Screen for life

Colorectal Cancer Control Program
Funded by the Centers for Disease Control and Prevention

Colorectal 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
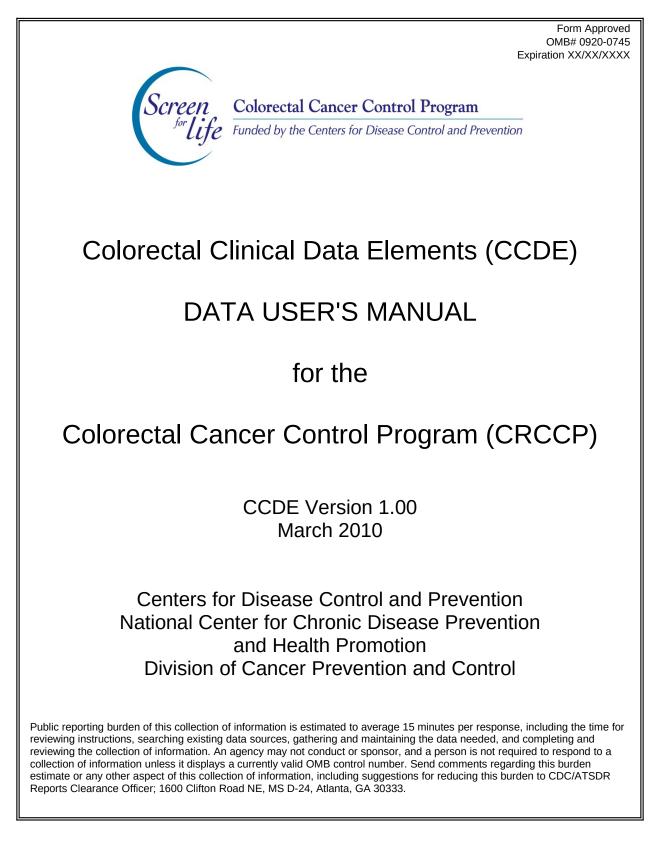
Introduction

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 4 chapters as follows:

Chapter 1 **Data Submission**
This chapter contains the dates that the Colorectal Cancer Clinical Data Elements (CCDEs) are to be submitted to IMS, along with the technical requirements for submission.

Chapter 2 **Colorectal Cancer Clinical Data Elements (CCDEs)**
This chapter includes a general introduction to the CCDEs and detailed information about each CCDE data item.

Chapter 3 **Registry Linkage**
This chapter provides variable definition tables that outline each of the collaborative stage variables collected in the CCDEs.

Chapter 4 **References**
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.

Table of Contents

Chapter 1   CCDE Data Submission

Chapter 2   Colorectal Cancer Clinical Data Elements (CCDEs)

Table of Contents

CHAPTER 1

CCDE Data Submission

What: CCDE data are submitted semi-annually to IMS. Each CCDE submission will include cumulative data from the beginning of screening through the submission's **screening cut-off date**, which is 2.5 months prior to the due date.   Do not include records dated after the screening cut-off date.   The 2.5 month lag time between the cut-off date and the reporting of the CCDE data will allow time to collect and perform quality control on these data. Submitted records may have incomplete data that will be updated on a subsequent submission. Each submission dataset will replace the previous submission in its entirety.

> *Screening Cut-off Date:*   CCDE Item 5.1 (Initial test appointment date, or date fecal kit distributed) should be used as the screening cut-off date to determine if the record should be included in the submission. Item 5.1 represents the date that screening was initiated for clients enrolled in the program, regardless of whether testing was completed or not. Refer to Chapter 2 for more information on tracking screening adherence in the CCDEs.

> For example, if the data are due to IMS on 09/15/2010, the data should cover all records indicating procedures initially scheduled or fecal kits distributed (CCDE Item 5.1) from the onset of the screening program through 06/30/2010.

> *Inclusion of records:*
> The CCDE data file should contain records on all clients who were enrolled in the Colorectal Cancer Control Program (CRCCP) and who received services paid for using CDC funds. This includes clients who are determined to be eligible and are scheduled for screening procedures or given a take-home fecal kit, regardless of whether they return the kit or adhere to screening.

> If authorized by CDC, records of clients screened using other non-CRCCP funding sources may be reported, but should be limited to publically funded screening of a similar eligible population.

When: CCDE data are submitted to IMS according to the schedule below.

All files should be received by IMS by close of business on the due date. If the submission due date falls on a weekend or holiday, then the data should be received by the close of business on the first business day after the submission due date.

Submission Due	Screening Cut-off Date
09/15/2010	06/30/2010
03/15/2011	12/31/2010
09/15/2011	06/30/2011
03/15/2012	12/31/2011
09/15/2012	06/30/2012
03/15/2013	12/31/2012

How: When a CCDE submission is due, the CCDE data must be extracted from your client database and put into the standardized CCDE format. The CCDE file consists of fixed length records in an ASCII file format. In Version 1.00 of the CCDE data file format, each record consists of 526 columns which includes 524 columns for reporting screening, diagnosis, treatment and Cancer Registry information and a 2 character end-of-record delimiter in the form of a "carriage return-line feed". A detailed description of the CCDE items in each record is included in Chapter 2.

The CCDE file must be submitted electronically using the secure www.CRCCP.org Web site. IMS and the CDC require the use of compression software such as WinZip or Gzip to compress the CCDE data file prior to submission.

It is necessary for each grantee to name their CCDE file using the following naming convention:

> YP -> Your Program's abbreviation (e.g. AL = Alabama)
> MM -> Month of submission due date, with leading zeroes (09 = September)
> YY   -> Year of submission due date (10 = 2010)
> VVV -> CCDE version number (100 = CCDE version 1.00)

For example, the compressed file that Alabama submits to IMS for the September 2010 submission will have the following name: AL0910100.zip or AL0910100.gz. The WinZip or Gzip file would contain an ASCII file called AL0910100.txt. Please do not include other files, such as the Submission Narrative or other supporting documents in the CCDE zip file. Those files should be submitted separately.

Updates and Corrections: For each CCDE submission, grantees are required to submit a cumulative data set through the screening cut-off date. Therefore, if any changes or updates to a particular record occur between CCDE submissions, these changes will be incorporated within the next CCDE data file.

CCDE Edits Program: IMS will develop an edits program for grantee use that should be used to evaluate the CCDE data file prior to each CCDE submission. The edits program will perform basic validation routines and report on invalid values, missing fields, and cross-field edits. The edits program and further instructions on its use will be provided via the www.CRCCP.org Web site.

Submission Narrative: A Submission Narrative should be provided with each data submission. CCDE data are regularly reviewed by the CDC, IMS, and grantee staff. Often questions arise from these reviews, and sometimes these questions lead to modifications to the CCDE data and/or its processing. The Submission Narrative provides a structured way for grantees to report responses to these questions or to report the details of data modifications.

The Submission Narrative has two sections. Section I is where responses to Action Items (written questions from the CDC and IMS based on a data review conference call) are provided. Section II is comprised of five standard questions that require grantees to do a prospective review of their CCDE data prior to submitting it to IMS. A hard copy of the CCDE Submission Narrative Guidelines can also be located in Appendix A.   An electronic copy may be found on the www.CRCCP.org Web site. A response to each of the five standard questions is required in the Submission Narrative, even if that response is "N/A - Not applicable". It is expected that

grantees should have the capability to review and manage their data, and should not rely solely on the CCDE submission feedback provided by CDC and IMS.

Submission Narrative Standards: The narrative file should be created in *.doc or *.pdf format and submitted using the following naming convention:

> *YPMMYY-NARRATIVE*
>
> YP = Your Program's abbreviation (e.g. AL = Alabama)
> MM = Month of submission due date, with leading zeroes (09 = September)
> YY = Year of submission due date (10 = 2010)

For example, the submission narrative file that Alabama submits to IMS in *.doc format for the September 2010 CCDE submission will have the following name: AL0910-narrative.doc. The narrative file should be submitted separately from the CCDE data zip file.

IMS and the CCDEs: Once these CCDE data are received at IMS they are reviewed and validated.   Using SAS, listings and printouts of sample records for each grantee are produced to check data quality. A SAS analysis file is created that attempts to clean up invalid data and eliminate duplicate screening results. A series of reports are then generated to assess the completeness and accuracy of these data, as well as to document the percentage of abnormal screening results that have complete diagnostic and treatment data. These data are assessed to determine progress in meeting program goals.

Semi-annual CCDE Data Submission Process

Grantees

CCDE file (Cumulative data)

There are six steps in the CCDE Submission Process that repeat semi-annually:

CCDE Submission Process

Semi-annual Timeline · Export · IMS www.crccp.org Web site · Validation and Analysis · Steps · National and Grantee Specific Reports · Submission Narrative · Reports, data reviews, and conference calls with CDC/IMS

March	**September**	**Grantee programs prepare and submit a CCDE file** and Submission Narrative on March 15 and September 15.
May	**November**	**IMS creates an analysis file** that is provided to the CDC, within a specified time frame, for review and approval.
June	**December**	**IMS generates feedback reports** which are reviewed and posted to the www.crccp.org Web site within a specified time frame.
July	**January**	CCDE **Data Review Calls are held** within approximately one month of the posting of the feedback reports. Data Notes, prepared by the IMS Technical Consultant, are posted three business days in advance of the scheduled call.
July	**January**	The **IMS Clinical Data Consultant sends Action Items** requiring investigation or response to the Program Consultant and the Grantee within 5 business days after a data call. The CDC Program Consultant communicates a summary of the data review in a letter to the Grantee.
August	**February**	The **Grantee investigates Action Items** and completes responses in Sections I and II of the Submission Narrative and submits to IMS with the next CCDE submission.

Software Selection: Each grantee needs to identify computer software to use for data management. The decision must balance the unique needs of the program, the cost of developing an in-house system, as well as the suitability of available software. CDC provides an optional use database management system called Cancer Screening and Tracking (CaST) System, developed to track clients screened for cancer and to generate the data items required for CCDE reporting. Other options include developing a custom in-house system, adding to an existing health system in your Program, or purchasing software from vendors that have developed other CRCCP systems.

If at any time a grantee chooses to convert their existing data system to a different software package, please notify your CDC Program Consultant and IMS Clinical Data Consultant of your plans and timeline. It is also strongly recommended that a test data submission be sent to IMS for review once the conversion process is completed and validated. Grantees should wait for feedback on the test data submission prior to implementation of the new data system. The test submission should be done well in advance of a CCDE submission due date. The IMS Clinical Data Consultant should be notified prior to sending the test data file.

Similarly, it is strongly recommended that revised data collection forms should be sent to CDC and IMS for data management and clinical review before your program finalizes and implements the forms.

CHAPTER 2

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.

  The www.crccp.org Web site contains documentation of the revisions made between the draft CCDE data set and the final version of the 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.

Section 11: Registry Information for Cancer/High Grade Dysplasia
This section collects staging information obtained after linking with the central cancer registry for diagnoses of cancer and high grade dysplasia.

Section 12: Record Information
This section includes the CCDE version for data reported and an end of record mark.

Race and Hispanic Origin

Federal Programs are required to use standards defined by the U.S. Office of Management and Budget (OMB) for the classification of race and ethnicity data. Additional information is available on the OMB Web site at http://www.whitehouse.gov/omb.

The race codes collected in the CCDEs model those required by the OMB. However, grantees may expand these categories during data collection to include racial subgroups that are represented in the local population if they choose. For example, a grantee may be established in an ethnic neighborhood where the clients may not feel that the CCDE category of 'White' is appropriate. In this instance, expanding the category to include 'Egyptian' or 'Israeli' may promote a more complete collection of race information. In these instances, the data system would then collapse these categories into 'White' prior to the CCDE submission to the CDC.

The same would hold true for the collection of Hispanic or Latino origin. If a grantee finds that the Race fields are frequently left blank when Hispanic or Latino origin is reported as "Yes", then it may be more advantageous to expand the Race categories to include 'White – Hispanic', 'White – Non-Hispanic', etc. These categories could then be expanded to report Hispanic Origin and Race prior to the CCDE submission to the CDC.

An expanded list of the CDC Race and Ethnicity Code Set is included in Appendix B to assist grantees in collapsing more specific race concepts into the standard race code set.

Unique Client Identifier

The client identification number used in the CCDEs must be unique and consistent throughout the entire data system. It is important, for program purposes, to be able to track clients over time. A client identification number which is unique only to a clinic is not acceptable because it cannot track a client between clinics. Grantees may not have the capability to assign the same unique identifier to a client who changes clinics. In these programs, matching is routinely done to identify the relatively small number of clients who change clinics. Matching can be done using date of birth, name (first, last, and maiden), and Social Security Number. Using a combination of these items assures a greater number of accurate matches.

Completely numeric identifiers are preferred; however, the CCDEs allow the use of alpha-numeric client identifiers, if necessary. Confidentiality is of the utmost importance. The CDC does not want an identification number that could be used to link the CCDEs to other databases. While a Social Security Number could be used, you must encode it prior to submission to the CDC.   See the item description on Client ID for encoding procedures.

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 7 and columns 8 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: <u>004</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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:

Procedure	Before/After
Nines-complement of digits 2,4,8,9	1**2**3-**4**5-67**89** **/** 1**7**3-**5**5-67**10**
Rotate left - digits 1,3,5,6	**1**7**3**-5**5**-**6**710 / **3**7**5**-5**6**-**1**710
Rotate right - digits 2,3,8,9	3**75**-56-17**10** **/** 3**07**-66-17**51**

EXAMPLE: Client identifier is 001000002357901: 001000002357901

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>05011953</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

ITEM NO / NAME: **2.2: Gender**

PURPOSE: To specify the gender self-reported 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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>3</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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.

                   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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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. 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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> = 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 pre-cancerous 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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>2</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> = 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 <u>not</u> = 3 (Diagnostic). If the first test to be provided is a DCBE, then the Indication for test 1 should <u>not</u> = 1 (Screening).

EXAMPLE: If the purpose of the first test provided is for screening: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> = 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: <u>3</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.01	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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": <u>3</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>virtual colonoscopy</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>5</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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.

CONTENTS: 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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>2</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.01	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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).

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 clients "cycle": 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>virtual colonoscopy</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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:

CCDE version	Date of revision	Type of revision
1.01	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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": <u>3</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>virtual colonoscopy</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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.

Chapter 2 – CCDE Field Descriptions

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.01	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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:
   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

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: <u>11</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

The following table was designed to assist grantees in mapping specific ICD-O morphology codes to the CCDE Histology categories.

CCDE Colorectal Histology Categories	International Classification of Disease for Oncology, 3rd Edition, Acceptable Morphology Codes and Terminology from Common Codes
1=Normal or other non-polyp histology	**n/a**
2=Non-adenomatous polyp (inflammatory, hamartomatous, etc.)	**n/a**
3=Hyperplastic polyp	**n/a**
4=Adenoma, NOS (no high-grade dysplasia noted)	**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)*
	8140/0 Adenoma, NOS 8210/0 Adenomatous polyp, NOS 8212/0 Flat adenoma 8220/0 Adenomatous polyposis coli 8221/0 Multiple adenomatous polyps
5=Adenoma, tubular (no high-grade dysplasia noted)	**8211** *(with behavior code of /0)*
	8211/0 Tubular adenoma, NOS
6=Adenoma, mixed tubular villous (no high-grade dysplasia noted)	**8263** *(with behavior code of /0)*
	8263/0 Tubulovillous adenoma, NOS
7=Adenoma, villous (no high-grade dysplasia noted)	**8261** *(with behavior code of /0)*
	8261/0 Villous adenoma, NOS
8=Adenoma, serrated (no high-grade dysplasia noted)	**8213** *(with behavior code of /0)*
	8213/0 Serrated adenoma
9=Adenoma with high-grade dysplasia (includes in situ carcinoma)	**8140-8147, 8160-8162, 8180-8221, 8250-8506, 8520-8550, 8560, 8570-8573, 8940-8941** *(with behavior codes of /2)*
	8140/2 Adenocarcinoma in situ, NOS 8210/2 Adenocarcinoma in situ in adenomatous polyp 8261/2 Adenocarcinoma in situ in villous adenoma 8263/2 Adenocarcinoma in situ in tubulovillous adenoma
10=Adenocarcinoma, invasive	**8140-8147, 8160-8162, 8180-8221, 8250-8506, 8510, 8520-8550, 8560, 8570-8573, 8940-8941** *(with behavior codes of /3)*
	8140/3 Adenocarcinoma, NOS 8141/3 Scirrhous adenocarcinoma 8210/3 Adenocarcinoma in adenomatous polyp
10=Adenocarcinoma, invasive (continued)	8211/3 Tubular adenocarcinoma

CCDE Colorectal Histology Categories	International Classification of Disease for Oncology, 3rd Edition, Acceptable Morphology Codes and Terminology from Common Codes	
	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: <u>08</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>2</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>11</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> = 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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>1</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> = 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: <u>24</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> = 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: <u>5</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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 <u>not</u> 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: <u>12152010</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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, 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.

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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.

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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": <u>3</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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).

CONTENTS: Valid values for CS-derived AJCC stage include: 000, 010, 020, 100, 110, 120, 130, 140, 121, 150, 160, 170, 151, 180, 190, 230, 240, 200, 210, 220, 300, 310, 320, 321, 322, 323, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 500, 510, 520, 530, 540, 541, 542, 550, 560, 570, 580, 590, 600, 610, 620, 630, 700, 710, 720, 721, 722, 730, 740, 888, 900, 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 AJCC stage [NAACCR data item #3000] obtained from the cancer registry database.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>994</u>

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

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: <u>100</u>.

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	12/02/2009	Add new

CHAPTER 3

Registry Linkage

Included in this chapter are tables from the *SEER Program Coding and Staging Manual 2007* (http://seer.cancer.gov); and the *Collaborative Staging Manual and Coding Instructions, version 2.0,* jointly published by the American Joint Committee on Cancer (AJCC) and the U.S. Department of Health and Human Services (DHHS) (http://www.cancerstaging.org).

These cancer staging manuals provide detailed descriptions for the following items in the CCDEs. These tables should be referenced in order to ensure accurate reporting of these variables and their values:

- CCDE Item 11.03: Registry Histologic type
- CCDE Item 11.04: Registry behavior
- CCDE Item 11.05: Registry primary site
- CCDE Item 11.06: Registry CS-derived SS2000
- CCDE Item 11.07: Registry CS-derived AJCC stage group
- CCDE Item 11.08: Registry CS extension
- CCDE Item 11.09: Registry CS lymph nodes
- CCDE Item 11.10: Registry CS mets at diagnosis
- CCDE Item 11.11: Registry CS tumor size

CCDE Item 11.03: Registry Histologic Type and CCDE Item 11.04 Registry Behavior

Registry Histologic Type [NAACCR data item #522] and Behavior [NAACCR data item #523] are often reported together. For example, 'Adenocarcinoma in situ' may be reported as '8140/2', where '8140' is the Histologic type, and '2' is the behavior. For the purposes of this data user's manual, we will provide the International Classification of Disease (ICD) Histology codes (ICD-0-3) that are most commonly associated with colorectal cancer. **If Programs receive a Histology/Behavior combination that is not listed below, they should verify the value with their State Central Cancer Registry.** The Histology table will include the Histology and Behavior codes together in order to provide a more detailed description of each value.

11.04 Registry Behavior (alone)

Value	Description
0	Benign
1	Uncertain whether benign or malignant/Borderline malignancy
2	Carcinoma In Situ
3	Malignant

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
NEOPLASM	800	8000/3	Neoplasm, malignant
		8001/3	Tumor cells, malignant
		8002/3	Malignant tumor, small cell type
		8003/3	Malignant tumor, giant cell type
		8004/3	Malignant tumor, spindle cell type
		8005/3	Malignant tumor, clear cell type
CARCINOMA, NOS	801	8010/2	Carcinoma in situ, NOS
		8010/3	Carcinoma, NOS
		8011/3	Epithelioma, malignant
		8012/3	Large cell carcinoma, NOS
		8013/3	Large cell neuroendocrine carcinoma
		8014/3	Large cell carcinoma with rhabdoid phenotype
		8015/3	Glassy cell carcinoma
CARCINOMA, UNDIFF., NOS	802	8020/3	Carcinoma, undifferentiated type, NOS
		8021/3	Carcinoma, anaplastic type, NOS
		8022/3	Pleomorphic carcinoma
GIANT & SPINDLE CELL CARCINOMA	803	8030/3	Giant cell and spindle cell carcinoma
		8031/3	Giant cell carcinoma
		8032/3	Spindle cell carcinoma
		8033/3	Pseudosarcomatous carcinoma
		8034/3	Polygonal cell carcinoma
		8035/3	Carcinoma with osteoclast-like giant cells
SMALL CELL CARCINOMA, NOS	804	8041/3	Small cell carcinoma, NOS
		8043/3	Small cell carcinoma, fusiform cell
PAPILLARY CARCINOMA, NOS	805	8050/2	Papillary carcinoma in situ

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
		8050/3	Papillary carcinoma, NOS
		8051/3	Verrucous carcinoma, NOS
		8052/2	Papillary squamous cell carcinoma, non-invasive
		8052/3	Papillary squamous cell carcinoma
SQUAMOUS CELL CARCINOMA, NOS	807	8070/2	Squamous cell carcinoma in situ, NOS
		8070/3	Squamous cell carcinoma, NOS
		8071/3	Sq. cell carcinoma, keratinizing, NOS
		8072/3	Sq. cell carcinoma, lg. cell, non-ker.
		8073/3	Sq. cell carcinoma, sm. cell, non-ker.
		8074/3	Sq. cell carcinoma, spindle cell
		8075/3	Squamous cell carcinoma, adenoid
		8076/2	Sq. cell carc. in situ with question. stromal invas.
		8076/3	Sq. cell carcinoma, micro-invasive
		8078/3	Squamous cell carcinoma with horn formation
TRANSITIONAL CELL CARCINOMA, NOS	812	8120/2	Transitional cell carcinoma in situ
		8120/3	Transitional cell carcinoma, NOS
		8121/3	Schneiderian carcinoma
		8122/3	Trans. cell carcinoma, spindle cell
		8123/3	Basaloid carcinoma
		8124/3	Cloacogenic carcinoma
ADENOCARCINOMA, NOS	814	8140/2	Adenocarcinoma in situ
		8140/3	Adenocarcinoma, NOS
		8141/3	Scirrhous adenocarcinoma

ADENOCARCINOMA, NOS (cont'd)	814	8143/3	Superficial spreading adenocarcinoma
		8145/3	Carcinoma, diffuse type

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
		8147/3	Basal cell adenocarcinoma
ADENOCA. IN ADENOMA. POLYP	821	8210/2	Adenocarcinoma in situ in adenomatous polyp
		8210/3	Adenocarcinoma in adenomatous polyp
		8211/3	Tubular adenocarcinoma
ADENOCA IN FAMIL POLYP COLI	822	8220/2	Adenocarcinoma in situ in familial polyp. coli
		8220/3	Adenocarcinoma in adenoma. polyposis coli
		8221/2	Adenocarc. in situ in mult. adenomatous polyps
		8221/3	Adenocarcinoma in mult. adenomatous polyps
SOLID CARCINOMA, NOS	823	8230/2	Duct carcinoma in situ, solid type
		8230/3	Solid carcinoma, NOS
		8231/3	Carcinoma simplex
CARCINOID TUMOR, MALIGNANT	824	8240/3	Carcinoid tumor, malignant
		8241/3	Enterochromaffin cell carcinoid
		8242/3	Enterochromaffin-like cell tumor, malignant
		8243/3	Goblet cell carcinoid
		8244/3	Composite carcinoid
		8245/3	Adenocarcinoid tumor
		8246/3	Neuroendocrine carcinoma
		8249/3	Atypical carcinoid tumor
BRONCHIOLO-ALVEOLAR ADENOCA.	825	8255/3	Adenocarcinoma with mixed subtypes
PAPILLARY ADENOCARCINOMA, NOS	826	8260/3	Papillary adenocarcinoma, NOS
		8261/2	Adenocarcinoma in situ in villous adenoma
		8261/3	Adenocarcinoma in villous adenoma
		8262/3	Villous adenocarcinoma
PAPILLARY ADENOCARCINOMA, NOS	826	8263/2	Adenocarcinoma in situ in tubulovillous adenoma
		8263/3	Adenocarcinoma in tubulovillous adenoma
MUCOEPIDERMOID CARCINOMA	843	8430/3	Mucoepidermoid carcinoma

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
CYSTADENOCARCINOMA, NOS	844	8440/3	Cystadenocarcinoma, NOS
MUCINOUS ADENOCARCINOMA	848	8480/3	Mucinous adenocarcinoma
		8481/3	Mucin-producing adenocarcinoma
SIGNET RING CELL CARCINOMA	849	8490/3	Signet ring cell carcinoma
MEDULLARY CARCINOMA, NOS	851	8510/3	Medullary carcinoma, NOS
ACINAR CELL CARCINOMA	855	8550/3	Acinar cell carcinoma
		8551/3	Acinar cell cystadenocarcinoma
ADENOSQUAMOUS CARCINOMA	856	8560/3	Adenosquamous carcinoma
		8562/3	Epithelial-myoepithelial carcinoma
ADENOCA. WITH METAPLASIA	857	8570/3	Adenocarcinoma with squamous metaplasia
		8571/3	Adenocarcinoma w cartilag. & oss. metaplas.
		8572/3	Adenocarcinoma with spindle cell mataplasia
		8573/3	Adenocarcinoma with apocrine metaplasia
		8574/3	Adenocarcinoma with neuroendocrine differen.
		8575/3	Metaplastic carcinoma, NOS
		8576/3	Hepatoid adenocarcinoma
NEVI & MELANOMAS	872	8720/2	Melanoma in situ
		8720/3	Malignant melanoma, NOS
		8721/3	Nodular melanoma
		8722/3	Balloon cell melanoma
		8723/3	Malignant melanoma, regressing
AMELANOTIC MELANOMA	873	8730/3	Amelanotic melanoma
MAL. MEL. IN JUNCT. NEVUS	874	8743/3	Superficial spreading melanoma
		8745/3	Desmoplastic melanoma, malignant
		8746/3	Mucosal lentiginous melanoma
MAL. MELAN. IN GIANT PIGMT. NEVUS	876	8761/3	Mal. melanoma in giant pigmented nevus

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
EPITHELIOID CELL MELANOMA	877	8770/3	Mixed epithel. & spindle cell melanoma
		8771/3	Epithelioid cell melanoma
		8772/3	Spindle cell melanoma, NOS
SARCOMA, NOS	880	8800/3	Sarcoma, NOS
		8801/3	Spindle cell sarcoma
		8802/3	Giant cell sarcoma
		8803/3	Small cell sarcoma
		8804/3	Epithelioid sarcoma
		8805/3	Undifferentiated sarcoma
		8806/3	Desmoplastic small round cell tumor
FIBROMATOUS NEOPLASMS	881	8810/3	Fibrosarcoma, NOS
		8811/3	Fibromyxosarcoma
		8813/3	Fascial fibrosarcoma
		8814/3	Infantile fibrosarcoma
		8815/3	Solitary fibrous tumor, malignant
LIPOSARCOMA NEOPLASMS	885	8850/3	Liposarcoma, NOS
		8851/3	Liposarcoma, well differentiated
		8852/3	Myxoid liposarcoma
		8853/3	Round cell liposarcoma
		8854/3	Pleomorphic liposarcoma

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
LIPOSARCOMA NEOPLASMS (cont'd)	885	8855/3	Mixed type liposarcoma
		8857/3	Fibroblastic liposarcoma
		8858/3	Dedifferentiated liposarcoma
MYOMATOUS NEOPLASMS	889	8890/3	Leiomyosarcoma, NOS
		8891/3	Epithelioid leiomyosarcoma

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
		8894/3	Angiomyosarcoma
		8895/3	Myosarcoma
		8896/3	Myxoid leiomyosarcoma
STROMAL SARCOMA	893	8934/3	Carcinofibroma
		8935/3	Stromal sarcoma, NOS
		8936/3	Gastrointestinal stromal sarcoma
CARCINOSARCOMA, NOS	898	8980/3	Carcinosarcoma, NOS
		8981/3	Carcinosarcoma, embryonal type
		8982/3	Malignant myoepithelioma
MALIGNANT LYMPHOMA, NOS	959	9590/3	Malignant lymphoma, NOS
		9591/3	Malignant lymphoma, non-Hodgkin
		9596/3	Composite Hodgkin and non-Hodgkin lymphoma
HODGKIN LYMPHOMA	965	9650/3	Hodgkin lymphoma, NOS
		9651/3	Hodgkin lymphoma, lymphocyte-rich
		9652/3	Hodgkin lymphoma, mixed cellularity, NOS
		9653/3	Hodgkin lymphoma, lymphocytic deplet., NOS
		9654/3	Hodgkin lymphoma, lymphocytic deplet., diffuse fibrosis
		9655/3	Hodgkin lymphoma, lymphocyt. deplet., reticular
		9659/3	Hodgkin lymph., nodular lymphocyte predom.

HODGKIN LYMPHOMA, NOD. SCLER.	966	9661/3	Hodgkin granuloma [obs]
		9662/3	Hodgkin sarcoma [obs]
		9663/3	Hodgkin lymphoma, nodular sclerosis, NOS
		9664/3	Hodgkin lymphoma, nod. scler., cellular phase
		9665/3	Hodgkin lymphoma, nod. scler., grade 1
		9667/3	Hodgkin lymphoma, nod. scler., grade 2

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
ML, SMALL B-CELL LYMPHOCYTIC	967	9670/3	ML, small B lymphocytic, NOS
		9671/3	ML, lymphoplasmacytic
		9673/3	Mantle cell lymphoma
		9675/3	ML, mixed sm. and lg. cell, diffuse
ML, LARGE B-CELL, DIFFUSE	968	9680/3	ML, large B-cell, diffuse
		9684/3	ML, large B-cell, diffuse, immunoblastic, NOS
		9687/3	Burkitt lymphoma, NOS
		9688/3	T-cell histiocyte rich large B-cell lymphoma
FOLLIC. & MARGINAL LYMPH, NOS	969	9690/3	Follicular lymphoma, NOS
		9691/3	Follicular lymphoma, grade 2
		9695/3	Follicular lymphoma, grade 1
		9698/3	Follicular lymphoma, grade 3
		9699/3	Marginal zone B-cell lymphoma, NOS
T-CELL LYMPHOMAS	970	9701/3	Sezary syndrome
		9702/3	Mature T-cell lymphoma, NOS
		9705/3	Angioimmunoblastic T-cell lymphoma
OTHER SPEC. NON-HODGKIN LYMPHOMA	971	9712/3	Intravascular large B-cell lymphoma
		9714/3	Anaplastic large cell lymphoma, T-cell and Null cell type
		9717/3	Intestinal T-cell lymphoma
OTHER SPEC. NON-HODGKIN LYMPHOMA	971	9719/3	NK/T-cell lymphoma, nasal and nasal-type
PRECURS. CELL LYMPHOBLASTIC LYMPH.	972	9724/3	SystemicEBV pos. T-cell lymphoproliferative disease of childhood
		9727/3	Precursor cell lymphoblastic lymphoma, NOS
		9728/3	Precursor B-cell lymphoblastic lymphoma
		9729/3	Precursor T-cell lymphoblastic lymphoma
PLASMA CELL TUMORS	973	9731/3	Plasmacytoma, NOS

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
		9734/3	Plasmacytoma, extramedullary
		9735/3	Plasmablastic lymphoma
		9737/3	ALK positive large B-cell lymphoma
		9738/3	Lrg B-cell lymphoma in HHV8-assoc. multicentric Castleman DZ
MAST CELL TUMORS	974	9740/3	Mast cell sarcoma
		9741/3	Malignant mastocytosis
NEOPLASMS OF HISTIOCYTES AND ACCESSORY LYMPHOID CELLS	975	9750/3	Malignant histiocytosis
		9751/3	Langerhans cell histiocytosis, NOS
		9754/3	Langerhans cell histiocytosis, disseminated
		9755/3	Histiocytic sarcoma
		9756/3	Langerhans cell sarcoma
NEOPLASMS OF HISTIOCYTES AND ACCESSORY LYMPHOID CELLS (cont'd)		9757/3	Interdigitating dendritic cell sarcoma
		9758/3	Follicular dendritic cell sarcoma
		9759/3	Fibroblastic reticular cell tumor
PRECURSOR LYMPHOID NEOPLASMS	981	9811/3	B lymphoblastic leukemia/lymphoma, NOS
		9812/3	Leukemia/lymphoma with t(9;22)(q34;q11.2);BCR-ABL1
		9813/3	Leukemia/lymphoma with t(v;11q23);MLL rearranged
PRECURSOR LYMPHOID NEOPLASMS	981	9814/3	Leukemia/lymphoma with t(12;21)(p13;q22);TEL-AML1(ETV6-RUNX1)
		9815/3	B lymphoblastic leukemia/lymphoma with hyperdiploidy
		9816/3	Leukemia/lymphoma with hypodiploidy (hypodiploid ALL)
		9817/3	B lymphblastic leukemia/lymphoma with t(5;14) (q31;q32);IL3-IGH

11.03 Registry Histologic Type (with behavior codes included)

Histology Description	Histology	Histology/ Behavior	Histology/Behavior Description
		9818/3	Leukemia/lymphoma with t(1;19)(q23;p13.3); E2A PBX1 (TCF3 PBX1)
PROLYMPH/PRECURS LEUKEMIA	983	9831/3	T-cell large granular lymphocytic leukemia
		9837/3	T lymphoblastic leukemia/lymphoma
CHRONIC MYELOPROLIFERATIVE DIS.	996	9965/3	Myeloid and lymphoid neoplasms with PDGFRB rearrangement
		9967/3	Myeloid and lymphoid neoplasm with FGFR1 abnormalities
MYELOPLASTIC/MYELOPROLIF. NEOPLASMS	997	9971/3	Polymorphic PTLD
		9975/3	Myelodysplastic/Myeloproliferative neoplasm, unclassifiable

CCDE Item 11.05: Registry primary site

Primary site [NAACCR data item #400] obtained from the central cancer registry database. See the SEER Program Coding and Staging Manual at http://seer.cancer.gov.

C000 = External upper lip
C001 = External lower lip
C002 = External lip, NOS
C003 = Mucosa of upper lip
C004 = Mucosa of lower lip
C005 = Mucosa of lip, NOS
C006 = Commissure of lip
C008 = Overlapping lesion of lip
C009 = Lip, NOS
C019 = Base of tongue, NOS
C020 = Dorsal surface of tongue, NOS
C021 = Border of tongue
C022 = Ventral surface of tongue, NOS
C023 = Anterior 2/3 of tongue, NOS
C024 = Lingual tonsil
C028 = Overlapping lesion of tongue
C029 = Tongue, NOS
C030 = Upper gum
C031 = Lower gum
C039 = Gum, NOS
C040 = Anterior floor of mouth
C041 = Lateral floor of mouth
C048 = Overlapping of floor of mouth
C049 = Floor of mouth, NOS
C050 = Hard palate
C051 = Soft palate, NOS
C052 = Uvula
C058 = Overlapping lesion of palate
C059 = Palate, NOS
C060 = Cheek mucosa
C061 = Vestibule of mouth
C062 = Retromolar area
C068 = Overlapping of other mouth
C069 = Mouth, NOS
C079 = Parotid gland
C080 = Submandibular gland
C081 = Sublingual gland
C088 = Overlapping maj salivary glands
C089 = Major salivary gland, NOS
C090 = Tonsillar fossa
C091 = Tonsillar pillar

C098 = Overlapping lesion of tonsil
C099 = Tonsil, NOS
C100 = Vallecula
C101 = Anterior surface of epiglottis
C102 = Lateral wall of oropharynx
C103 = Posterior wall of oropharynx
C104 = Branchial cleft
C108 = Overlapping of oropharynx
C109 = Oropharynx, NOS
C110 = Superior wall of nasopharynx
C111 = Posterior wall of nasopharynx
C112 = Lateral wall of nasopharynx
C113 = Anterior wall of nasopharynx
C118 = Overlapping of nasopharynx
C119 = Nasopharynx, NOS
C129 = Pyriform sinus
C130 = Postcricoid region
C131 = Aryepiglottic fold, hypophar.
C132 = Posterior wall of hypopharynx
C138 = Overlapping of hypopharynx
C139 = Hypopharynx, NOS
C140 = Pharynx, NOS
C142 = Waldeyer's ring
C148 = Overlap of pharynx, etc.
C150 = Cervical esophagus
C151 = Thoracic esophagus
C152 = Abdominal esophagus
C153 = Upper third of esophagus
C154 = Middle third of esophagus
C155 = Lower third of esophagus
C158 = Overlapping lesion of esophagus
C159 = Esophagus, NOS
C160 = Cardia, NOS
C161 = Fundus of stomach
C162 = Body of stomach
C163 = Gastric antrum
C164 = Pylorus
C165 = Lesser curvature stomach NOS
C166 = Greater curvature stomach NOS
C168 = Overlapping lesion of stomach
C169 = Stomach, NOS

C170 = Duodenum
C171 = Jejunum
C172 = Ileum
C173 = Meckel's diverticulum
C178 = Overlapping of small intestine
C179 = Small intestine, NOS
C180 = Cecum
C181 = Appendix
C182 = Ascending colon
C183 = Hepatic flexure of colon
C184 = Transverse colon
C185 = Splenic flexure of colon
C186 = Descending colon
C187 = Sigmoid colon
C188 = Overlapping of colon
C189 = Colon, NOS
C199 = Rectosigmoid junction
C209 = Rectum, NOS
C210 = Anus, NOS
C211 = Anal canal
C212 = Cloacogenic zone
C218 = Overlap of rectum, anus, etc.
C220 = Liver
C221 = Intrahepatic bile duct
C239 = Gallbladder
C240 = Extrahepatic bile duct
C241 = Ampulla of Vater
C248 = Overlapping of biliary tract
C249 = Biliary tract, NOS
C250 = Head of pancreas
C251 = Body of pancreas
C252 = Tail of pancreas
C253 = Pancreatic duct
C254 = Islets of Langerhans
C257 = Other spec pancreas
C258 = Overlapping of pancreas
C259 = Pancreas, NOS
C260 = Intestinal tract, NOS
C268 = Overlapping of digestive system
C269 = Gastrointestinal tract, NOS
C300 = Nasal cavity
C301 = Middle ear
C310 = Maxillary sinus
C311 = Ethmoid sinus
C312 = Frontal sinus
C313 = Sphenoid sinus

C318 = Overlap of accessory sinuses
C319 = Accessory sinus, NOS
C320 = Glottis
C321 = Supraglottis
C322 = Subglottis
C323 = Laryngeal cartilage
C328 = Overlapping of larynx
C329 = Larynx, NOS
C339 = Trachea
C340 = Main bronchus
C341 = Upper lobe, lung
C342 = Middle lobe, lung
C343 = Lower lobe, lung
C348 = Overlapping of lung
C349 = Lung, NOS
C379 = Thymus
C380 = Heart
C381 = Anterior mediastinum
C382 = Posterior mediastinum
C383 = Mediastinum, NOS
C384 = Pleura, NOS
C388 = Ovr. heart, mediastinum, pleura
C390 = Upper respiratory tract, NOS
C398 = Overlap of respiratory system
C399 = Ill-defined sites of resp sys
C400 = Long bones: upper limb, scapula
C401 = Short bones: upper limb
C402 = Long bones: lower limb
C403 = Short bones: lower limb
C408 = Overlap of bones, etc. of limbs
C409 = Bone of limb, NOS
C410 = Bones of skull and face
C411 = Mandible
C412 = Vertebral column
C413 = Rib, Sternum, Clavicle
C414 = Pelvic bones, Sacrum, Coccyx
C418 = Overlap bones, etc.
C419 = Bone, NOS
C420 = Blood
C421 = Bone marrow
C422 = Spleen
C423 = Reticuloendothelial system, NOS
C424 = Hematopoietic system, NOS
C440 = Skin of lip, NOS
C441 = Eyelid
C442 = External ear

C443 = Skin other/unspec parts of face
C444 = Skin of scalp and neck
C445 = Skin of trunk
C446 = Skin of upper limb and shoulder
C447 = Skin of lower limb and hip
C448 = Overlapping of skin
C449 = Skin, NOS
C470 = Periph nerves: head, face, neck
C471 = Peri nerves: upr limb, shoulder
C472 = Periph nerves: lower limb, hip
C473 = Periph nerves: thorax
C474 = Periph nerves: abdomen
C475 = Periph nerves: pelvis
C476 = Periph nerves: trunk, NOS
C478 = Overlap of peripheral nerves
C479 = Autonomic nervous system, NOS
C480 = Retroperitoneum
C481 = Specified parts of peritoneum
C482 = Peritoneum, NOS
C488 = Overlap retroper & peritoneum
C490 = Conn tissues: head, face, neck
C491 = Conn tissues: upr limb, shoulder
C492 = Conn tissues: lower limb, hip
C493 = Conn tissues: thorax
C494 = Conn tissues: abdomen
C495 = Conn tissues: pelvis
C496 = Conn tissues: trunk, NOS
C498 = Overlapping conn tissues
C499 = Conn tissues, NOS
C500 = Nipple
C501 = Central portion of breast
C502 = Upper-inner quadrant of breast
C503 = Lower-inner quadrant of breast
C504 = Upper-outer quadrant of breast
C505 = Lower-outer quadrant of breast
C506 = Axillary tail of breast
C508 = Overlapping of breast
C509 = Breast, NOS
C510 = Labium majus
C511 = Labium minus
C512 = Clitoris
C518 = Overlapping of vulva
C519 = Vulva, NOS
C529 = Vagina, NOS
C530 = Endocervix
C531 = Exocervix

C538 = Overlapping of cervix uteri
C539 = Cervix uteri
C540 = Isthmus uteri
C541 = Endometrium
C542 = Myometrium
C543 = Fundus uteri
C548 = Overlapping of corpus uteri
C549 = Corpus uteri
C559 = Uterus, NOS
C569 = Ovary
C570 = Fallopian tube
C571 = Broad ligament
C572 = Round ligament
C573 = Parametrium
C574 = Uterine adnexa
C577 = Other spec fem genital organs
C578 = Overlap of fem genital organs
C579 = Female genital tract, NOS
C589 = Placenta
C600 = Prepuce
C601 = Glans penis
C602 = Body of penis
C608 = Overlapping of penis
C609 = Penis, NOS
C619 = Prostate gland
C620 = Undescended testis
C621 = Descended testis
C629 = Testis, NOS
C630 = Epididymis
C631 = Spermatic cord
C632 = Scrotum, NOS
C637 = Other spec male genital organs
C638 = Overlap male genital organs
C639 = Male genital organs, NOS
C649 = Kidney, NOS
C659 = Renal pelvis
C669 = Ureter
C670 = Trigone of bladder
C671 = Dome of bladder
C672 = Lateral wall of bladder
C673 = Anterior wall of bladder
C674 = Posterior wall of bladder
C675 = Bladder neck
C676 = Ureteric orifice
C677 = Urachus
C678 = Overlapping of bladder

C679 = Bladder, NOS
C680 = Urethra
C681 = Paraurethral gland
C688 = Overlapping of urinary organs
C689 = Urinary system, NOS
C690 = Conjunctiva
C691 = Cornea, NOS
C692 = Retina
C693 = Choroid
C694 = Ciliary body
C695 = Lacrimal gland
C696 = Orbit, NOS
C698 = Overlapping of eye and adnexa
C699 = Eye, NOS
C700 = Cerebral meninges
C701 = Spinal meninges
C709 = Meninges, NOS
C710 = Cerebrum
C711 = Frontal lobe
C712 = Temporal lobe
C713 = Parietal lobe
C714 = Occipital lobe
C715 = Ventricle, NOS
C716 = Cerebellum, NOS
C717 = Brain stem
C718 = Overlapping of brain
C719 = Brain, NOS
C720 = Spinal cord
C721 = Cauda equina
C722 = Olfactory nerve
C723 = Optic nerve
C724 = Acoustic nerve

C725 = Cranial nerve, NOS
C728 = Overlap of brain & CNS
C729 = Nervous system, NOS
C739 = Thyroid gland
C740 = Cortex of adrenal gland
C741 = Medulla of adrenal gland
C749 = Adrenal gland, NOS
C750 = Parathyroid gland
C751 = Pituitary gland
C752 = Craniopharyngeal duct
C753 = Pineal gland
C754 = Carotid body
C755 = Aortic body & other paraganglia
C758 = Overlapping of endocrine glands
C759 = Endocrine gland, NOS
C760 = Head, face or neck, NOS
C761 = Thorax, NOS
C762 = Abdomen, NOS
C763 = Pelvis, NOS
C764 = Upper limb, NOS
C765 = Lower limb, NOS
C767 = Other ill-defined sites
C768 = Overlap of ill-defined sites
C770 = Lymph nodes: head, face & neck
C771 = Intrathoracic lymph nodes
C772 = Intra-abdominal lymph nodes
C773 = Lymph nodes of axilla or arm
C774 = Lymph nodes:inguinal region or leg
C775 = Pelvic lymph nodes
C778 = Lymph nodes of multiple regions
C779 = Lymph node, NOS
C809 = Unknown primary site

CCDE Item 11.06: Registry CS-derived SS2000

Collaborative stage (CS)-derived summary stage 2001 [NAACCR data item #3020] obtained from the central cancer registry database. See CS Staging Manual at http://www.cancerstaging.org and the SEER Summary Staging Manual at http://seer.cancer.gov .

Value	Description
0	In situ
1	Localized
2	Regional, direct extension
3	Regional, lymph nodes only
4	Regional, extension and nodes
5	Regional, NOS
7	Distant
8	Not applicable
9	Unknown/unstaged

CCDE Item 11.07: Registry CS-derived AJCC stage group

Collaborative stage (CS)-derived AJCC stage [NAACCR data item #3000] obtained from the central cancer registry database WHEN AVAILABLE.

Value	Description	Value	Description	Value	Description
000	Stage 0	322	Stage IIA1	590	Stage IIISB (lymphoma only)
010	Stage 0a	323	Stage IIA2	600	Stage IIIS (lymphoma only)
020	Stage 0is	330	Stage IIB	610	Stage IIIESA (lymphoma only)
100	Stage I	340	Stage IIC	620	Stage IIIESB (lymphoma only)
110	Stage I NOS	350	Stage IIEA (lymphoma only)	630	Stage IIIES (lymphoma only)
120	Stage IA	360	Stage IIEB (lymphoma only)	700	Stage IV
121	Stage IA NOS	370	Stage IIE (lymphoma only)	710	Stage IV NOS
130	Stage IA1	380	Stage IISA (lymphoma only)	720	Stage IVA
140	Stage IA2	390	Stage IISB (lymphoma only)	721	Stage IVA1
150	Stage IB	400	Stage IIS (lymphoma only)	722	Stage IVA2
151	Stage IB NOS	410	Stage IIESA (lymphoma only)	730	Stage IVB
160	Stage IB1	420	Stage IIESB (lymphoma only)	740	Stage IVC
170	Stage IB2	430	Stage IIES (lymphoma only)	888	Not applicable
180	Stage IC	500	Stage III	900	Stage Occult
190	Stage IS	510	Stage III NOS	999	Stage Unknown
230	Stage ISA (lymphoma only)	520	Stage IIIA		
240	Stage ISB (lymphoma only)	530	Stage IIIB		
200	Stage IEA (lymphoma only)	540	Stage IIIC		
210	Stage IEB (lymphoma only)	541	Stage IIIC1		
220	Stage IE (lymphoma only)	542	Stage IIIC2		
300	Stage II	550	Stage IIIEA (lymphoma only)		
310	Stage II NOS	560	Stage IIIEB (lymphoma only)		
320	Stage IIA	570	Stage IIIE (lymphoma only)		

CCDE Item 11.08: Registry CS extension

Collaborative stage (CS) extension [NAACCR data item #2810] obtained from the central cancer registry database. See CS Staging Manual at http://www.cancerstaging.org.

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
000	In situ; noninvasive; intraepithelial	In situ; noninvasive; intraepithelial	Tis	Tis	IS	IS
050	(Adeno)carcinoma in a polyp or adenoma, noninvasive	(Adeno)carcinoma in a polyp or adenoma, noninvasive	Tis	Tis	IS	IS
100	Invasive tumor confined to mucosa, NOS, including intramucosal, NOS	Invasive tumor confined to mucosa, NOS, including intramucosal, NOS	Tis	Tis	L	L
110	Lamina propria, including lamina propria in the stalk of a polyp	Lamina propria, including lamina propria in the stalk of a polyp	Tis	Tis	L	L
120	Confined to and not through the muscularis mucosae, including muscularis mucosae in the stalk of a polyp	Confined to and not through the muscularis mucosae, including muscularis mucosae in the stalk of a polyp	Tis	Tis	L	L
130	Confined to head of polyp, NOS	Confined to head of polyp, NOS	T1	T1	L	L
140	Confined to stalk of polyp, NOS	Confined to stalk of polyp, NOS	T1	T1	L	L
150	Invasive tumor in polyp, NOS	Invasive tumor in polyp, NOS	T1	T1	L	L
160	Invades submucosa (superficial invasion), including submucosa in the stalk of a polyp	Submucosa (superficial invasion), including submucosa in the stalk of a polyp	T1	T1	L	L
170	Stated as T1[NOS] with no other information on extension	Stated as T1[NOS] with no other information on extension	T1	T1	L	L

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
200	Muscularis propria invaded Stated as T2[NOS] with no other information on extension	Muscularis propria invaded Stated as T2[NOS] with no other information on extenision	T2	T2	L	L
300	Localized, NOS Confined to colon, NOS	Localized, NOS Confined to rectum, NOS	T1	T1	L	L
400	Extension through wall, NOS Invasion through muscularis propria or muscularis, NOS Non-peritonealized pericolic tissues invaded Perimuscular tissue invaded Subserosal tissue/(sub)serosal fat invaded Transmural, NOS	Extension through wall, NOS Invasion through muscularis propria or muscularis, NOS Perimuscular tissue invaded Subserosal tissue/(sub)serosal fat invaded Non-peritonealized pericolic tissues invaded Transmural, NOS	T3	T3	L	L
410	Stated as T2[NOS] with no other information on extension	Stated as T2[NOS] with no other information on extension	T3	T3	L	L
420	Fat, NOS	Fat, NOS	T3	T3	RE	RE

450	Extension to:
	   All colon sites:
	      Adjacent tissue(s), NOS
	      Connective tissue
	      Mesenteric fat
	      Mesentery
	      Mesocolon
	      Pericolic fat
	   Ascending and descending colon
	      Retroperitoneal fat
	   Transverse colon/flexures
	      Gastrocolic ligament
	      Greater omentum
		Adjacent (connective) tissue:
		   For all sites:
		      Perirectal fat
		   For rectosigmoid:
		      Mesentery (including mesenteric fat, mesocolon)
		      Pericolic fat
		   For rectum:
		      Extension to anus
		      Rectovaginal septum
			T3	T3	RE	RE

Chapter 3 – Registry Linkage

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
460	Adherent to other organs or structures, but no microscopic tumor found in adhesion(s)	Adherent to other organs or structures but no tumor found in adhesion(s)	T3	T3	RE	RE
490		Stated as T4[NOS] with no other information on extension	T4NOS	T4	RE	RE
500	Invasion of/through serosa (mesothelium) (visceral peritoneum)	Invasion of/through serosa (mesothelium) (visceral peritoneum)	T4a	T4	RE	RE
550	Any of [(420) to (450)] + (500)	(500) with [(420) or (450)]	T4a	T4	RE	RE
560	Stated as T4a with no other information on extension	Stated as T4a with no other information on extension	T4a	T4	RE	RE
570	Adherent to other organs or structures, NOS	Adherent to other organs or structures, NOS	T4b	T4	RE	RE

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000

600	All colon sites:
	   Small intestine
	Cecum and appendix:
	   Greater omentum
	Ascending colon:
	   Greater omentum
	   Liver, right lobe
	Transverse colon and flexures:
	   Gallbladder/bile ducts
	   Kidney
	   Liver
	   Pancreas
	   Spleen
	   Stomach
	Descending colon:
	   Greater omentum
	   Pelvic wall
	   Spleen
	Sigmoid colon:
	   Greater omentum
	   Pelvic wall
		Rectosigmoid:
		   Cul de sac (rectouterine pouch)
		   Pelvic wall
		   Small intestine
		Rectum:
		   Bladder for males only
		   Cul de sac (rectouterine pouch)
		   Ductus deferens
		   Pelvic wall
		   Prostate
		   Rectovesical fascia for male only
		   Seminal vesicle(s)
		   Skeletal muscle of pelvic floor
		   Vagina
			T4b	T4	RE	RE

650	All colon sites:
	   Abdominal wall
	   Retroperitoneum (excluding fat)
			T4b	T4	RE	RE

660	Ascending colon:
	   Right kidney
	   Right ureter
	Descending colon:
	   Left kidney
	   Left ureter
			T4b	T4	RE	RE

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000

700	Cecum, ascending, descending and sigmoid colon:
	    Fallopian tube
	    Ovary
	    Uterus
		Rectosigmoid:
		    Bladder
		    Colon via serosa
		    Fallopian tube(s)
		    Ovary(ies)
		    Prostate
		    Ureter(s)
		    Uterus
		Rectum:
		    Bladder for female only
		    Bone(s) of pelvis
		    Urethra
		    Uterus
			T4b	T4	D	D

750	All colon sites unless otherwise stated above:
	    Adrenal (suprarenal) gland
	    Bladder
	    Diaphragm
	    Fistula to skin
	    Gallbladder
	    Other segment(s) of colon via serosa
			T4b	T4	D	D

800	Further contiguous extension:
	    Cecum and appendix:
	        Kidney
	        Liver
	        Ureter
	    Transverse colon and flexures:
	        Ureter
	    Sigmoid colon:
	        Cul de sac (rectouterine pouch)
	        Ureter
	    Other contiguous extension
		Further contiguous extension	T4b	T4	D	D

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
850	Stated as T4b with no other information on extension	Stated as T4b with no other information on extension	T4b	T4	RE	RE
900	Stated as T4[NOS] with no other information on extension	Stated as T4[NOS] with no other information on extension	T4NOS	T4	RE	RE
950	No evidence of primary tumor	No evidence of primary tumor	T0	T0	U	U
999	Unknown extension Primary tumor cannot be assessed Not documented in patient record	Unknown extension Primary tumor cannot be assessed Not documented in patient record	TX	TX	U	U

CCDE Item 11.09: Registry CS lymph nodes

Collaborative stage (CS) lymph nodes [NAACCR data item #2830] obtained from the central cancer registry database.
See CS Staging Manual at http://www.cancerstaging.org.

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
000	None; no regional lymph node involvement	None; no regional lymph node involvement	N0	N0	None	None
050	Tumor deposit(s) in the subserosa, or non-peritonealized pericolic or perirectal tissues without regional nodal metastasis	Tumor deposit(s) in the subserosa, or non-peritonealized pericolic or perirectal tissues without regional nodal metastasis	N1c	N1	RN	RN

100	Regional lymph node(s) for all colon sites:
	    Colic (NOS)
	    Epicolic (adjacent to bowel wall)
	    Mesocolic (NOS)
	    Paracolic/pericolic
		Regional lymph node(s):
		Rectosigmoid:
		    Paracolic/pericolic
		    Perirectal
		    Rectal
		    Nodule(s) or foci in pericolic fat/adjacent mesentery/mesocolic fat
		Rectum:
		    Perirectal
		    Rectal, NOS
		    Nodule(s) or foci in perirectal fat
			^	*	RN	RN

200	Regional lymph node(s), for specific subsites:
	    Cecum:
	      Cecal: anterior (prececal), posterior (retrocecal); NOS
	      Ileocolic
	      Right colic
	    Ascending colon:
	      Ileocolic
	      Middle colic
	      Right colic
	    Transverse colon and flexures:
		Regional lymph node(s):
		Rectosigmoid:
		    Colic, NOS
		      Left colic
		    Hemorrhoidal, superior or middle
		    Inferior mesenteric
		    Middle rectal
		    Sigmoidal (sigmoid mesenteric)
		    Superior rectal
		Rectum:
		    Hemorrhoidal, superior, middle or inferior
			^	*	RN	RN

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000

	Inferior mesenteric for splenic flexure only
	Left colic for splenic flexure only
	Middle colic
	Right colic for hepatic flexure only
	Descending colon:
	   Inferior mesenteric
	   Left colic
	   Sigmoid
	Sigmoid colon:
	   Inferior mesenteric
	   Sigmoidal (sigmoid mesenteric)
	   Superior hemorrhoidal
	   Superior rectal
		Inferior mesenteric
		Internal iliac (hypogastric)
		   Obturator
		Rectal, superior, middle, or inferior
		Sacral, NOS
		   Lateral (laterosacral)
		   Middle (promontorial) (Gerota's node)
		   Presacral
		   Sacral promotory
		Sigmoidal (sigmoid mesenteric)				

300	Regional lymph node(s) for all colon sites:
	   Mesenteric, NOS
	   Regional lymph node(s), NOS
		Mesenteric, NOS
		Regional lymph node(s), NOS
			^	*	RN	RN

400	Stated as N1 pathologic	Stated as N1 pathologic	N1NOS	N1	RN	RN
410	Stated as N1a pathologic	Stated as N1a pathologic	N1a	N1	RN	RN
420	Stated as N1b pathologic	Stated as N1b pathologic	N1b	N1	RN	RN
450	Stated as N2 pathologic	Stated as N2 pathologic	N2NOS	N2	RN	RN
460	Stated as N2a pathologic	Stated as N2a pathologic	N2a	N2	RN	RN
470	Stated as N2b pathologic	Stated as N2b pathologic	N2b	N2	RN	RN
800	Lymph nodes, NOS	Lymph nodes, NOS	^	*	RN	RN
999	Unknown; not stated Regional lymph node(s) cannot be assessed	Unknown; not stated Regional lymph node(s) cannot be assessed	NX	NX	U	U

Chapter 3 – Registry Linkage

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
	Not documented in patient record	Not documented in patient record				

^ and * For codes 100-300 and 800 ONLY, please see collaborative stage manual for specific coding instructions.

CCDE Item 11.10: Registry CS mets at diagnosis

Collaborative stage (CS) metastases (mets) at diagnosis obtained from the central cancer registry database. North American Association of Central Cancer Registries (NAACCR) data item #2850. See the CS Staging Manual at http://www.cancerstaging.org .

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
00	No; none	No; none	M0	M0	None	None
05		Metastasis to a single distant lymph node chain, NOS	Ma1	M1	D	D
08	Cecum, ascending, hepatic flexure and transverse colon: Superior mesenteric lymph node(s) only		M1a	M1	RN	D
15	Metastasis to a single distant lymph node chain other than code 08 For all colon sites : Common iliac Distant lymph node(s), NOS External iliac Para-aortic Retroperitoneal For cecum, ascending colon, transverse colon, and hepatic flexure : Inferior mesenteric For splenic flexure, descending colon, and sigmoid colon : Superior mesenteric	Metastasis to a single distant lymph node chain Rectosigmoid : Internal iliac (hypogastric) Obturator	M1a	M1	D	D
20	Metastasis to a single distant organ	Metastasis to other single distant lymph node chains, including external iliac or common iliac	M1a	M1	D	D

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
22	Stated as M1a with no other information on distant metastases		M1a	M1	D	D
25	Metastasis to more than one distant lymph node chain other than code 08 For all colon sites : Common iliac Distant lymph node(s), NOS External iliac Para-aortic Retroperitoneal For cecum, ascending colon, transverse colon, and hepatic flexure : Inferior mesenteric Superior mesenteric For splenic flexure, descending colon, and sigmoid colon : Superior mesenteric	Metastasis to a single distant organ	M1b	M1	D	D
27		Stated as M1a, NOS	M1a	M1	D	D
30	Metastases to more than one distant organ Metastases to the peritoneum Carcinomatosis	Metastasis to more than one distant lymph node chain	M1b	M1	D	D
35	(08 or 15 or 25) PLUS 20 or 30) Distant lymph nodes plus other distant metastases	Distant metastases to more than one distant organ Metastases to the peritoneum Carcinomatosis Stated as M1b, NOS	M1b	M1	D	D
38	Stated as M1b with no other information on distant metastases		M1b	M1	D	D

Value	Description for Colon	Description for Rectum	TNM 7	TNM 6	SS77	SS2000
45		(05 or 15 or 20) plus (25 or 35) Distant lymph node(s) plus other distant metastases	M1b	M1	D	D
60	Distant metastasis, NOS Stated as M1[NOS] with no other information on distant metastases	Distant metastasis, NOS M1, NOS	N1NOS	M1	D	D
99	Unknown if distant metastasis Distant metastasis cannot be assessed Not documented in patient record	Unknown if distant metastasis Distant metastasis cannot be assessed Not documented in patient record	M0	MX	U	U

The following values for Colon are obsolete. They have been excluded from this table but will be considered valid responses if reported: 10, 40 and 50.

The following values for Rectum are obsolete. They have been excluded from this table, but will be considered valid responses if reported: 10, 11, 12, 40 and 50

CHAPTER 4

References

Appendix A

CCDE Submission
Narrative Guidelines

CCDE Submission Narrative Guidelines
January 1, 2010

The submission narrative provides a structured way for grantees to respond to questions or issues identified during the CCDE data review.

The submission narrative is comprised of two sections:

I. The first section should include written responses to any action items that were identified in the previous data submission. Following the review and discussion of the grantee's CCDE data file by the CDC Program Consultant, CDC Scientific Consultant and IMS Clinical Data Technical Consultant and grantee staff, an Action Plan will be developed. The CDC Program Consultant will provide this information to the appropriate staff at the program. Each action item should be addressed by the grantee in this first section.

II. The second section should address the following questions. If the question is not applicable to your program at this time, please indicate "N/A":

1. Summarize reasons for any significant data issues identified by the program but not resolved prior to submitting the CCDE file to the CDC.

2. Identify any modifications made to the software which generates the CCDE file that would cause significant changes in the distribution of the values for individual data items.

3. Identify any batch recoding of records in the CCDE file that would cause significant changes in the distribution of the values for individual data items.

4. Identify any data management staffing, system, or procedural changes that would affect the data management capacity. Examples of these include staff turnover, revision of data collection forms, revision of data entry screens, a change in the data collection model (i.e. centralized to decentralized), etc.

5. Identify any plans to significantly upgrade existing data management software, or to develop and migrate the client database to a new data management system.

SAMPLE
CCDE Submission Narrative for Your Program
September 2010 Submission

<u>Part 1. Action Item Responses</u>

<u>Standard Quality Indicator Guide (SQIG)</u>

Item 8:   There are several records where Status of Final Diagnosis = Complete, but the Final Diagnosis and Date of Final Diagnosis are missing.
RESPONSE: We used the CCDE Edit program to identify 20 records with incomplete data. These records were reviewed and corrected.

Item 10: The CDC provides a recommendation that at least 80% of clients should take less than 60 days from the beginning of screening until final diagnosis. Your program does not meet this recommendation. Please discuss causes for the delay between screening and diagnosis.
RESPONSE: While reviewing the cases we have discovered some reporting issues. At the time of submission, we continue to evaluate all the causes for the delay in timeliness. We will report on any findings as soon as possible.

<u>Part 2: Address the following questions:</u>

1. Summarize reasons for any significant data issues identified by the program but not resolved prior to submitting the CCDE file to the CDC.
Please see response to SQIG Item 10.

2. Identify any modifications made to the software which generates the CCDE file that would cause significant changes in the distribution of the values for individual data items.
Not applicable.

3. Identify any batch recoding of records in the CCDE file that would cause significant changes in the distribution of the values for individual data items.
We modified how our export program creates the record ID. The record ID has been changed for all records reported in this submission.

4.   Identify any data management staffing, system, or procedural changes that would affect the data management capacity.
Not applicable.

5. Identify any plans to significantly upgrade existing data management software, or to develop and migrate the client database to a new data management system.
Not applicable.

APPENDIX B

CDC RACE AND ETHNICITY CODE SET

TABLE 1 – RACE CONCEPTS AND CODES

CCDE CATEGORY	CONCEPT
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
	ARAB
2. Black or African American	BLACK
	AFRICAN AMERICAN
	AFRICAN (which may include:)
	Botswanan
	Ethiopian
	Liberian
	Namibian
	Nigerian
	Zairian
	Bahamian
	Barbadian
	Dominican
	Dominican Islander
	Haitian
	Jamaican

2. Black or African	

CCDE CATEGORY	CONCEPT
American (cont'd)	**Tobagoan**
	Trinidadian
	West Indian
3. Asian	**Asian Indian**
	Bangladeshi
	Bhutanese
	Burmese
	Cambodian
	Chinese
	Taiwanese
	Filipino
	Hmong
	Indonesian
	Japanese
	Korean
	Laotian
	Malaysian
	Okinawan
	Pakistani
	Sri Lankan
	Thai
	Vietnamese
	Iwo Jiman
	Maldivian
	Nepalese
	Singaporean
	Madagascar
4. Native Hawaiian or Other Pacific Islander	**POLYNESIAN (which may include:)**
	Native Hawaiian
	Samoan
	Tahitian
	Tongan
	Tokelauan
	MICRONESIAN (which may include:)
	Guamanian
	Chamorro
	Mariana Islander
	Marshallese
4. Native Hawaiian or	

CCDE CATEGORY	CONCEPT
Other Pacific Islander (Cont'd)	Palauan
	Carolinian
	Kosraean
	Pohnpeian
	Yapese
	Saipanese
	Kiribati
	Chuukese
	MELANESIAN (which may include:)
	Fijian
	Papua New Guinean
	Solomon Islander
	New Hebrides
	OTHER PACIFIC ISLANDER
5. American Indian or Alaskan Native	**AMERICAN INDIAN**
	CANADIAN AND LATIN AMERICAN INDIAN (which may include:)
	Canadian Indian
	Central American Indian
	French American Indian
	Mexican American Indian
	South American Indian
	Spanish American Indian
	ALASKAN NATIVE (which may include:)
	Alaskan Indian
	Inuit
	Aleut

TABLE 2 – ETHNICITY CONCEPTS AND CODES

CCDE CATEGORY	CONCEPT
Hispanic or Latino	**Spaniard**
	Mexican
	Central American
	South American
	Latin American
	Puerto Rican
	Cuban
	Dominican
Not Hispanic or Latino	

APPENDIX C

CCDE DATA DEFINITION TABLE

APPENDIX D

GLOSSARY OF TERMS

ACS:	http://www.cancer.org
Adenomatous polyp	See "Polyp". More likely to develop into cancer than a non-adenomatous polyp. Also known as "adenoma".
CDC CRCCP Home Page:	http://www.cdc.gov/cancer/crccp/
CO-RADS	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.
Colonoscope:	A flexible, lighted instrument with a built-in tiny camera used to view the inside of the entire colon and rectum.
Colonoscopy:	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.
Colorectal:	Related to the colon, rectum or both.
CRCCP Resource Web Site:	www.CRCCP.org
CS Coding Manual:	www.cancerstaging.org
Double-Contrast Barium Enema	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.
Fecal Immunochemical Test (FIT)	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.
Fecal Occult Blood Test (FOBT)	A guaiac based test to check for hidden blood in stool. Fecal refers to stool. Occult means hidden. Sometimes called "F.O.B.T.".

Flexible Sigmoidoscopy

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.

Gastroenterologist

A doctor who specializes in diagnosing and treating disorders of the digestive system (which includes the esophagus, stomach, pancreas, intestines, and liver).

Polyp

An abnormal, often precancerous growth of tissue (colorectal polyps are growths of tissue inside the intestine).

Rectum

The last 8 to 10 inches of the large intestine. The rectum stores solid waste until it leaves the body through the anus.

Screening Test

"Screening tests" 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 "diagnostic" test).

SEER Coding Manual:

www.seer.cancer.gov

Sigmoidoscope

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.

Stool DNA

A stool DNA test looks for traces of DNA (genetic material) shed by polyps and/or colorectal tumors.

Virtual Colonoscopy

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.