>
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</tr>
<tr>
<td>11.01</td>
<td>Registry linkage status</td>
<td>1</td>
<td>1 = Pending linkage&lt;br&gt;2 = Linked, matched&lt;br&gt;3 = Linked, not matched</td>
<td>Range check.</td>
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<td></td>
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</tr>
<tr>
<td>11.02</td>
<td>Registry date of diagnosis</td>
<td>8</td>
<td>MMDDYYYY</td>
<td>Leave blank if 11.01 = 1, 3.&lt;br&gt;If not blank, must be a valid date.</td>
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</table>
Colorectal Cancer Control Program (CRCCP)
Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

<table>
<thead>
<tr>
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<th>Variable Name</th>
<th>Length</th>
<th>Column Begin</th>
<th>End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks / Skip Patterns</th>
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<tbody>
<tr>
<td>11.03</td>
<td>Registry histologic type [NAACCR data item #522]</td>
<td>4</td>
<td>501</td>
<td>504</td>
<td>Range: 8000-9989</td>
<td>Range check.</td>
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<td>A complete list of valid values/labels will be provided for reference in Chapter 3 of the Data User's Manual.</td>
<td>Leave blank if 11.01 = 1, 3.</td>
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<tr>
<td>11.04</td>
<td>Registry behavior [NAACCR data item #523]</td>
<td>1</td>
<td>505</td>
<td>505</td>
<td>0 = Benign 1 = Uncertain whether benign or malignant/Borderline malignancy 2 = Carcinoma In Situ 3 = Malignant</td>
<td>Range check.</td>
</tr>
<tr>
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<td>Range check. Leave blank if 11.01 = 1, 3.</td>
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<tr>
<td>11.05</td>
<td>Registry primary site [NAACCR data item #400]</td>
<td>4</td>
<td>506</td>
<td>509</td>
<td>C000-C999</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
<td>See SEER Program Coding and Staging Manual: <a href="http://seer.cancer.gov">http://seer.cancer.gov</a></td>
<td></td>
<td></td>
<td></td>
<td>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.</td>
<td>Leave blank if 11.01 = 1, 3</td>
</tr>
<tr>
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<td></td>
<td>Alphanumeric, left justify</td>
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<tr>
<td>11.06</td>
<td>Registry CS-derived SS2000 [NAACCR data item #3020]</td>
<td>1</td>
<td>510</td>
<td>510</td>
<td>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</td>
<td>Range check.</td>
</tr>
<tr>
<td>11.07</td>
<td>Registry CS-derived AJCC stage group [NAACCR data item #3000]</td>
<td>3</td>
<td>511</td>
<td>513</td>
<td>Range: 000-999</td>
<td>Range check.</td>
</tr>
<tr>
<td></td>
<td>See CS Staging Manual: <a href="http://www.cancerstaging.org">http://www.cancerstaging.org</a></td>
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<td></td>
<td>A complete list of valid values/labels is available for reference in the CCDE User's Manual.</td>
<td>Leave blank if 11.01 = 1, 3</td>
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# Colorectal Cancer Clinical Data Elements (CCDE) Data Definition Table

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<th>Edit Checks / Skip Patterns</th>
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<tbody>
<tr>
<td>11.08</td>
<td>Registry CS extension</td>
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<td>514</td>
<td>516</td>
<td>Range: 000-999</td>
<td>Range check. Leave blank if 11.01 = 1, 3</td>
</tr>
<tr>
<td>11.09</td>
<td>Registry CS lymph nodes</td>
<td>3</td>
<td>517</td>
<td>519</td>
<td>Range: 000-999</td>
<td>Range check. Leave blank if 11.01 = 1, 3</td>
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<tr>
<td>11.10</td>
<td>Registry CS mets at diagnosis</td>
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<td>520</td>
<td>521</td>
<td>Range: 00-99</td>
<td>Range check. Leave blank if 11.01 = 1, 3</td>
</tr>
<tr>
<td>11.11</td>
<td>Registry CS tumor size</td>
<td>3</td>
<td>522</td>
<td>524</td>
<td>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</td>
<td>Range check and skip pattern check. Leave blank if 11.01 = 1, 3.</td>
</tr>
<tr>
<td></td>
<td>[NAACCR data item #2800]</td>
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## 12. Record Information – Completed for each CCDE record

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<th>Length</th>
<th>Column Begin</th>
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<tr>
<td>12.1</td>
<td>CCDE version</td>
<td>3</td>
<td>525</td>
<td>527</td>
<td>100 = Data collected beginning 10/01/2009</td>
<td>Range check. Example: Carriage Return – Line Feed (CR-LF)</td>
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<tr>
<td></td>
<td>End of record mark</td>
<td>1</td>
<td>528</td>
<td>528</td>
<td>Character that ends the current record and begins a new line of text.</td>
<td>Example: Carriage Return – Line Feed (CR-LF)</td>
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</table>
APPENDIX C

GLOSSARY OF TERMS
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Adenomatous polyp</td>
<td>See “Polyp”. More likely to develop into cancer than a non-adenomatous polyp. Also known as “adenoma”.</td>
</tr>
<tr>
<td>CO-RADS</td>
<td>Colonoscopy Reporting and Data System (CO-RADS), a standardized colonoscopy reporting and data system. CO-RADS specifies the elements that should be included in all colonoscopy reports and presents a standard method for reporting them.</td>
</tr>
<tr>
<td>Colonoscope</td>
<td>A flexible, lighted instrument with a built-in tiny camera used to view the inside of the entire colon and rectum.</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>An examination in which the doctor looks at the internal walls of the entire colon through a flexible, lighted instrument called a colonoscope. The doctor may collect samples of tissue or cells for closer examination. The doctor may also remove polyps during colonoscopy.</td>
</tr>
<tr>
<td>Colorectal</td>
<td>Related to the colon, rectum or both.</td>
</tr>
<tr>
<td>CRCCP Resource Web Site</td>
<td><a href="http://www.CRCCP.org">www.CRCCP.org</a></td>
</tr>
<tr>
<td>CS Coding Manual</td>
<td><a href="http://www.cancerstaging.org">www.cancerstaging.org</a></td>
</tr>
<tr>
<td>Double-Contrast Barium Enema</td>
<td>A series of x-rays of the colon and rectum. The x-rays are taken after the patient is given an enema, followed by an injection of air. The barium outlines the intestines on the x-rays, allowing many abnormal growths to be visible.</td>
</tr>
<tr>
<td>Fecal Immunochemical Test (FIT)</td>
<td>Like a fecal occult blood test (FOBT), an FIT also detects hidden blood in the stool using a different technique than guaiac based FOBT. FIT is effectively done the same way as an FOBT, but it may be more specific or more sensitive than a guaiac based FOBT.</td>
</tr>
<tr>
<td>Fecal Occult Blood Test (FOBT)</td>
<td>A guaiac based test to check for hidden blood in stool. Fecal refers to stool. Occult means hidden. Sometimes called &quot;F.O.B.T.&quot;.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Flexible Sigmoidoscopy</td>
<td>A procedure in which the doctor looks inside the rectum and the lower portion of the colon (sigmoid colon) through a flexible, lighted tube called a sigmoidoscope. The doctor may collect samples of tissue or cells for closer examination and remove some polyps within view.</td>
</tr>
<tr>
<td>Gastroenterologist</td>
<td>A doctor who specializes in diagnosing and treating disorders of the digestive system (which includes the esophagus, stomach, pancreas, intestines, and liver).</td>
</tr>
<tr>
<td>Polyp</td>
<td>An abnormal, often precancerous growth of tissue (colorectal polyps are growths of tissue inside the intestine).</td>
</tr>
<tr>
<td>Rectum</td>
<td>The last 8 to 10 inches of the large intestine. The rectum stores solid waste until it leaves the body through the anus.</td>
</tr>
<tr>
<td>Screening Test</td>
<td>&quot;Screening tests&quot; are tests used to check, or screen, for disease when there are no symptoms. Screening tests for colorectal cancer include: fecal occult blood test, flexible sigmoidoscopy, colonoscopy, and double contrast barium enema. (When a test is performed to find out why symptoms exist, it is called a &quot;diagnostic&quot; test).</td>
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<tr>
<td>Sigmoidoscope</td>
<td>A flexible, lighted instrument with a built-in tiny camera that allows the doctor to view the lining of the rectum and lower portion of the colon.</td>
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<tr>
<td>Stool DNA</td>
<td>A stool DNA test looks for traces of DNA (genetic material) shed by polyps and/or colorectal tumors.</td>
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<tr>
<td>Virtual Colonoscopy</td>
<td>A screening examination of the colon in which x-rays obtained by CAT scan are used to generate computerized three-dimensional images of the colonic mucosa.</td>
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