Colorectal Cancer Screening Demonstration Program

Funded by the Centers for Disease Control and Prevention

DATA USER'S MANUAL

for the

Colorectal Cancer Screening Demonstration Program

Version 1.01
April 2006

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention
and Health Promotion

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 Screening Demonstration Program (CRCSDP). This manual refers to the CRCSDP awardees as 'programs'. One goal of the manual is to provide the technical information necessary for the programs to produce the Colorectal Cancer Clinical Data Elements (CCDEs). Another goal is to highlight the technical assistance provided to the programs by the CDC and the data contractor, Information Management Services, Inc. (IMS). A common goal of the CDC and the programs 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 program staff responsible for the collection and aggregation of the CCDE data. It is divided into 7 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, detailed field descriptions, a listing of the aggregate data required for non-enrolled clients and information on reporting complications.

Chapter 3 **Data Quality Assessment**
This chapter describes a variety of ways to assess the quality of program data including computer listings and the CCDE Service Quality Indicators used by the CDC for evaluation.

Chapter 4 **Registry Linkage**
This chapter describes methods to be used to assist in linking with the state cancer registry and variable definition tables that outline each of the collaborative stage variables collected in the CCDEs.

Chapter 5 **Communications**
This chapter provides a central location to store the information provided to the program from the CDC.

Chapter 6 **Meeting Minutes**
This chapter provides a central location to store notes and minutes from conference calls and meetings.

Chapter 7 **References**
This chapter contains optional reading material related to colorectal cancer screening. Also included are definitions for common program abbreviations and concepts.

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CHAPTER 1

Data Submission

CCDE Data Submission

What: CCDE data are submitted quarterly to IMS. Each CCDE submission will include cumulative data from the beginning of screening through the submission cut-off date, which is three months prior to the due date. For example, if the data are due to IMS on 9/1/2006, the data should cover procedures performed from the onset of the screening program through 5/31/2006. Note that the date used for the cut-off should be the date of first test provided and not, for example, the date of eligibility. It is important to use the cut-off date and not send all data through the submission date. The three month lag time between the procedure date and the reporting of the CCDE data will allow time to collect and clean the data. Submitted records may have incomplete diagnostic or treatment data that will be updated on a subsequent submission. Each submission dataset will replace the previous submission in its entirety. The CCDE data file should only contain records on clients who were enrolled in the colorectal screening program and who received services using CDC funds. This includes clients who are determined eligible and who are given a take-home FOBT/FIT kit, regardless of whether they complete the test.

Any data regarding clients seen, but not screened through this program due to medical ineligibility should be reported in the aggregate data file. Details regarding the aggregate data file, a sample form, and submission information can be found in subchapter "Non-clinical Aggregate Data Submissions".

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

Please notify your IMS Clinical Data Technical Consultant if your data are going to be late. Data not received by the submission due date may not be included in the analyses performed for that specific submission.

Submission Due	Submission Cut-off Date
9/1/2006	5/31/2006
12/1/2006	8/31/2006
3/1/2007	11/30/2006
6/1/2007	2/28/2007
9/1/2007	5/31/2007
12/01/2007	8/31/2007
3/1/2008	11/30/2007
6/1/2008	2/29/2008
9/1/2008	5/31/2008
12/1/2008	8/31/2008

How: When a CCDE submission is due, the CCDE data must be extracted from your dataset and put into the standardized CCDE format. The CCDE file consists of fixed length records in an ASCII format. In Version 1.01 of the CCDE Data Definition Table, each record will have 548 characters of screening, diagnosis, and treatment information and a 2 character end-of-record delimiter for a total of 550 characters per record. The end-of-record delimiter will be a "carriage return-line feed". A detailed description of the CCDE fields in each record is included in Chapter 2.

The CCDE file must be submitted electronically using the secure www.crcsdp.org Web site. The size of a file can be reduced by using a data compression routine, such as WinZip, PKZip, etc. IMS and the CDC request the use of compression software to compress your CCDE data prior to submission.

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

XXX -> Program code (001=Maryland)
MM -> Month of submission due date, with leading zeroes (09=September)
YY -> Year of submission due date (06=2006)
VVV -> CCDE version number (100=CCDE version 1.00)

Example: 0010906100.txt = (XXXMMYYVVV.txt)

All files should be received by IMS by close of business on the due date. Please notify Bill Helsel (helselb@imsweb.com) at IMS, the first time that data are submitted electronically so that we can monitor the data transmission.

Also to be included with each submission is a Submission Narrative. A hard copy of the CCDE Submission Narrative Guidelines can also be located at the end of this chapter – Appendix A. An electronic copy may be found on the www.crcsdp.org Web site.

The following extensions should be used for the various file names:

CCDE data file -> *.TXT
Compressed CCDE file -> *.ZIP
Submission Narrative -> *.NAR

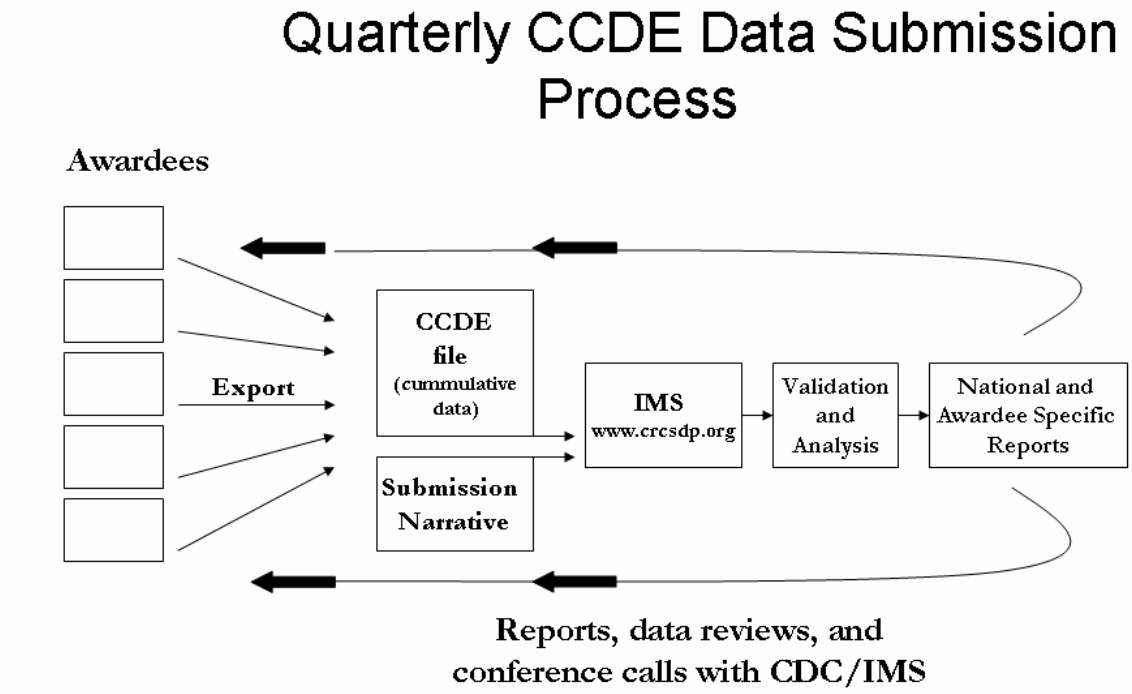
Updates and Corrections: For each data submission, programs are required to submit a cumulative data set through the cut-off date. Therefore, if any changes or updates to a particular record occur between submissions, these changes will be incorporated within the next CCDE data file.

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

Submission Narrative: CCDE data are regularly reviewed by the CDC, IMS, and program 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 Guidelines provide a structured way for programs to report responses to these questions or data

modifications. The Guidelines have two main sections. Section I is where responses to Action Items (written questions from the CDC and IMS based on a data conference call) are provided. Section II is comprised of five questions that require programs to do a prospective review of their CCDE data prior to submitting it to IMS. It is expected that programs 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. A response to each of the five questions is required, even if that response is "N/A - Not applicable".

IMS and the CCDEs: Once the CCDE data are received at IMS they are reviewed and validated. Using SAS, listings and print sample records for each program 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. Samples of the reports will be provided in Chapter 3 "Data Quality Assessment" of this manual once they have been finalized.



Submitting Annual Aggregate Data on Medically Ineligible Clients

What: Each program is asked to submit an aggregate data report which contains counts of clients who are assessed as medically ineligible and referred outside of the CRCSDP for appropriate clinical evaluation and management. These data will be used by the CDC and Research Triangle Institute (RTI) for program evaluation. A copy of the Annual Aggregate Data on Medically Ineligible Clients report form can be found on the www.crcsdp.org Web site and in the CRCSDP Policy Manual, Appendix 4.

When: All programs will submit the aggregate data reporting form according to the submission schedule listed below:

Information on clients deemed ineligible from	Data due to CDC
March 1, 2006 – August 31, 2006	December 1, 2006
September 1, 2006 – August 31, 2007	December 1, 2007
September 1, 2006 – August 31, 2008	December 1, 2008

How: The form should be submitted to the CDC Program Consultant.

Software Selection

Each program needs to decide which 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.

If at any time a program chooses to convert their existing data system to a different software package, it is strongly recommended that a test data submission be sent to IMS for review. The test submission should be done well in advance of a CCDE submission deadline. The IMS Clinical Data Technical Consultant should be notified prior to sending the test data.

Appendix A

CCDE Submission Narrative Guidelines

CCDE Submission Narrative Guidelines
March 31, 2006

The submission narrative provides a structured way for programs 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 program's CCDE data file by the CDC Program Consultant, CDC Scientific Consultant and IMS Clinical Data Technical Consultant and program 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 program 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.

Appendix B

Annual Aggregate Data on Medically Ineligible Clients

This appendix is a placeholder for the Annual Aggregate Data on Medically Ineligible Clients Form which can be located in the CRCSDP Policy Manual, Appendix 4.

CHAPTER 2

Colorectal Cancer Clinical Data Elements (CCDEs)

Introduction to the CCDE Chapter

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

- **Understanding CCDE data**
  This 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**
  A detailed description of each CCDE data item. This is the format that must be followed for the CCDE data submissions to the CDC.

- **Appendix C - CCDE Data Definitions**
  The list of CCDE variables with brief field descriptions and file layout specifications. This is appropriate for quick reference.

- **Appendix D – CDC Race and Ethnicity Code Set**
  A table which lists each of the Standard Race Categories, along with an expanded subset of concepts.

- **Appendix E – Adverse Events Reporting Form**
  These guidelines should be used when reporting any adverse events experienced by clients who receive a sigmoidoscopy, colonoscopy, or double contrast barium enema for screening or diagnostic purposes through the CRCSDP.

- **Appendix F – CCDE Revision History**
  These tables will be used to identify changes made to specific variables over the history of the program.

Understanding 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 and treatment information are collected on clients screened or diagnosed with program funds. These are the data items that are necessary for the programs and the CDC to manage and evaluate the clinical component of this demonstration program. Programs may collect additional data for local use (not to be reported to 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. A CCDE cycle begins with either an initial colorectal cancer screening test, which can include the distribution of an FOBT/FIT kit, or a surveillance colonoscopy, performed on a client who enters the program with a prior history of colorectal polyps or cancer. Once the cycle begins, it 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

Structure of the CCDEs

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

Section 1: Program and Enrollment Data
This section contains detailed information about eligibility and how the client heard about the program. It must be completed for each client and each CCDE record for that client.

Section 2: Client and Record Identification
This section contains client identification (to identify one client among many) and record identification (to identify one screening cycle among many for a client). It must be completed for each client and each CCDE record for that client.

Section 3: Demographic Information
This section contains specific demographic information about the client. The information collected in this section must be self-reported by the client. This information must be completed for each client and each CCDE record for that client.

Section 4: Screening History
This section contains information regarding previous screening and diagnostic 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 5: Colorectal Cancer Risk Factors
This section contains risk factor information, such as previously diagnosed polyps or colorectal cancer. It must be completed for each client and each CCDE record for that client.

Section 6: Screening and Diagnostic Tests Provided
This section contains information regarding the types of screening or diagnostic tests performed within each screening cycle. This information must be completed for each client and each CCDE record for that client.

Section 7: Diagnosis Information for All Polyps/Lesions
This section contains data regarding size, location and histology of any polyps or lesions discovered during the screening cycle. It also contains information regarding the next recommended procedure for the client within the current screening cycle. This section must be completed for each client and each CCDE record for that client.

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 diagnosis for the screening cycle.

Section 9: Final Diagnosis
This section contains data regarding a final diagnosis for the screening cycle and the recommended tests for the next screening cycle. This section should be completed for each client and each CCDE record for that client.

Section 10: Diagnosis Information for Cancer/High Grade Dysplasia
This section collects staging information at time of diagnosis, and staging information collected after linking with the state cancer registry. Guidance for this section will be provided by summer 2006.

Section 11: Treatment Information
This section collects treatment information for all clients with either a final diagnosis of “Polyp with high grade dysplasia” or “Cancer”.

Section 12: Record Information
This section includes the CCDE version for data collected 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/inforeg/statpolicy.html#dr.

The race codes collected in the CCDEs mirror those required by the OMB. However, programs may expand these categories during data collection to include racial subgroups that are represented in the local population if they choose. For example, a program 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 collection of Hispanic origin. If a program finds that Hispanic origin is being completed, with the Race fields being left blank, 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 D to assist programs 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 screening 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. Programs 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 any or all of these items assures a greater number of matches.

Completely numeric identifiers tend to work better, however the CCDEs allow the use of alpha-numeric identifiers, if necessary. A social security number has the necessary attributes for a good client identifier; however it is not always available. Additionally, confidentiality is of the utmost importance. We, at the federal level, do not want an identification number that could be used to link the CCDEs to other databases. Thus, if the Social Security number is used, you must encode it prior to submission to the CDC. See the field description on Client ID for encoding procedures.

It is important to realistically assess the various possibilities for the client identifier in your program. This is how information is linked, and the importance of a unique and consistent personal identifier cannot be over-emphasized.

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 or MMYYYY. For example, January 6, 1942 would be entered as 01061942 for MMDDYYYY, or 011942 for MMYYYY. 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, the "Knowledge of program - other" field is left-justified in the CCDE file. The starting and ending positions are columns 18 and 42, respectively. If the Other Specify is Church Bulletin, then "Church Bulletin" would be placed in columns 18 through 32 with the "C" being placed at column 18 and the "n" being placed in column 32. Columns 33 through 42 would be filled with blanks.

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, the "Largest Number of Polyps" field (Item 5.2.2) is a 2-digit numeric code and it is right justified. The starting and ending positions are columns 162 and 163, respectively. If the largest number of polyps is 8, then "8" would be placed in column 163. Column 162 would be a blank. Numeric fields may also be reported using the leading zero. So in the example given above, if the largest number of polyps is 8, the “0” would be placed in column 162 and “8” would be placed in column 163. The SAS programs used to analyze the CCDE data will recognize both conditions. Programs 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, if it were appropriate to blank fill the field, it would contain six blank characters. It is only appropriate to blank fill a field when it is indicated in the field description. A blank 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

TYPE: Numeric – right justify

SKIP PATTERN: This field should always be completed.

CONTENTS: 001 = Baltimore, MD
002 = St. Louis, MO
003 = State of NE
004 = Stony Brook, NY
005 = Seattle and King County, WA

EXPLANATION: This is the three-digit code assigned by the CDC to be used by your program for identification in lieu of state and territory FIPS codes.

EXAMPLE: For Baltimore, MD: 001

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **1.2: Date of eligibility**

PURPOSE: To indicate the date that a client was determined to be eligible to be screened in the program.

LENGTH: 8

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 of eligibility. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006). At the minimum, the year must be reported.

EXPLANATION: This is the date that the client was determined to be eligible to be screened in the program. This could be the date of the initial interview, the date that an enrollment form was completed, or the test referral date.

EXAMPLE: For a client determined eligible for the program on March 12, 2006: 03122006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **1.3.1: Knowledge of program (1)**

PURPOSE: To indicate how a client learned about the program.

LENGTH: 2

TYPE: Numeric – right justify

SKIP PATTERN: This field should always be completed.

CONTENTS:
1 = Doctor
2 = Other health care provider
3 = NBCCEDP
4 = Family member
5 = Friend
6 = Radio
7 = Television
8 = Magazine article
9 = Newspaper
10 = Mailing/flyer
11 = Community event
12 = Other

EXPLANATION: The source for information about the program should be self-reported by the client. If the client indicates a source other than those listed in 1 – 11, then report a response of 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field”. If more than one source, report using 1.3.2 and 1.3.3.

If programs choose to offer additional response options for this question, plans should be made to collapse those additional responses to 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field” when these data are exported to the CCDE data file for reporting to CDC.

EXAMPLE: If a client learns of the program from a radio advertisement: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **1.3.2: Knowledge of program (2)**

PURPOSE: To indicate how a client learned about the program.

LENGTH: 2

TYPE: Numeric – right justify

SKIP PATTERN: This field should be completed when more than one source is indicated for knowledge of the program; otherwise leave blank.

CONTENTS:
1 = Doctor
2 = Other health care provider
3 = NBCCEDP
4 = Family member
5 = Friend
6 = Radio
7 = Television
8 = Magazine article
9 = Newspaper
10 = Mailing/flyer
11 = Community event
12 = Other

EXPLANATION: The source for information about the program should be self-reported by the client. Use this field if the client indicates more than one source for his/her knowledge of the program. No primary source for knowledge of the program is collected. The first source indicated by the client has no significance over any subsequent source, and may simply be the first source mentioned by the client. If the client indicates a source other than those listed 1 – 11, report a response of 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field”. If more than two sources, report in 1.3.3.

If programs choose to offer additional response options for this question, plans should be made to collapse those additional responses to 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field” when these data are exported to the CCDE data file for reporting to CDC.

EXAMPLE: If a client learns of the program from a community event: 11

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **1.3.3: Knowledge of program (3)**

PURPOSE: To indicate how a client learned about the program.

LENGTH: 2

TYPE: Numeric – right justify

SKIP PATTERN: This field should be completed when more than two sources are indicated for knowledge of the program; otherwise leave blank.

CONTENTS:
1 = Doctor
2 = Other health care provider
3 = NBCCEDP
4 = Family member
5 = Friend
6 = Radio
7 = Television
8 = Magazine article
9 = Newspaper
10 = Mailing/flyer
11 = Community event
12 = Other

EXPLANATION: The source for information about the program should be self-reported by the client. Use this field if the client indicates more than two sources for his/her knowledge of the program. No primary source for knowledge of the program is collected. The second source indicated by the client has no significance over any subsequent source, and may simply be the second source mentioned by the client. If the client indicates a source other than those listed 1 – 11, report a response of 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field”.

If programs choose to offer additional response options for this question, plans should be made to collapse those additional responses to 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field” when these data are exported to the CCDE data file for reporting to CDC.

EXAMPLE: If a client learns of the program from a radio advertisement: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **1.3.4: Knowledge of program other text field**

PURPOSE: To indicate an other source used to learn about the program.

LENGTH: 25

TYPE: Alphanumeric – left justify

SKIP PATTERN: If Item 1.3.1, 1.3.2, or 1.3.3 “Knowledge of program 1-3” is 12, then this field must be completed; otherwise it should be blank.

CONTENTS: This is a free form text field.

EXPLANATION: The purpose of this field is to report client-identified sources for knowledge of the program that are not among the response options (1-11) that are provided in the three knowledge of program fields.

If programs choose to offer response options in addition to those response options (1-11) that are provided in Items 1.3.1, 1.3.2, or 1.3.3 “Knowledge of program 1-3”, then plans should be made to collapse those additional responses to 12 (Other) and complete the free text field in Item 1.3.4 “Knowledge of program other text field” when these data are exported to the CCDE data file for reporting to CDC.

Please try to use this field appropriately. Reclaiming inappropriate responses is time-consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a client learns of the program via a Web site: Web site

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **2.1: 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

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 tend to work better; 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. 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. 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 back 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 will be 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 complement of 2 is 7, the complement of 5 is 4 and the 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	02/06/2006	Add new

ITEM NO / NAME: **2.2: Record identifier**

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

LENGTH: 6

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 screening or surveillance test, or distribution of an FOBT/FIT kit, continues through any additional tests or procedures 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 data files. 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 numbering (e.g. 1 = first cycle, 2 = second cycle, etc).

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

EXAMPLE: Using a date of 4/1/2006: 040106
Using a cycle number of 1: 000001 or 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **3.1: Date of birth**

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

LENGTH: 8

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is a number from 1 to 12, DD is a number from 1 to 31, and YYYY is the year of birth, including the century. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01 1955). At a minimum, the year of birth must be reported.

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

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **3.2: Gender**

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

LENGTH: 1

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	02/06/2006	Add new

ITEM NO / NAME: **3.3 Hispanic or Latino origin**

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

LENGTH: 1

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 3.3 "Hispanic or Latino origin" should be reported as 1 (Yes) and race 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 3.3 "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 client: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **3.4.1: Race 1**

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

LENGTH: 1

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 Items 3.4.2 “Race 2” through Item 3.4.5 “Race 5” should be used 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 by the client.

If Item 3.3 “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 3.3 “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 D. The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client self-identifies as Asian: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **3.4.2: Race 2**

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

LENGTH: 1

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 D. 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	02/06/2006	Add new

ITEM NO / NAME: **3.4.3: Race 3**

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

LENGTH: 1

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 D. 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	02/06/2006	Add new

ITEM NO / NAME: **3.4.4: Race 4**

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

LENGTH: 1

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 D. 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	02/06/2006	Add new

ITEM NO / NAME: **3.4.5: Race 5**

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

LENGTH: 1

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 D. 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	02/06/2006	Add new

ITEM NO / NAME: **3.5: State of residence**

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

LENGTH: 2

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	02/06/2006	Add new

ITEM NO / NAME: **3.6 County of residence**

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

LENGTH: 3

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 3.5.

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 your state 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	02/06/2006	Add new

ITEM NO / NAME: **4.1.1: Previous take-home CRC fecal test (FOBT/FIT)**

PURPOSE: To indicate if a client has previously had either a take-home Fecal Occult Blood Test (FOBT) or Fecal Immunochemical Test (FIT).

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS:
1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client has previously had a take-home guaiac-based Fecal Occult Blood Test (FOBT) or a take-home Fecal Immunochemical Test (FIT). These are both examples of tests looking for occult, or hidden, blood in the stool.

A FOBT is used to detect blood in stool by placing a small sample of stool on a chemically treated card window. The client will collect the stool sample and return the card to a laboratory or program office, as instructed by the program. A chemical solution is then placed on top of the sample by laboratory personnel; and if the card window turns blue, then there is blood in the stool. A FIT also detects blood in the stool by detecting part of the hemoglobin molecule. FIT is performed in a similar manner as FOBT, although the testing process is automated, but it is more specific and may reduce the number of false positive results. Other possible terms for FOBT may include hemoccult, guaiac, and immunochemical FOBT (iFOBT).

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 a take-home FOBT or FIT test in the past, then complete this field as 1 (Yes). In such cases, both the date performed (Item 4.1.2) and the test result (Item 4.1.3) should also be reported. If the client has never had a take-home FOBT/FIT test prior to the visit, then complete this field as 2 (No). If the client has had a previous FOBT/FIT test within the program (as part of a separate screening cycle), complete this field as 1 (Yes).

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

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.1.2: Previous take-home CRC fecal test date**

PURPOSE: To indicate the date of a client's most recent FOBT or FIT test.

LENGTH: 6

TYPE: Date

SKIP PATTERN: If Item 4.1.1 "Previous take-home CRC fecal test FOBT/FIT" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: A 6-digit date field of the form MMYYYY, where MM is a number from 1 to 12, and YYYY is the year of the prior FOBT/FIT. If just the year is known, then blank fill the month (e.g., _1995).

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. If the client has had more than one FOBT/FIT previously, then report the date of the most recent FOBT/FIT test that is indicated by the client. It is acceptable to report any date that the client can recall including the date of the test, the date the test was returned, or the date that the test results were received by the client.

If client is unsure of the actual month, this part of the field may be left blank, and just the year reported. If client is unsure of the year, they should be prompted to provide an estimate: within the last year? Less than 3 years ago? Less than 5 years ago? The date field can be completed with the estimated date.

EXAMPLE: If a client's most recent prior FOBT was May 1, 1995: 051995

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.1.3: Previous take-home CRC fecal test result**

PURPOSE: To indicate the result of a client's most recent FOBT or FIT test.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 4.1.1 "Previous take-home CRC fecal test FOBT/FIT" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: 1 = Normal/negative test
2 = Abnormal/positive test result
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. If the client has had more than one FOBT/FIT test previously, report the result of the most recent test.

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 the result of the client's most recent FOBT was positive: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.2.1: Previous sigmoidoscopy**

PURPOSE: To indicate if a client has previously had a sigmoidoscopy.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS:
1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client has previously had a sigmoidoscopy. Sigmoidoscopy is the direct visual examination of the inside of the rectum and sigmoid colon using an instrument called a sigmoidoscope. The client should have cleaned out their bowels using a prescribed enema or cathartic. The test examines the lower half of the colon. A sigmoidoscope is a lighted, flexible tube with a camera attached to it. It is inserted into the colon to examine the lining of the rectum, sigmoid and descending portions of the colon. Some other possible terms for sigmoidoscopy include sig, flex sig, and flexible sigmoidoscopy.

Rigid sigmoidoscopy or proctoscopy should not be used as an alternative to flexible sigmoidoscopy for CRC 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 has had a sigmoidoscopy in the past, then complete this field as 1 (Yes). In such cases, both the date performed (Item 4.2.2) and the test result (Item 4.2.3) should also be reported. If the client has not had a sigmoidoscopy prior to the visit, complete this field as 2 (No). If the client had a previous sigmoidoscopy 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 sigmoidoscopy: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.2.2: Previous sigmoidoscopy test date**

PURPOSE: To indicate the date of a client's most recent sigmoidoscopy.

LENGTH: 6

TYPE: Date

SKIP PATTERN: If Item 4.2.1 "Previous sigmoidoscopy" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: A 6-digit date field of the form MMYYYY, where MM is a number from 1 to 12, and YYYY is the year of the client's previous sigmoidoscopy. If just the year is known, then blank fill the month (e.g., 1995).

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. If the client has had more than one prior sigmoidoscopy, then report the date of the most recent sigmoidoscopy procedure indicated by the client.

If client is unsure of the actual month, this part of the field may be left blank, and just the year reported. If client is unsure of the year, they should be prompted to provide an estimate: within the last year? Less than 3 years ago? Less than 5 years ago? The date field can be completed with the estimated date.

EXAMPLE: If a client's most recent sigmoidoscopy was May 1, 1998: 051998

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.2.3: Result of previous sigmoidoscopy**

PURPOSE: To indicate the result of a client's most recent sigmoidoscopy.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 4.2.1 "Previous sigmoidoscopy" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: 1 = Normal/negative/results other than polyp(s), tumor(s), or cancer
2 = Polyp(s)/tumor(s)/cancer
3 = Incomplete
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. If the client has had more than one prior sigmoidoscopy, then report the result of the most recent sigmoidoscopy procedure indicated by the client.

A response of 3 (Incomplete) should mean that that sigmoidoscopy procedure was incomplete, and a result is therefore not available.

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 the result of the client's most recent sigmoidoscopy was polyps:
2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.3.1: Previous colonoscopy**

PURPOSE: To indicate if a client has previously had a colonoscopy.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS:
1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client has previously had a colonoscopy. Colonoscopy is an internal examination of the full length of the colon using an instrument called a colonoscope. The client should have cleaned out their bowels using a prescribed enema or cathartic. A colonoscope is a lighted, flexible tube with a camera attached to it. It also may be used to biopsy polyps and lesions.

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 has had a colonoscopy in the past, then complete this field as 1 (Yes). In such cases, both the date performed (Item 4.3.2) and the test result (Item 4.3.3) should also be reported. If the client has not had a colonoscopy prior to the visit, complete this field as 2 (No). If the client had a previous colonoscopy within the program (as part of a separate screening cycle), then 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 not previously had a colonoscopy: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.3.2: Previous colonoscopy test date**

PURPOSE: To indicate the date of a client's most recent colonoscopy.

LENGTH: 6

TYPE: Date

SKIP PATTERN: If Item 4.3.1 "Previous colonoscopy" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: A 6-digit date field of the form MMYYYY, where MM is a number from 1 to 12, and YYYY is the year of the client's previous colonoscopy. If just the year is known, then blank fill the month (e.g., _1998).

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. If the client has had more than one prior colonoscopy, then report the date of the most recent colonoscopy procedure indicated by the client.

If client is unsure of the actual month, this part of the field may be left blank, and just the year reported. If client is unsure of the year, they should be prompted to provide an estimate: within the last year? Less than 3 years ago? Less than 5 years ago? The date field can be completed with the estimated date.

EXAMPLE: If a client's most recent colonoscopy was June 8, 1993: 061993

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.3.3: Result of previous colonoscopy**

PURPOSE: To indicate the result of a client's most recent colonoscopy.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 4.3.1 "Previous colonoscopy" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS:
1 = Normal/negative/results other than polyp(s), tumor(s), or cancer
2 = Polyp(s)/tumor(s)/cancer
3 = Incomplete
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. If the client has had more than one prior colonoscopy, then report the result of the most recent colonoscopy procedure indicated by the client.

A response of 3 (Incomplete) should mean that that colonoscopy procedure was incomplete, and a result is therefore not available. Incomplete examinations are those in which the endoscopist was unable to complete the examination due to pain, inadequate bowel preparation or client anatomy.

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 the result of the client's most recent colonoscopy was normal: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.4.1: Previous DCBE**

PURPOSE: To indicate if a client has previously had a double-contrast barium enema (DCBE).

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS:
1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client has previously had a DCBE. A DCBE involves a series of x-rays of the colon and rectum that are taken after the client is given an enema with a white, chalky solution that contains barium. The client should have previously cleaned their bowels using a prescribed enema or cathartic. The barium outlines the intestines on the x-rays, permitting the detection of colon and rectal abnormalities including polyps and cancers of the colon and rectum. Air is instilled into the colon to further define structures. Some other terms for DCBE may include barium enema, air-contrast barium enema, barium enema x-ray, and lower GI series.

A single-contrast enema should not be performed as an alternative for a double-contrast barium enema for the purposes of CRC 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 has had a DCBE in the past, then complete this field as 1 (Yes). In such cases, both the date performed (Item 4.4.2) and the prior test result (Item 4.4.3) should also be reported. If the client has not had a DCBE prior to the visit, then complete this field as 2 (No). If the client has had a previous DCBE 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 does not know if he/she has had a prior DCBE: 9

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.4.2: Previous DCBE test date**

PURPOSE: To indicate the date of a client's most recent DCBE.

LENGTH: 6

TYPE: Date

SKIP PATTERN: If Item 4.4.1 "Previous DCBE" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: A 6-digit date field of the form MMYYYY, where MM is a number from 1 to 12, and YYYY is the year of the client's most recent DCBE. If just the year is known, then blank fill the month (e.g., 1998).

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. If the client has had more than one prior DCBE, then report the date of the most recent DCBE procedure indicated by the client.

If client is unsure of the actual month, this part of the field may be left blank, and just the year reported. If client is unsure of the year, they should be prompted to provide an estimate: within the last year? Less than 3 years ago? Less than 5 years ago? The date field can be completed with the estimated date.

EXAMPLE: If a client's most recent DCBE was August 25, 2001: 082001

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **4.4.3: Result of previous DCBE**

PURPOSE: To indicate the result of a client's most recent DCBE.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 4.3.1 "Previous DCBE" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS:
1 = Normal/negative/results other than polyp(s), tumor(s), or cancer
2 = Polyp(s)/tumor(s)/cancer
3 = Incomplete
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. If the client has had more than one prior DCBE, then report the result of the most recent DCBE procedure indicated by the client.

A response of 3 (Incomplete) should mean that that DCBE procedure was incomplete, and a result is therefore not available. Incomplete examinations are those in which the radiologist was unable to complete the examination due to pain, inadequate bowel preparation or client anatomy.

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 the result of the client's most recent DCBE was incomplete: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **5.1.1: Personal history of CRC (colorectal cancer)**

PURPOSE: To indicate if a client has ever been diagnosed with CRC.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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.

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, then this field should be completed as 1 (Yes). In such cases, the year that the CRC was diagnosed should be reported in Item 5.1.2. If the client has been previously diagnosed with CRC more than once, report the year of the most recent CRC diagnosis that is indicated by the client. If the client has never been diagnosed with CRC prior to the visit, then complete this field as 2 (No).

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

EXAMPLE: A client indicates he/she was diagnosed with CRC previously: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **5.1.2: Year CRC diagnosed**

PURPOSE: To indicate the date of a client's most recent CRC diagnosis.

LENGTH: 4

TYPE: Date

SKIP PATTERN: If Item 5.1.1 "Personal History of CRC" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: A 4-digit date field of the form YYYY to indicate the year of the client's most recent CRC diagnosis.

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. If the client has been previously diagnosed with CRC more than once, report the date of the most recent CRC diagnosis indicated by the client.

EXAMPLE: A client's most recent CRC diagnosis was May 7, 2001: 2001

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **5.2.1: Personal history of polyp(s)**

PURPOSE: To specify if a client has ever been diagnosed with polyps.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client has ever been diagnosed with polyps of the colon or rectum. A polyp is a growth, or mass of tissue that develops on the inside wall of a hollow organ, such as the colon. It projects, usually on a stalk, from the lining of the colon or rectum and can sometimes develop into cancer. Other possible terms for polyp include growth, mass, outgrowth, adenoma, and intestinal polyps

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 previously been diagnosed with polyps of any type, this field should be completed as 1 (Yes). In such cases, the year that the polyps were diagnosed should be reported in Item 5.2.2. If the client has been previously diagnosed with polyps more than once, report the year of the most recent polyp diagnosis that is indicated by the client. If the client has never been diagnosed with polyps prior to the visit, 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: If the client has been told that they had polyps, based on a previous exam: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **5.2.2: Largest number of polyps diagnosed during a single procedure**

PURPOSE: To indicate a client's largest number of polyps diagnosed during a single procedure.

LENGTH: 2

TYPE: Numeric – right justify

SKIP PATTERN: If Item 5.2.1 "Personal History of polyps" is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS:
1 - 49 = Number of polyps
50 = ≥ 50 polyps
91 = < 10 polyps (if exact number not known)
92 = ≥ 10 polyps (if exact number not known)
99 = 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. It is preferred that an exact number of polyps is obtained if possible. If the client reports an exact number of polyps that is less than fifty, then complete this field with the exact number. If the client reports an exact number of polyps that is fifty or greater, complete this field as 50 (≥ 50 polyps). If the client does not know the exact number of polyps but reports that it was less than ten, complete this field as 91 (< 10 polyps). If the client does not know the exact number of polyps but reports that it was ten or greater, complete this field as 92 (≥ 10 polyps).

A response of 99 (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: Client largest number of polyps diagnosed during a single procedure is an estimate of less than ten polyps: 91

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **5.2.3: Were any of these polyps adenomatous?**

PURPOSE: To indicate if a client has ever been diagnosed with adenomatous polyps.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 5.2.1 “Personal History of polyps” is 1 (Yes), then this field should be completed; otherwise leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: There are two types of polyps commonly identified: adenomatous polyps (also known as adenomas) and hyperplastic polyps. The purpose of this field is to collect information about adenomatous polyps only, which are pre-cancerous or pre-malignant polyps.

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 previously been diagnosed with adenomatous polyps, then this field should be completed as 1 (Yes). The diagnosis of adenomatous polyps can be from any previous test or visit; not just the most recent diagnosis. If the client has never been diagnosed with adenomatous polyps before, complete this field as 2 (No).

Along with adenomatous and hyperplastic polyps, other types of polyps do exist, including inflammatory polyps. If only a type of polyp other than an adenomatous polyp is reported, this field should be completed 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 no prior diagnosis of adenomatous polyps: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that "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"

ITEM NO / NAME: **5.3: High risk due to family history of CRC**

PURPOSE: To indicate if a client is at high risk for CRC due to family history.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field is used to indicate if a client is considered by the program to be at high risk due to a family history of CRC. Each program has its own documented definition of high risk due to family history of CRC.

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.0: Initial test recommended**

PURPOSE: To indicate the initial test recommended for a client by the program

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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)
9 = Unknown

EXPLANATION: This field should report the recommended procedure for this client that will begin the screening cycle. This is the test recommended by the program.

In some cases, the initial test recommended and the actual first test received (Item 6.1.01) may not be the same. This is acceptable. Analysis will be performed on the data to examine the relationship between the initial test recommended and the actual first test performed.

EXAMPLE: If it is recommended that the client receive a sigmoidoscopy: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.0: Indication for 1st test provided**

PURPOSE: This is the indication for the actual test provided, reported in 6.1.01 "First test provided".

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Screening
2 = Surveillance after a positive colonoscopy
9 = Unknown

EXPLANATION: The field should be used to indicate the purpose for the first test given to the client. For this program, "provided" is the same as "paid for", therefore, this could include a screening FOBT/FIT that was mailed, but not returned.

A screening test (1) is a test provided for someone who has no symptoms, and may have never been screened, or may have had a previous negative screening test and is due for their next re-screen. A surveillance test (2) is a test (typically a colonoscopy) done at more frequent intervals than screening to evaluate someone 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.

EXAMPLE: If the purpose of the first test provided is for screening: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.01: First test provided**

PURPOSE: To indicate the actual first test provided through the program. For the purposes of this study “provided” = “paid for”.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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)

EXPLANATION: This field should be reported with the actual first test provided by the program. It is possible that this first test provided is not the same as the initial test recommended (Item 6.0).

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.02: Date of 1st test**

PURPOSE: To specify the date of the first test.

LENGTH: 8

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 of the procedure. 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 2006). This field should not be left completely blank.

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

If Item 6.1.05 "Results of take-home FOBT/FIT" is 3 (Refused), then complete this field with an administrative close-out date as defined by your program.

If Item 6.1.05 "Results of take-home FOBT/FIT" is 4 (Did Not Return Card), then complete this field with the date that the FOBT/FIT kit was distributed to the client.

EXAMPLE: If a colonoscopy was performed on August 1, 2006: 08012006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.03: Provider specialty**

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

LENGTH: 2

TYPE: Numeric - right justify

SKIP PATTERN: This field should always be completed.

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
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 an FOBT/FIT should be provided to the client, not the individual that mailed out the card.

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	02/06/2006	Add new

ITEM NO / NAME: **6.1.04: Clinical practice site**

PURPOSE: To report the type of clinical practice for the provider reported in 6.1.03.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS:
1 = Doctor's office
2 = Ambulatory endoscopy/surgery center
3 = Hospital
4 = Health clinic
5 = Administrator, if FOBT/FIT mailed by non-clinician
9 = Unknown

EXPLANATION: This field should report the type of clinical practice for the provider reported in Item 6.1.03 (Provider specialty).

EXAMPLE: If the provider's practice is located in a hospital: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.05: Result of take-home FOBT/FIT**

PURPOSE: To specify the results of an FOBT or FIT, if this test was the first test provided. This field is not available for the second (6.2.05), third (6.3.05), or fourth (6.4.05) test due to FOBT/FIT not being an allowable procedure as a subsequent test within a cycle (Items 6.2.01, 6.3.01, and 6.4.01).

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 = 1 (Take-home FOBT) or 2 (Take-home FIT); otherwise, leave blank.

CONTENTS:
1 = Normal/negative
2 = Positive
3 = Refused
4 = Did not return card
5 = Pending
9 = Unknown

EXPLANATION: If Item 6.1.01 = 1 (Take-home FOBT) or 2 (Take-home FIT), then this field should be completed, otherwise, leave blank.

If a response of 3 (Refused) is indicated, then Item 6.1.02 “Date of 1st test” should be completed with an administrative close-out date as defined by your program.

If a response of 4 (Did not return card) is indicated, then Item 6.1.02 “Date of 1st test” should be completed with the date that the FOBT/FIT kit was distributed to the client. Item 6.1.13 “Recommended next follow-up” should be reported as 8 (None) and Item 9.1 “Status of Diagnosis” should be reported as 9 (Unknown). If the chart records any gradation of positive (i.e. “weakly positive” or “slightly positive”), the response should be recorded as Positive (2).

EXAMPLE: If result of the take-home FOBT was positive: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.06: Results of endoscopy or DCBE**

PURPOSE: To specify the results of a sigmoidoscopy, colonoscopy or DCBE, if it was the first test performed.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE).

CONTENTS:
1 = Normal/negative/diverticulosis/hemorrhoids
2 = Other finding not suggestive of cancer/polyp(s)
3 = Polyp(s)/suspicious for cancer/presumed cancer
4 = No findings/inconclusive
5 = Pending
9 = Unknown

EXPLANATION: This field should be completed if Item 6.1.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), otherwise, leave blank.

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

Results from an incomplete or inconclusive test should always be coded as 4 (No Findings/inconclusive), regardless if any specific findings were noted. An incomplete test may be due to patient discomfort or distress. Inconclusive findings may be due to obstruction, inadequate preparation and retained fecal material, physician fatigue or cecum not reached. Any specific findings that were noted from an incomplete or inconclusive test should be captured and reported elsewhere in the CCDE, including reporting in Sections 6 “Screening and Diagnostic Tests Provided” and Section 7 “Diagnosis Information for All Polyps/Lesions” on polyps/lesions identified or removed. Another screening test should be recommended following an incomplete or inconclusive test.

EXAMPLE: If result of the DCBE was suspicious for cancer: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the first test performed.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE).

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should be completed if Item 6.1.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), otherwise, leave blank.

Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) can only be reported if the procedure report explicitly states that the bowel preparation was adequate, otherwise report 9 (Unknown).

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

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

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy, if it was the first procedure performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: If the first procedure performed was a colonoscopy, indication of whether the cecum was reached during the procedure should be reported.

The procedure report must explicitly state that the cecum was reached during the colonoscopy in order to report 1 (Yes); otherwise report 9 (Unknown).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.09: Complications of endoscopy or DCBE?**

PURPOSE: To indicate whether there were complications due to the sigmoidoscopy, colonoscopy or DCBE, if it was the first test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No/unknown

EXPLANATION: If Item 6.1.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), indicate whether or not complications occurred from the procedure which required medical attention.

If complications = 1 (Yes), then the complication should be reported on the Adverse Events Reporting form and submitted to the CDC on a quarterly basis, as detailed in the Adverse Events Reporting Form (Appendix E).

If the client is hospitalized because of an immediate complication, please notify your consultation team at CDC with 72 hours of the hospitalization by email. You should then send a completed Adverse Events Report Form to the CDC within five (5) days. Please see the Adverse Events Reporting Form (Appendix E) for further guidance.

EXAMPLE: If rectal bleeding occurred 3 days after a procedure: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.10: Was a biopsy/polypectomy performed during the endoscopy?**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 is 3 (Sigmoidoscopy) or 4 (Colonoscopy); otherwise, it should be blank.

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.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.11: Number of specimens sent to pathology (from endoscopy)**

PURPOSE: To report the actual number of specimens removed during a biopsy or polypectomy, and sent to pathology.

LENGTH: 2

TYPE: Numeric – right justified

SKIP PATTERN: This field should be completed if Item 6.1.01 was 3 (Sigmoidoscopy) or 4 (Colonoscopy) **AND** Item 6.1.10 (Biopsy/polypectomy performed) is 1 (Yes); otherwise, it should be blank.

CONTENTS:
0 = Biopsy performed, no specimens sent
1 = One
2 = Two specimens
…
97 = Ninety-seven
98 = ≥ Ninety-eight
99 = Unknown

EXPLANATION: The actual number of specimens sent to pathology should be acquired and reported. If a biopsy/polypectomy was performed, but no specimens were sent to pathology (e.g. specimen contaminated), code 0 (Biopsy performed, no specimen sent).

When more than 98 specimens are collected during the colonoscopy/sigmoidoscopy, report 98 (≥ 98 specimens).

If it is unknown whether any specimens were sent to pathology, code 99 (Unknown). If the exact number of specimens sent to pathology is unknown, code 99 (Unknown).

This field includes samples removed entirely or in part. If a single polyp is removed piecemeal, report the number of specimens, not the number of polyps.

EXAMPLE: If a biopsy was performed during a colonoscopy and 6 specimens were sent to pathology: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.1.12: Completeness of polyp removal (from colonoscopy).**

PURPOSE: To indicate if polyps were completely removed during the first test, if it was a colonoscopy. Do not complete this field if no polyps were identified.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 = 4 (Colonoscopy) **and** Item 6.1.06 = 3 (Polyps/suspicious for cancer/presumed cancer) **and** Item 7.0 ≠ 0 (No polyps/lesions).

This field should be completed if Item 6.1.01 = 4 (Colonoscopy) **and** Item 6.1.06 = 4 (No findings/inconclusive) **and** Item 7.0 ≠ 0 (No polyps/lesions).

Otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The intent of this field is to report if the colon was cleared of all polyps noted during the colonoscopy. This field should only be completed if the first test performed is a colonoscopy and polyps were identified. Do not complete this field if no polyps were identified.

If 6.1.06 = 3 and 7.0 ≠ 0; or
If 6.1.06 = 4 and 7.0 ≠ 0, then:

- If all polyps noted during colonoscopy were removed, code 1 (Yes)
- If all polyps noted were not removed, code 2 (No)
- If no polyps were seen or suspected, code 9 (Unknown)

If 6.1.06 ≠ 3 or 4, then leave blank.

If this field is coded as 2 (No) or 9 (Unknown), and a second colonoscopy is performed within the cycle to complete the removal of polyps, see Item 9.2 “Final diagnosis” and Item 9.3 “Date of diagnosis” for guidance on how to report histological findings.

EXAMPLE: If all polyps were completely removed: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised skip pattern to include directions: Leave blank if 6.1.06 ≠ 3, 4

ITEM NO / NAME: **6.1.13: Recommended next follow-up procedure within this cycle after 1st test.**

PURPOSE: To indicate the next recommended procedure following the completion of the first test.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

EXPLANATION: Once the first test 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 the first screening test was incomplete or inconclusive.

If the next recommended procedure for the client is surgery, 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 (6.2.01, 6.3.01 or 6.4.01) should be reported. Items 6.2.01, 6.3.01 and 6.4.01 will be completed with 0 (None).

If the initial screening test 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. Items 6.2.01, 6.3.01 and 6.4.01 will be completed with 0 (None)

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	02/06/2006	Add new

ITEM NO / NAME: **6.2.01: 2nd Test provided**

PURPOSE: To indicate the actual second test provided through the program. For the purposes of this study “provided” = “paid for”.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast barium enema (DCBE)

EXPLANATION: Report the next test provided. Only funded colorectal diagnostic tests should be reported in the CCDEs. If a non-funded test is provided (e.g. an MRI), then that test should not be reported in the CCDEs. If the non-funded test is the only additional test performed, then this field should be completed as 0 (None).

This test should match the test reported in 6.1.13, however it is understood that client compliance may dictate that they will not be the same.

If a second test was not performed, indicate 0 (None), and leave items 6.2.03 through 6.2.13 blank.

The second test may not be an FOBT or FIT. These exams are considered screening tests, which would begin a new record.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.02: Date of 2nd test**

PURPOSE: To specify the date of the second test.

LENGTH: 8

TYPE: Date

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

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 of the procedure. 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 2006). This field should not be left completely blank.

EXPLANATION: This field captures the date that the second test was performed.

EXAMPLE: If a colonoscopy was performed on August 1, 2006: 08012006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.03: Provider specialty**

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

LENGTH: 2

TYPE: Numeric, right justify.

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

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
99 = Unknown

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

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.04: Clinical practice site**

PURPOSE: To report the type of clinical practice for the provider reported in 6.2.03.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Doctor's office
2 = Ambulatory endoscopy/surgery center
3 = Hospital
4 = Health clinic
9 = Unknown

EXPLANATION: This field should report the type of clinical practice for the provider reported in Item 6.2.03 (Provider specialty).

EXAMPLE: If the provider's practice is located in a hospital: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.06: Results of endoscopy or DCBE**

PURPOSE: To specify the results of a sigmoidoscopy, colonoscopy or DCBE, if it was the second test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS:
1 = Normal/negative/diverticulosis/hemorrhoids
2 = Other finding not suggestive of cancer/polyp(s)
3 = Polyp(s)/suspicious for cancer/presumed cancer
4 = No findings/inconclusive
5 = Pending
9 = Unknown

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

Results from an incomplete or inconclusive test should always be coded as 4 (No Findings/inconclusive), regardless if any specific findings were noted. An incomplete test may be due to patient discomfort or distress. Inconclusive findings may be due to obstruction, inadequate preparation and retained fecal material, physician fatigue or cecum not reached. Any specific findings that were noted from an incomplete or inconclusive test should be captured and reported elsewhere in the CCDE, including reporting in Sections 6 “Screening and Diagnostic Tests Provided” and Section 7 “Diagnosis Information for All Polyps/Lesions” on polyps/lesions identified or removed. Another screening test should be recommended following an incomplete or inconclusive test.

EXAMPLE: If result of the DCBE was suspicious for cancer: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the second test performed.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE); 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) can only be reported if the procedure report explicitly states that the bowel preparation was adequate, otherwise report 9 (Unknown).

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the second procedure performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: If the second procedure performed was a colonoscopy, indication of whether the cecum was reached during the procedure should be reported.

The procedure report must explicitly state that the cecum was reached during the colonoscopy in order to report 1 (Yes); otherwise report 9 (Unknown).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.09: Complications of endoscopy or DCBE.**

PURPOSE: To indicate whether there were complications due to the sigmoidoscopy, colonoscopy or DCBE, if it was the second test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No/unknown

EXPLANATION: If Item 6.2.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), indicate whether or not complications occurred from the procedure which required medical attention.

If complications = 1 (Yes), then the complication should be reported on the Adverse Events Reporting form and submitted to the CDC on a quarterly basis, as detailed in the Adverse Events Reporting Form (Appendix E).

If the client is hospitalized because of an immediate complication, please notify your consultation team at CDC with 72 hours of the hospitalization by email. You should then send a completed Adverse Events Report Form to the CDC within five (5) days. Please see the Adverse Events Reporting Form (Appendix E) for further guidance.

EXAMPLE: If rectal bleeding occurred 3 days after a procedure: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.10: Was a biopsy/polypectomy performed during the endoscopy?**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 is 3 (Sigmoidoscopy) or 4 (Colonoscopy); otherwise, it should be blank.

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.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.11: Number of specimens sent to pathology (from endoscopy)**

PURPOSE: To report the actual number of specimens removed during a biopsy or polypectomy, and sent to pathology.

LENGTH: 2

TYPE: Numeric – right justified

SKIP PATTERN: This field should be completed if Item 6.2.01 was 3 (Sigmoidoscopy) or 4 (Colonoscopy) **AND** Item 6.2.10 (Biopsy/polypectomy performed) is 1 (Yes); otherwise, it should be blank.

CONTENTS:
0 = Biopsy performed, no specimens sent
1 = One
2 = Two specimens
…
97 = Ninety-seven
98 = ≥ Ninety-eight
99 = Unknown

EXPLANATION: The actual number of specimens sent to pathology should be acquired and reported. If a biopsy/polypectomy was performed, but no specimens were sent to pathology (e.g. specimen contaminated), code 0 (Biopsy performed, no specimen sent).

When more than 98 specimens are collected during the colonoscopy/sigmoidoscopy, report 98 (≥ 98 specimens).

If it is unknown whether any specimens were sent to pathology, code 99 (Unknown). If the exact number of specimens sent to pathology is unknown, code 99 (Unknown).

This field includes samples removed entirely or in part. If a single polyp is removed piecemeal, report the number of specimens, not the number of polyps.

EXAMPLE: If a biopsy was performed during a colonoscopy and 6 specimens were sent to pathology: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.2.12: Completeness of polyp removal (from colonoscopy).**

PURPOSE: To indicate if polyps were completely removed during the second test, if it was a colonoscopy. Do not complete this field if no polyps were identified.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 = 4 (Colonoscopy) **and** Item 6.2.06 = 3 (Polyps/suspicious for cancer/presumed cancer) **and** Item 7.0 ≠ 0 (No polyps/lesions).

This field should be completed if Item 6.2.01 = 4 (Colonoscopy) **and** Item 6.2.06 = 4 (No findings/inconclusive) **and** Item 7.0 ≠ 0 (No polyps/lesions).

Otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The intent of this field is to report if the colon was cleared of all polyps noted during the colonoscopy. This field should only be completed if the second test performed is a colonoscopy and polyps were identified. Do not complete this field if no polyps were identified.

If 6.2.06 = 3 and 7.0 ≠ 0; or
If 6.2.06 = 4 and 7.0 ≠ 0, then:

- If all polyps noted during colonoscopy were removed, code 1 (Yes)
- If all polyps noted were not removed, code 2 (No)
- If no polyps were seen or suspected, code 9 (Unknown)

If 6.2.06 ≠ 3 or 4 then leave blank.

If this field is coded as 2 (No) or 9 (Unknown), and a second colonoscopy is performed within the cycle to complete the removal of polyps, see Item 9.2 “Final diagnosis” and Item 9.3 “Date of diagnosis” for guidance on how to report histological findings.

EXAMPLE: If all polyps were completely removed: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised skip pattern to include directions: Leave blank if 6.2.06 ≠ 3, 4

ITEM NO / NAME: **6.2.13: Recommended next follow-up procedure within this cycle after 2nd test.**

PURPOSE: To indicate the next recommended procedure following the completion of the second test.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

EXPLANATION: Once the second test is completed, the next recommended procedure to be completed within the screening cycle to rule out cancer, or not, should be reported.

If the next recommended procedure for the client is surgery, 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 (6.3.01, 6.4.01) should be reported. Items 6.3.01 and 6.4.01 will be completed with 0 (None).

If the next test recommended is a screening exam (FOBT or FIT), indicate 8 (None). The new screening test will begin a new CCDE record. Items 6.3.01 and 6.4.01 will be completed with 0 (None).

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	02/06/2006	Add new

ITEM NO / NAME: **6.3.01: 3rd Test provided**

PURPOSE: To indicate the actual third test provided through the program. For the purposes of this study "provided" = "paid for".

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast barium enema (DCBE)

EXPLANATION: Report the next test performed. Only funded colorectal diagnostic tests should be reported in the CCDEs. If a non-funded test is provided (e.g. an MRI), then that test should not be reported in the CCDEs. If the non-funded test is the only additional test performed, then this field should be completed as 0 (None).

This test should match the test reported in 6.2.13, however it is understood that client compliance may dictate that they will not be the same.

If a third test was not performed, indicate 0 (None), and leave items 6.3.03 through 6.3.13 blank.

The third test may not be an FOBT or FIT. These exams are considered screening tests, which would begin a new record.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.02: Date of 3rd test**

PURPOSE: To specify the date of the third test.

LENGTH: 8

TYPE: Date

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

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 of the procedure. 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 2006). This field should not be left completely blank.

EXPLANATION: This field captures the date that the third test was performed.

EXAMPLE: If a colonoscopy was performed on August 1, 2006: 08012006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.03: Provider specialty**

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

LENGTH: 2

TYPE: Numeric, right justify.

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

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
99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the third 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	02/06/2006	Add new

ITEM NO / NAME: **6.3.04: Clinical practice site**

PURPOSE: To report the type of clinical practice for the provider reported in 6.3.03.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Doctor's office
2 = Ambulatory endoscopy/surgery center
3 = Hospital
4 = Health clinic
9 = Unknown

EXPLANATION: This field should report the type of clinical practice for the provider reported in Item 6.3.03 (Provider specialty).

EXAMPLE: If the provider's practice is located in a hospital: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.06: Results of endoscopy or DCBE**

PURPOSE: To specify the results of a sigmoidoscopy, colonoscopy or DCBE, if it was the third test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS:
1 = Normal/negative/diverticulosis/hemorrhoids
2 = Other finding not suggestive of cancer/polyp(s)
3 = Polyp(s)/suspicious for cancer/presumed cancer
4 = No findings/inconclusive
5 = Pending
9 = Unknown

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

Results from an incomplete or inconclusive test should always be coded as 4 (No Findings/inconclusive), regardless if any specific findings were noted. An incomplete test may be due to patient discomfort or distress. Inconclusive findings may be due to obstruction, inadequate preparation and retained fecal material, physician fatigue or cecum not reached. Any specific findings that were noted from an incomplete or inconclusive test should be captured and reported elsewhere in the CCDE, including reporting in Sections 6 “Screening and Diagnostic Tests Provided” and Section 7 “Diagnosis Information for All Polyps/Lesions” on polyps/lesions identified or removed. Another screening test should be recommended following an incomplete or inconclusive test.

EXAMPLE: If result of the DCBE was suspicious for cancer: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the third test performed.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE); 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) can only be reported if the procedure report explicitly states that the bowel preparation was adequate, otherwise report 9 (Unknown).

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the third procedure performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: If the 3rd procedure performed was a colonoscopy, indication of whether the cecum was reached during the procedure should be reported.

The procedure report must explicitly state that the cecum was reached during the colonoscopy in order to report 1 (Yes); otherwise report 9 (Unknown).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.09: Complications of endoscopy or DCBE?**

PURPOSE: To indicate whether there were complications due to the sigmoidoscopy, colonoscopy or DCBE, if it was the third test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No/unknown

EXPLANATION: If Item 6.3.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), indicate whether or not complications occurred from the procedure which required medical attention.

If complications = 1 (Yes), then the complication should be reported on the Adverse Events Reporting form and submitted to the CDC on a quarterly basis, as detailed in the Adverse Events Reporting Form (Appendix E).

If the client is hospitalized because of an immediate complication, please notify your consultation team at CDC with 72 hours of the hospitalization by email. You should then send a completed Adverse Events Report Form to the CDC within five (5) days. Please see the Adverse Events Reporting Form (Appendix E) for further guidance.

EXAMPLE: If rectal bleeding occurred 3 days after a procedure: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.10: Was a biopsy/polypectomy performed during the endoscopy?**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 is 3 (Sigmoidoscopy) or 4 (Colonoscopy); otherwise, it should be blank.

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.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.11: Number of specimens sent to pathology (from endoscopy)**

PURPOSE: To report the actual number of specimens removed during a biopsy or polypectomy, and sent to pathology.

LENGTH: 2

TYPE: Numeric – right justified

SKIP PATTERN: This field should be completed if Item 6.3.01 was 3 (Sigmoidoscopy) or 4 (Colonoscopy) **AND** Item 6.3.10 (Biopsy/polypectomy performed) is 1 (Yes); otherwise, it should be blank.

CONTENTS:
0 = Biopsy performed, no specimens sent
1 = One
2 = Two specimens
…
97 = Ninety-seven
98 = ≥ Ninety-eight
99 = Unknown

EXPLANATION: The actual number of specimens sent to pathology should be acquired and reported. If a biopsy/polypectomy was performed, but no specimens were sent to pathology (e.g. specimen contaminated), code 0 (Biopsy performed, no specimen sent).

When more than 98 specimens are collected during the colonoscopy/sigmoidoscopy, report 98 (≥ 98 specimens).

If it is unknown whether any specimens were sent to pathology, code 99 (Unknown). If the exact number of specimens sent to pathology is unknown, code 99 (Unknown).

This field includes samples removed entirely or in part. If a single polyp is removed piecemeal, report the number of specimens, not the number of polyps.

EXAMPLE: If a biopsy was performed during a colonoscopy and 6 specimens were sent to pathology: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.3.12: Completeness of polyp removal (from colonoscopy).**

PURPOSE: To indicate if polyps were completely removed during the third test, if it was a colonoscopy. Do not complete this field if no polyps were identified.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 = 4 (Colonoscopy) **and** Item 6.3.06 = 3 (Polyps/suspicious for cancer/presumed cancer) **and** Item 7.0 ≠ 0 (No polyps/lesions).

This field should be completed if Item 6.3.01 = 4 (Colonoscopy) **and** Item 6.3.06 = 4 (No findings/inconclusive) **and** Item 7.0 ≠ 0 (No polyps/lesions).

Otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The intent of this field is to report if the colon was cleared of all polyps noted during the colonoscopy. This field should only be completed if the third test performed is a colonoscopy and polyps were identified. Do not complete this field if no polyps were identified.

If 6.3.06 = 3 and 7.0 ≠ 0; or
If 6.3.06 = 4 and 7.0 ≠ 0, then:

- If all polyps noted during colonoscopy were removed, code 1 (Yes)
- If all polyps noted were not removed, code 2 (No)
- If no polyps were seen or suspected, code 9 (Unknown)

If 6.3.06 ≠ 3 or 4 then leave blank.

If this field is coded as 2 (No) or 9 (Unknown), and a second colonoscopy is performed within the cycle to complete the removal of polyps, See Item 9.2 “Final diagnosis” and Item 9.3 “Date of diagnosis” for guidance on how to report histological findings.

EXAMPLE: If all polyps were completely removed: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised skip pattern to include directions: Leave blank if 6.3.06 ≠ 3, 4

ITEM NO / NAME: **6.3.13: Recommended next follow-up procedure within this cycle after 3rd test.**

PURPOSE: To indicate the next recommended procedure following the completion of the third test.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

EXPLANATION: Once the third test is completed, the next recommended procedure to be completed within the screening cycle to rule out cancer, or not, should be reported.

If the next recommended procedure for the client is surgery, 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 (6.4.01) should be reported. Item 6.4.01 will be completed with 0 (None).

If the next test recommended is a screening exam (FOBT or FIT), indicate 8 (None). The new screening test will begin a new CCDE record. Item 6.4.01 will be completed with 0 (None).

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	02/06/2006	Add new

ITEM NO / NAME: **6.4.01: 4th Test provided**

PURPOSE: To indicate the actual fourth test provided through the program. For the purposes of this study "provided" = "paid for".

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast barium enema (DCBE)

EXPLANATION: Report the next test provided. Only funded colorectal diagnostic tests should be reported in the CCDEs. If a non-funded test is provided (e.g. an MRI), then that test should not be reported in the CCDEs. If the non-funded test is the only additional test performed, then this field should be completed as 0 (None).

This test should match the test reported in 6.3.13, however it is understood that client compliance may dictate that they will not be the same.

If a fourth test was not performed, indicate 0 (None), and leave items 6.4.03 through 6.4.13 blank.

The fourth test may not be an FOBT or FIT. These exams are considered screening tests, which would begin a new record.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.02: Date of 4th test**

PURPOSE: To specify the date of the fourth test.

LENGTH: 8

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 of the procedure. 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 2006). This field should not be left completely blank.

EXPLANATION: This field should be completed if Item 6.4.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE); otherwise leave blank.

EXAMPLE: If a colonoscopy was performed on August 1, 2006: 08012006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.03: Provider specialty**

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

LENGTH: 2

TYPE: Numeric, right justify.

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

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
99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the fourth 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	02/06/2006	Add new

ITEM NO / NAME: **6.4.04: Clinical practice site**

PURPOSE: To report the type of clinical practice for the provider reported in 6.4.03.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Doctor's office
2 = Ambulatory endoscopy/surgery center
3 = Hospital
4 = Health clinic
9 = Unknown

EXPLANATION: This field should report the type of clinical practice for the provider reported in Item 6.4.03 (Provider specialty).

EXAMPLE: If the provider's practice is located in a hospital: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.06: Results of endoscopy or DCBE**

PURPOSE: To specify the results of a sigmoidoscopy, colonoscopy or DCBE, if it was the fourth test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS:
1 = Normal/negative/diverticulosis/hemorrhoids
2 = Other finding not suggestive of cancer/polyp(s)
3 = Polyp(s)/suspicious for cancer/presumed cancer
4 = No findings/inconclusive
5 = Pending
9 = Unknown

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

Results from an incomplete or inconclusive test should always be coded as 4 (No Findings/inconclusive), regardless if any specific findings were noted. An incomplete test may be due to patient discomfort or distress. Inconclusive findings may be due to obstruction, inadequate preparation and retained fecal material, physician fatigue or cecum not reached. Any specific findings that were noted from an incomplete or inconclusive test should be captured and reported elsewhere in the CCDE, including reporting in Sections 6 “Screening and Diagnostic Tests Provided” and Section 7 “Diagnosis Information for All Polyps/Lesions” on polyps/lesions identified or removed. Another screening test should be recommended following an incomplete or inconclusive test.

EXAMPLE: If result of the DCBE was suspicious for cancer: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the fourth test performed.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE); 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) can only be reported if the procedure report explicitly states that the bowel preparation was adequate, otherwise report 9 (Unknown).

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	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, if it was the fourth procedure performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: If the 4th procedure performed was a colonoscopy, indication of whether the cecum was reached during the procedure should be reported.

The procedure report must explicitly state that the cecum was reached during the colonoscopy in order to report 1 (Yes); otherwise report 9 (Unknown).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.09: Complications of endoscopy or DCBE.**

PURPOSE: To indicate whether there were complications due to the sigmoidoscopy, colonoscopy or DCBE, if it was the fourth test performed.

LENGTH: 1

TYPE: Numeric

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

CONTENTS: 1 = Yes
2 = No/unknown

EXPLANATION: If Item 6.4.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), indicate whether or not complications occurred from the procedure which required medical attention.

If complications = 1 (Yes), then the complication should be reported on the Adverse Events Reporting form and submitted to the CDC on a quarterly basis, as detailed in the Adverse Events Reporting Form (Appendix E).

If the client is hospitalized because of an immediate complication, please notify your consultation team at CDC with 72 hours of the hospitalization by email. You should then send a completed Adverse Events Report Form to the CDC within five (5) days. Please see the Adverse Events Reporting Form (Appendix E) for further guidance.

EXAMPLE: If rectal bleeding occurred 3 days after a procedure: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.10: Was a biopsy/polypectomy performed during the endoscopy?**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 is 3 (Sigmoidoscopy) or 4 (Colonoscopy); otherwise, it should be blank.

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.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.11: Number of specimens sent to pathology (from endoscopy)**

PURPOSE: To report the actual number of specimens removed during a biopsy or polypectomy, and sent to pathology.

LENGTH: 2

TYPE: Numeric – right justified

SKIP PATTERN: This field should be completed if Item 6.4.01 was 3 (Sigmoidoscopy) or 4 (Colonoscopy) **AND** Item 6.4.10 (Biopsy/polypectomy performed) is 1 (Yes); otherwise, it should be blank.

CONTENTS:
0 = Biopsy performed, no specimens sent
1 = One
2 = Two specimens
…
97 = Ninety-seven
98 = ≥ Ninety-eight
99 = Unknown

EXPLANATION: The actual number of specimens sent to pathology should be acquired and reported. If a biopsy/polypectomy was performed, but no specimens were sent to pathology (e.g. specimen contaminated), code 0 (Biopsy performed, no specimen sent).

When more than 98 specimens are collected during the colonoscopy/sigmoidoscopy, report 98 (≥ 98 specimens).

If it is unknown whether any specimens were sent to pathology, code 99 (Unknown). If the exact number of specimens sent to pathology is unknown, code 99 (Unknown).

This field includes samples removed entirely or in part. If a single polyp is removed piecemeal, report the number of specimens, not the number of polyps.

EXAMPLE: If a biopsy was performed during a colonoscopy and 6 specimens were sent to pathology: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **6.4.12: Completeness of polyp removal (from colonoscopy).**

PURPOSE: To indicate if polyps were completely removed during the fourth test, if it was a colonoscopy. Do not complete this field if no polyps were identified.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 = 4 (Colonoscopy) **and** Item 6.4.06 = 3 (Polyps/suspicious for cancer/presumed cancer) **and** Item 7.0 ≠ 0 (No polyps/lesions).

This field should be completed if Item 6.4.01 = 4 (Colonoscopy) **and** Item 6.4.06 = 4 (No findings/inconclusive) **and** Item 7.0 ≠ 0 (No polyps/lesions).

Otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The intent of this field is to report if the colon was cleared of all polyps noted during the colonoscopy. This field should only be completed if the fourth test performed is a colonoscopy and polyps were identified. Do not complete this field if no polyps were identified.

If 6.4.06 = 3 and 7.0 ≠ 0; or
If 6.4.06 = 4 and 7.0 ≠ 0, then:

- If all polyps noted during colonoscopy were removed, code 1 (Yes)
- If all polyps noted were not removed, code 2 (No)
- If no polyps were seen or suspected, code 9 (Unknown)

If 6.4.06 ≠ 3 or 4 then leave blank.

If this field is coded as 2 (No) or 9 (Unknown), and a second colonoscopy is performed within the cycle to complete the removal of polyps, See Item 9.2 “Final diagnosis” and Item 9.3 “Date of diagnosis” for guidance on how to report histological findings.

EXAMPLE: If all polyps were completely removed: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised skip pattern to include directions: Leave blank if 6.4.06 ≠ 3, 4

ITEM NO / NAME: **6.4.13: Recommended next follow-up procedure within this cycle after 4th test.**

PURPOSE: To indicate the next recommended procedure following the completion of the fourth test.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

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

If the next test recommended is a screening exam (FOBT/FIT), indicate 8 (None). The new screening test will begin a new CCDE record.

EXAMPLE: If no further diagnostic tests are recommended: 8

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **7.0: Total number of polyps/lesions**

PURPOSE: To indicate the total number of unique polyps/lesions identified through all colonoscopies and/or sigmoidoscopies during the client's "cycle". Do not report specimens from surgical resections.

LENGTH: 2

TYPE: Numeric - right justify

SKIP PATTERN: This field should always be completed.

CONTENTS:
0 = No polyps/lesions
1 = One polyp/lesion
2 = Two polyps/lesions
…
97 = ≥ Ninety-seven polyps/lesions
98 = At least one polyp/lesion, exact number not known
99 = Unknown

EXPLANATION: The actual number of polyps or lesions should be acquired and reported. If a colonoscopy or sigmoidoscopy was performed, but no polyps or lesions were noted, code 0 (No polyps or lesions).

When more than 97 polyps or lesions are collected during the colonoscopy/sigmoidoscopy, report 97 (≥ 97 polyps/lesions).

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

If it is unknown whether any polyps or lesions were seen, code 99 (Unknown).

EXAMPLE: If 8 polyps/lesions are noted: 8

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **7.01.1: Location of 1st polyp/lesion***

PURPOSE: To report the location of the polyp or lesion reported in the endoscopy/pathology report.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.1, 7.03.1, …, 7.15.1). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 location fields. The rest should be left blank.

LENGTH: 2

TYPE: Numeric - right justify

SKIP PATTERN: If 7.0 "Total number of polyps/lesions" is reported as 1 through 98, this field should be completed. Otherwise, leave blank.

CONTENTS:

1 = Rectum
2 = Rectosigmoid junction
3 = Sigmoid
4 = Descending
5 = Splenic flexure
6 = Transverse
7 = Hepatic flexure
8 = Ascending
9 = Cecum
10 = Appendix
11 = Overlapping lesions
99 = Unknown

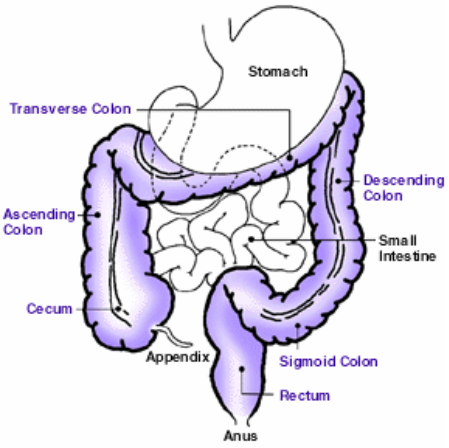


Diagram of the Colon and Rectum

EXPLANATION: The location of the polyp/lesion is generally found on the endoscopy report. The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and the pathology report in order to "match up" the correct polyps/lesions.

Programs should encourage their endoscopists to report the anatomic location of each polyp, rather than distance in centimeters from the anal verge. If the only information given is the distance, indicate 99 (Unknown).

If the location for a lesion is not reported, indicate 99 (Unknown).

EXAMPLE: If a lesion was noted on the transverse colon: 6

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **7.01.2: Size of 1st polyp/lesion***

PURPOSE: To report the size of the polyp or lesion reported in the endoscopy/pathology report.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.2, 7.03.2, …, 7.15.2). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 size fields. The rest should be left blank.

LENGTH: 2

TYPE: Numeric – right justify

SKIP PATTERN: If Item 7.0 "Total number of polyps/lesions" is 0 (No polyps), then this field should be left blank.

CONTENTS:
0 = < 1 mm
1 = One mm
2 = Two mm
…
98 = ≥ 98 mm
99 = Unknown

EXPLANATION: Report the diameter of the polyp lesion in millimeters (mm) 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.

The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and the pathology report in order to "match up" the correct polyps.

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 14 mm: 14

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **7.01.3.1: Procedure for removal of 1st polyp/lesion (1)***

PURPOSE: To report the procedure performed during the removal of the polyp/lesion reported in 7.01.1.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.3.1, 7.03.3.1, …, 7.15.3.1). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 sets of procedure fields. The rest should be left blank.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 7.0 "Total number of polyps/lesions" is 0 (No polyps), then this field should be left blank.

CONTENTS:
1 = Snare polypectomy
2 = Hot biopsy forceps or cautery
3 = Cold biopsy
4 = Ablation
5 = Submucosal injection
6 = Control of bleeding
7 = Not biopsied or removed
9 = Unknown

EXPLANATION: For each polyp/lesion reported in 7.01 through 7.15, up to three (3) procedures may be reported. There is no specification as to the order in which the procedures are reported.

If the polyp/lesion identified on the endoscopy report was not biopsied or removed, code 7 (Not biopsied or removed) in Item 7.01.3.1; Items 7.01.3.2 and 7.01.3.3 should be left blank.

EXAMPLE: If a cold biopsy was performed: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **7.01.3.2: Procedure for removal of 1st polyp/lesion (2)***

PURPOSE: To report a second procedure performed during the removal of the polyp/lesion reported in 7.01.1.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.3.2, 7.03.3.2, …, 7.15.3.2). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 sets of procedure fields. The rest should be left blank.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 7.0 "Total number of polyps/lesions" is 0 (No polyps), then this field should be left blank. If Item 7.01.3.1 "Procedure for removal of the 1st polyp/lesion (1)" is reported as 7 (Not biopsied or removed), then this field should be left blank.

CONTENTS:
1 = Snare polypectomy
2 = Hot biopsy forceps or cautery
3 = Cold biopsy
4 = Ablation
5 = Submucosal injection
6 = Control of bleeding
9 = Unknown

EXPLANATION: For each polyp/lesion reported in 7.01 through 7.15, up to three (3) procedures may be reported. There is no specification as to the order in which the procedures are reported.

If more than one procedure was performed during the removal of the polyp/lesion reported in 7.01.1, then report the second procedure here.

EXAMPLE: If a cold biopsy was performed: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Removed response '7 – Not biopsied'

ITEM NO / NAME: **7.01.3.3: Procedure for removal of 1st polyp/lesion (3)***

PURPOSE: To report a third procedure performed during the removal of the polyp/lesion reported in 7.01.1.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.3.3, 7.03.3.3, …, 7.15.3.3). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 sets of procedure fields. The rest should be left blank.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 7.0 "Total number of polyps/lesions" is 0 (No polyps), then this field should be left blank. If Item 7.01.3.1 "Procedure for removal of 1st polyp/lesion (1)" is reported as 7 (Not biopsied or removed), then this field should be left blank.

CONTENTS:
1 = Snare polypectomy
2 = Hot biopsy forceps or cautery
3 = Cold biopsy
4 = Ablation
5 = Submucosal injection
6 = Control of bleeding
9 = Unknown

EXPLANATION: For each polyp/lesion reported in 7.01 through 7.15, up to three (3) procedures may be reported. There is no specification as to the order in which the procedures are reported.

If more than two procedures were performed during the removal of the polyp/lesion reported in 7.01.1, then report the third procedure here.

EXAMPLE: If a cold biopsy was performed: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Removed response '7 – Not biopsied'

ITEM NO / NAME: **7.01.4: Was 1st polyp/lesion completely removed?***

PURPOSE: Indicate whether the polyp/lesion reported in 7.01.1 was completely removed.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.4, 7.03.4, …, 7.15.4). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 "removed" fields. The rest should be left blank.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 7.0 "Total number of polyps/lesions" is 0 (No polyps/lesions), or Item 7.01.3.1 "Procedure for removal of 1st polyp/lesion (1)" is 7 (Not biopsied or removed), then this field should be left blank; otherwise this item should be completed.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: For each polyp/lesion reported in 7.01 through 7.15, indicate if that polyp/lesion was completely removed.

EXAMPLE: If the polyp/lesion was completely removed: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **7.01.5: Histology of 1st polyp/lesion***

PURPOSE: Report the histology of the polyp/lesion reported in 7.01.1.

*NOTE: This Item is repeated for polyps/lesions 1 through 15 (Items 7.02.5, 7.03.5, …, 7.15.5). For brevity, it will only be listed once. Up to 15 responses (if needed) should use the values listed here. For example: if Item 7.0 is reported as 5, you would only complete the first 5 histology fields. The rest should be left blank.

LENGTH: 2

TYPE: Numeric - right justify

SKIP PATTERN: If Item 7.0 "Total number of polyps/lesions" is 0 (No polyps/lesions), or Item 7.01.3.1 "Procedure for removal of 1st polyp/lesion (1)" is 7 (Not biopsied or removed), then this field should be left blank; otherwise this item should be completed.

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 = Carcinoma, other
99 = Unknown/other lesions ablated, not retrieved or confirmed

EXPLANATION: For each polyp/lesion reported in 7.01 through 7.15, indicate the histology for each polyp/lesion that was removed. All histologies should be reviewed and a final diagnosis recorded in Item 9.2 "Final Diagnosis".

If the polyp/lesion was submitted to pathology as a piecemeal fragments and more than one histological diagnosis was reported, report the worst. The response options are listed in general order of severity.

EXAMPLE: If the histology for the polyp/lesion removed is carcinoma: 11

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

The following table was designed to assist programs 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 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=Carcinoma, 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: **8.1: Histology from surgical resection**

PURPOSE: Report the worst histopathological diagnosis made from the surgical resection reported in 6.x.13 (where x is either the 1st, 2nd, 3rd or 4th test reported in section 6) if the client underwent surgery.

LENGTH: 2

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.13 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 = Carcinoma, 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 table following Item 7.01.5 “Histology of 1st polyp/lesion”.

EXPLANATION: Most often, if a polyp is detected on colonoscopy, it can be removed during the colonoscopy and the client will not need surgery. 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 entirety during the colonoscopy, but instead will be removed during a subsequent surgery.

This is the worst histopathological diagnosis made from surgical resection. The response options are listed in general order of severity. If more than one surgery was performed in order to obtain a final diagnosis (Item 9.2), report the worst histopathological diagnosis made from the surgical resection which provided the final diagnosis.

If surgery was recommended in 6.x.13 “Recommended next follow-up procedure…”, but was not completed, code 0 (Surgery recommended but not performed). If no surgery was recommended in these fields, 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 all of the polyp/lesion histologies in Item 9.2 “Final Diagnosis”.

EXAMPLE: If the histology for the polyp/lesion removed is carcinoma: 11

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **8.2: Date surgery performed**

PURPOSE: Indicate the date of the surgical resection.

LENGTH: 8

TYPE: Date

SKIP PATTERN: If Item 6.x.13 is 4 (Surgery to complete diagnosis), then this field should be completed; otherwise, leave blank.

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 of the procedure. 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 2006). This field should not be left completely blank.

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, report the date of the surgery which provided the final diagnosis (Item 9.2).

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

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

EXAMPLE: If a surgery was performed on August 1, 2006: 08012006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **9.1: Status of diagnosis**

PURPOSE: To specify the status of final diagnosis.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should always be completed

CONTENTS:
1 = Complete (final diagnosis made)
2 = Pending final diagnosis
3 = Verbal/written refusal for any test needed to obtain a final diagnosis
4 = Client moved before final diagnosis was made
5 = Client died before final diagnosis was made
6 = Lost to follow-up
9 = Unknown

EXPLANATION: After all screening and diagnostic tests were performed/offered to the client, report the status of the client's care.

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

If a client's tests have not yet been completed, and no final diagnosis has been determined, but it is time to submit data to the CDC, the status of diagnosis should be reported as 2 (Pending). These records should be monitored so that as the client's tests are completed, and a final diagnosis is made, this field should be updated to the appropriate status of diagnosis.

If the client severs his or her relationship with the program and receives further screening or diagnostic tests outside of the program report the status of diagnosis as 3 (Refused).

All programs must have a policy in place to define how much time can elapse before the client is deemed 3 (Refused) or 6 (Lost to follow-up).

If the only test provided to the client was an FOBT/FIT kit, and it was not returned, report the status of diagnosis as 9 (Unknown).

EXAMPLE: If status of client's care for the current CCDE record is complete: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that categories 3 – 6 should have an administrative close-out date reported in Item 9.3)Date of Diagnosis)

ITEM NO / NAME: **9.2: Final diagnosis**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 9.1 “Status of final diagnosis” is 1 (Complete), then this field should be completed; otherwise, leave blank.

CONTENTS: 1 = Normal/negative
2 = Polyp, no high grade dysplasia[2]
3 = Polyp with high grade dysplasia[1, 2]
4 = Cancer[1, 2]

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

If the only test performed in the screening cycle (Items 6.1.01) was an FOBT or FIT that was negative, then complete this field as 1 (Normal/negative).

[1]Section 10 Diagnosis Information for Cancer/High Grade Dysplasia, must be completed if Item 9.2 “Final Diagnosis” is 3 (Polyp with high grade dysplasia) or 4 (Cancer).

[2]Section 11 Treatment Information, must be completed if Item 9.2 “Final Diagnosis” is 2 (Polyp, no high grade dysplasia), 3 (Polyp with high grade dysplasia) or 4 (Cancer).

EXAMPLE: If the final diagnosis is Normal: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **9.3: Date of diagnosis**

PURPOSE: To specify the date of final diagnosis.

LENGTH: 8

TYPE: Date

SKIP PATTERN: This field should be completed if Item 9.1 “Status of Diagnosis” is 1 (Complete), 3 (Refused), 4 (Moved), 5 (Died) or 6 (Lost); otherwise, it should be blank.

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 of the biopsy. 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 2006).

EXPLANATION: This field should indicate the date of the final pathology report or 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 was the first occurrence of a diagnosis of cancer (or worst histology) as the date of final diagnosis.

If the client refused, or was determined to be lost to follow-up or deceased, an administrative close-out date should be reported here. If client moved before all tests were completed and a final diagnosis obtained, an administrative close-out date should be used as the date of diagnosis.

EXAMPLE: If the date of the final pathology report is July 15, 2006: 07152006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **9.4: Recommended screening or surveillance test for next cycle**

PURPOSE: To indicate the next recommended procedure to the client at the end of the "cycle".

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 9.1 "Status of diagnosis" is 1 (Complete), this field should always be completed; otherwise leave blank.

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

EXPLANATION: Report the next screening or surveillance test recommended to the client at the end of the cycle. This can be 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, then code this as 6 (None).

EXAMPLE: If a FOBT is recommended as the next screening procedure: 1

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **9.5: Indication for screening or surveillance test for next cycle**

PURPOSE: To indicate the next recommended test made to the client.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 9.1 “Status of diagnosis” is 1 (Complete), this field should always be completed; otherwise leave blank.

If Item 9.4 “Recommended screening or surveillance test for next cycle” is 6 (None) or 9 (Unknown), leave blank.

CONTENTS: 1 = Screening
2 = Surveillance after a positive colonoscopy and/or surgery

EXPLANATION: If a test was recommended in Item 9.4, then the indication for this test (screening vs. surveillance) should be reported.

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

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised skip pattern to include directions: Leave blank if 9.1≠ 1

ITEM NO / NAME: **9.6: Number of months before screening or surveillance test for next cycle.**

PURPOSE: To indicate the recommended interval between Item 9.3 “Date of final diagnosis” and next recommended screening/surveillance test.

LENGTH: 3

TYPE: Numeric - right justify

SKIP PATTERN: If Item 9.1 “Status of diagnosis” is 1 (Complete) AND Item 9.4 “Recommended screening or surveillance test for next cycle” has a reported value of 1 – 5, then this field should be completed; otherwise leave blank.

CONTENTS:
12 = Twelve months
13 = Thirteen months
…
180 = One hundred eighty months
999 = Unknown

EXPLANATION: If a test was recommended in Item 9.4, then the report the interval between the final diagnosis and the next test date. If Item 9.4 is reported as 6 (None) or 9 (Unknown), this field should be left blank.

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised skip pattern to include directions: Leave blank if 9.1≠ 1

ITEM NO / NAME: **10.1: Stage at diagnosis/treatment**

PURPOSE: To report the stage for a final diagnosis of 3 (High grade dysplasia) or 4 (Cancer), as reported in Item 9.2.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should only be completed if Item 9.2 “Final Diagnosis” is 3 (High grade dysplasia) or 4 (Cancer); otherwise, leave blank.

CONTENTS: 0 = Stage 0 (high grade dysplasia, severe dysplasia, or in situ)
1 = Stage I
2 = Stage II
3 = Stage III
4 = Stage IV
9 = Unknown/unstaged

EXPLANATION: If Item 9.2 “Final Diagnosis” indicates 3 (Polyp with High grade dysplasia) or 4 (Cancer) was found, then the AJCC cancer stage used as a basis for clinical decisions should be reported. This can be based on clinical and/or pathological information.

EXAMPLE: If the Stage at Diagnosis for cancer 1 is Stage II: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **10.2: Recurrent cancers**

PURPOSE: Indicate if the cancer reported in Item 9.2 “Final Diagnosis” is a new primary or a recurrent cancer.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is 4 (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 9.2 is a new colorectal primary cancer, report 1 (New CRC primary). If the cancer is a metastasis of a non-colorectal primary, then report as 3 (Non-CRC primary).

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

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **10.3: Registry linkage status**

PURPOSE: Indicate if the diagnosis for this client reported in Item 9.2 “Final Diagnosis” has been linked to the state cancer registry.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should only be completed if Item 9.2 “Final Diagnosis” was reported as 3 (High grade dysplasia) or 4 (Cancer); otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

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

EXPLANATION: A final diagnosis of high grade dysplasia or cancer should be linked with the program’s state cancer registry. At the time of each CCDE submission, this field should be updated to indicate if the record has been linked or not.

If during the linkage process a client identified as having high-grade dysplasia or cancer in the CCDEs is NOT identified in the state cancer registry (based on matching algorithm guidelines being 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 cancer registry: 2

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **10.4: Registry primary site**

PURPOSE: Report the primary site obtained from the cancer registry.

LENGTH: 4

TYPE: Alphanumeric - left justify

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is reported as 3 (High grade dysplasia) or 4 (Cancer), and Item 10.3 “Registry linkage status” is reported as 2 (Linked, matched), then this field should be completed; otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

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

Chapter 4 (Registry Linkage) of this Data User’s Manual 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 10.3 “Registry linkage status” is reported as 2 (Linked and 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	02/06/2006	Add new

ITEM NO / NAME: **10.5: Registry CS-derived SS2000**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 9.2 "Final Diagnosis" is reported as 3 (High grade dysplasia) or 4 (Cancer), and Item 10.3 "Registry linkage status" is reported as 2 (Linked, matched), then this field should be completed; otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

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 10.3 "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/cstage/csmanualpart1.pdf for general instructions provided to cancer registry sites on reporting this information.

Chapter 4 (Registry Linkage) of this Data User's Manual 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	02/06/2006	Add new

ITEM NO / NAME: **10.6: Registry CS-derived AJCC stage group**

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

LENGTH: 2

TYPE: Numeric

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is reported as 3 (High grade dysplasia) or 4 (Cancer), and Item 10.3 “Registry linkage status” is reported as 2 (Linked, matched), then this field should be completed; otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

CONTENTS: Valid values for CS-derived AJCC stage include: 00-02, 10-24, 30-43, 50-63, 70-74, 88, 90, 99.

NOTE: See Chapter 4 (Registry Linkage) of this Data User’s Manual for a complete list of all available codes and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 10.3 “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: 30

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **10.7: Registry CS extension**

PURPOSE: Indicate the extension of disease, as reported by the cancer registry.

LENGTH: 2

TYPE: Numeric

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is reported as 3 (High grade dysplasia) or 4 (Cancer), and Item 10.3 “Registry linkage status” is reported as 2 (Linked, matched), then this field should be completed; otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

CONTENTS: Valid values for CS extension include: 00, 05, 10-16, 20, 30, 40, 42, 45, 46, 50, 55, 57, 60, 65, 66, 70, 75, 80, 95, 99.

NOTE: See Chapter 4 (Registry Linkage) of this Data User’s Manual for a complete list of all available codes and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 10.3 “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”: 30

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **10.8: Registry CS lymph nodes**

PURPOSE: Indicate the lymph node involvement, as reported by the cancer registry.

LENGTH: 2

TYPE: Numeric

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is reported as 3 (High grade dysplasia) or 4 (Cancer), and Item 10.3 “Registry linkage status” is reported as 2 (Linked, matched), then this field should be completed; otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

CONTENTS: Valid values for CS lymph nodes are 00, 10, 20, 30, 80, and 99.

NOTE: See Chapter 4 (Registry Linkage) of this Data User’s Manual for a complete list of all available codes and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 10.3 “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: 20

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **10.9: Registry CS mets at diagnosis**

PURPOSE: Indicate any distant metastases at the time of diagnosis, as reported by the cancer registry.

LENGTH: 2

TYPE: Numeric

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is reported as 3 (High grade dysplasia) or 4 (Cancer), and Item 10.3 “Registry linkage status” is reported as 2 (Linked, matched), then this field should be completed; otherwise leave blank.

NOTE: The skip pattern for this field may be modified once a finalized Registry linkage protocol has been developed.

CONTENTS:
00 = No; none
08 = Superior mesenteric lymph node(s)
10 = Distant lymph node(s)
11 = Rectosigmoid
Intermal iliac (hypogastric)
Obturator
12 = Other distant lymph node(s), including external iliac or common iliac
40 = Distant metastases except code 10-12
Distant metastasis, NOS
Carcinomatosis
50 = (40) + (10); or (40) + any of [(10) to (12)]
99 = Unknown; distant metastasis cannot be assessed; not stated in patient record

NOTE: See Chapter 4 (Registry Linkage) of this Data User’s Manual for a complete list of all available codes and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 10.3 “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	02/06/2006	Add new

ITEM NO / NAME: **11.1: Status of treatment**

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

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: If Item 9.2 “Final Diagnosis” is reported as 2 (Polyp, no high grade dysplasia), 3 (High grade dysplasia) or 4 (Cancer), then this field should be completed; otherwise leave blank.

CONTENTS:
1 = Treatment started and/or completed
2 = Treatment pending
3 = Treatment not indicated
4 = Verbal/written refusal of treatment*
5 = Client moved
6 = Deceased
7 = Lost to follow-up*
9 = Unknown

EXPLANATION: For the purpose of this demonstration 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 instead of standard treatment, this field should be coded as 4 (Verbal/written refusal).

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 when the program 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.

A colonoscopy 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 Provided section (6.x.01), Treatment would be 1 (Started), and Item 11.2 “Date of Treatment” will be the day of the procedure. In this instance, Item 9.3 “Date of Diagnosis” and Item 11.2 “Date of Treatment” would be the same.

In the circumstance that surgical removal of a polyp or cancer is complete, with no evidence of spread, surgery would also be considered both diagnostic and the only required treatment. In this case, the date of surgery should be reported in the Diagnosis Information for Surgeries Performed section (Item 8.2), Treatment would be 1 (Started), and Item 11.2 "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 program must have a policy in place to define how much time can elapse before the client is deemed 4 (Refused) or 7 (Lost to follow-up).

EXAMPLE: If client refused treatment: 4

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new
1.01	04/26/2006	Revised to indicate that categories 3 – 7 should have an administrative close-out date reported in Item 11.2 (Date of Treatment)

ITEM NO / NAME: **11.2: Date of treatment**

PURPOSE: To report the date treatment began.

LENGTH: 8

TYPE: Date

SKIP PATTERN: If Item 11.1 “Status of treatment” is 2 (Pending) or 9 (Unknown), this field may be blank; otherwise it must 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 of the biopsy. 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 2006).

EXPLANATION: If Item 11.1 “Status of Treatment” is 1 (Started), then complete with the date the treatment began.

The fact that a client is referred for standard treatment is NOT sufficient confirmation that treatment has been started. A client should be classified as having started treatment when the program 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.

A colonoscopy 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 Provided section (6.x.01), Treatment would be 1 (Started), and Item 11.2 “Date of Treatment” will be the day of the procedure. In this instance, Item 9.3 “Date of Diagnosis” and Item 11.2 “Date of Treatment” would be the same.

Surgery may also be considered both diagnostic and the only required treatment. In this case, the date of surgery should be reported in the Diagnosis Information for Surgeries Performed section (Item 8.2), Item 11.1 “Status of Treatment” would be 1 (Started), and “Date of Treatment” will be the day of the surgery.

If any additional treatment beyond a polypectomy or surgery is required, 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 program must have a policy in place to define how much time can elapse before the client is deemed to be “Refused” or “Lost to follow-up”

EXAMPLE: Client began chemotherapy on December 15, 2006: 12152006

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

ITEM NO / NAME: **11.3: Who paid for treatment**

PURPOSE: To report primary funding source for the treatment.

LENGTH: 1

TYPE: Numeric

SKIP PATTERN: This field should only be completed if Item 11.1 is 1 (Treatment Started); otherwise, leave blank.

CONTENTS:
1 = Medicaid
2 = Other, state
3 = Medicare
4 = Self-pay (by client)
5 = Charity care/uncompensated
6 = Other
9 = Unknown

EXPLANATION: If Item 11.1 “Status of Treatment” indicates that treatment was started, then the primary funding source for the treatment should be reported.

If funding for treatment comes from multiple sources, report the most significant contributor to the funding cost.

A colonoscopy 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 funding source would be the CDC which should be reported as 6 (Other).

Surgery may also be considered both diagnostic and the only required treatment, which is funded by CDC. In these cases, indicate 6 (Other).

EXAMPLE: Medicare funds are used to cover treatment: 3

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

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

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

LENGTH: 3

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

EXPLANATION: As the demonstration 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.

When a change in CCDE versions occurs, Item 12.1 should not be changed to reflect the new version, but continue to indicate the version in which the record was originally collected.

EXAMPLE: Clinical data for a client was collected in March 2006: 100.

REVISION HISTORY:

CCDE version	Date of revision	Type of revision
1.00	02/06/2006	Add new

APPENDIX C

CCDE DATA DEFINITION TABLE

Table of Contents:

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
1. Program and Enrollment Data – Complete for each CCDE record						
1.1	**Program** *Unique identifier for each program.*	3	1	3	001 = Baltimore, MD 002 = St. Louis, MO 003 = State of NE 004 = Stony Brook, NY 005 = Seattle and King County, WA	Valid code for your program.
1.2	**Date of eligibility** *The date that the client was determined to be eligible to be screened in the program. This could be the date of the initial interview or the date that an enrollment form was filled out.*	8	4	11	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
1.3.1	**Knowledge of program (1)** *Indicates how client learned about the program.*	2	12	13	1 = Doctor 2 = Other health care provider 3 = NBCCEDP 4 = Family member 5 = Friend 6 = Radio 7 = Television 8 = Magazine article 9 = Newspaper 10 = Mailing/flyer 11 = Community event 12 = Other **Right justify**	Range check.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
1.3.2	**Knowledge of program (2)** *Indicates how client learned about the program.* *Use this field if client indicates that he/she learned about the program from more than one source.*	2	14	15	1 = Doctor 2 = Other health care provider 3 = NBCCEDP 4 = Family member 5 = Friend 6 = Radio 7 = Television 8 = Magazine article 9 = Newspaper 10 = Mailing/flyer 11 = Community event 12 = Other **Right justify**	Range check.
1.3.3	**Knowledge of program (3)** *Indicates how client learned about the program.* *Use this field if client indicates that he/she learned about the program from more than two sources.*	2	16	17	1 = Doctor 2 = Other health care provider 3 = NBCCEDP 4 = Family member 5 = Friend 6 = Radio 7 = Television 8 = Magazine article 9 = Newspaper 10 = Mailing/flyer 11 = Community event 12 = Other **Right justify**	Range check.
1.3.4	**Knowledge of program other text field**	25	18	42	If "Knowledge of program" = 12, then enter the description in free text format. **Alphanumeric, left justify**	If 1.3.1, 1.3.2 or 1.3.3 = 12, this field should be completed. Otherwise, leave blank.
	Reserved for future use	10	43	52		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
2. Client and Record Identification- Complete for each CCDE record						
2.1	**Client identifier** *System generated ID for each client and will be consistent for client throughout database.*	15	53	67	If Social Security Number (SSN) is used, it must be encoded. The ID number should be unique and constant for each client in order to track the client over time. This field should not contain any identifiable information, including partial names or dates. **Alphanumeric (no special symbols), left justify** **Alphabetic characters must be entered consistently in uppercase or lowercase for all records for each client.**	
2.2	**Record identifier** *Each CCDE record identifies a unique CRC "cycle" for a client. A client can have multiple "cycles".*	6	68	73	This field will be used to uniquely identify one record among many for a client. This can be a visit date or a sequential record number. **Numeric, right justify**	
	Reserved for future use	10	74	83		Leave blank.
3. Demographic Information – Complete for each CCDE record, and MUST be self-reported by client						
3.1	**Date of birth** *Date of birth for the client.*	8	84	91	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
3.2	**Gender** *Indicates gender of client.*	1	92	92	1 = Male 2 = Female 9 = Other/unknown	Range check.
3.3	**Hispanic or Latino origin** *Indicates self-reported Hispanic or Latino origin of client.*	1	93	93	1 = Yes 2 = No 9 = Unknown/missing	Range check.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
3.4.1	**Race 1** *The first of five (5) race fields used to capture the self-reported race(s) of a client.*	1	94	94	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native 9 = Unknown *Note: Racial groups are OMB-defined. No primary race is collected. Race 1 has no significance over Race 2-5, and may simply be the first race mentioned.*	Range check. This field should be populated first. If a client self-identifies more than one race, then each race identified should be reported in a separate race field.
3.4.2	**Race 2** *Complete field if client self-identifies more than one race.*	1	95	95	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check. This field should be left blank, unless the client reports more than one race.
3.4.3	**Race 3** *Complete field if client self-identifies more than two races.*	1	96	96	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check. This field should be left blank, unless the client reports more than two races.
3.4.4	**Race 4** *Complete field if client self-identifies more than three races.*	1	97	97	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check. This field should be left blank, unless the client reports more than three races.
3.4.5	**Race 5** *Complete field if client self-identifies more than four races.*	1	98	98	1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian or Other Pacific Islander 5 = American Indian or Alaska Native	Range check. This field should be left blank, unless the client reports more than four races.
3.5	**State of residence** *Client's state of residence*.	2	99	100	2-digit FIPS code (If unknown, blank fill) **Right justify**	Valid FIPS code for state.
3.6	**County of residence** *Client's county of residence.*	3	101	103	3-digit FIPS code (If unknown, blank fill) **Right justify**	Valid FIPS county code for state in 3.5.
	Reserved for future use	10	104	113		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
4. Screening History – Complete for each CCDE record. This information can be self-reported, or can come from information documented in the client's medical record (preferred).						
4.1.1	**Previous take-home CRC fecal test (FOBT/FIT)** *Information on most recent previous take-home CRC fecal testing (FOBT/FIT).*	1	114	114	1 = Yes 2 = No 9 = Unknown	Range check.
4.1.2	**Previous take-home CRC fecal test date** *Most recent date for previous take-home CRC fecal test indicated in 4.1.1. This can be any date that the client remembers.*	6	115	120	MMYYYY *If just the year is known, blank fill the month (e.g., 2006).*	If 4.1.1 = 1, then "MMYYYY" or "YYYY". Leave blank if 4.1.1 = 2, 9
4.1.3	**Previous take-home CRC fecal test result** *Result of most recent previous take-home CRC fecal test indicated in 4.1.1.*	1	121	121	1 = Normal/negative test 2 = Abnormal/positive test result 9 = Unknown	Range check. Leave blank if 4.1.1 = 2, 9
4.2.1	**Previous sigmoidoscopy** *Information on most recent previous sigmoidoscopy.*	1	122	122	1 = Yes 2 = No 9 = Unknown	Range check.
4.2.2	**Previous sigmoidoscopy test date** *Most recent date for previous sigmoidoscopy indicated in 4.2.1.*	6	123	128	MMYYYY *If just the year is known, blank fill the month (e.g., 2006).*	If 4.2.1 = 1, then "MMYYYY" or "YYYY". Leave blank if 4.2.1 = 2, 9
4.2.3	**Result of previous sigmoidoscopy** *Result of most recent previous sigmoidoscopy indicated in 4.2.1.*	1	129	129	1 = Normal/negative/results other than polyp(s), tumor(s), or cancer 2 = Polyp(s)/tumor(s)/cancer 3 = Incomplete 9 = Unknown	Range check. Leave blank if 4.2.1 = 2, 9
4.3.1	**Previous colonoscopy** *Information on most recent previous colonoscopy.*	1	130	130	1 = Yes 2 = No 9 = Unknown	Range check.

Data Definition Table

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
4.3.2	**Previous colonoscopy test date** *Most recent date for previous colonoscopy indicated in 4.3.1.*	6	131	136	MMYYYY *If just the year is known, blank fill the month (e.g., 2006).*	If 4.3.1 = 1, then "MMYYYY" or "YYYY". Leave blank if 4.3.1 = 2, 9
4.3.3	**Result of previous colonoscopy** *Result of most recent previous colonoscopy indicated in 4.3.1.*	1	137	137	1 = Normal/negative/results other than polyp(s), tumor(s), or cancer 2 = Polyp(s)/tumor(s)/cancer 3 = Incomplete 9 = Unknown	Range check. Leave blank if 4.3.1 = 2, 9
4.4.1	**Previous DCBE** *Information on most recent previous DCBE.*	1	138	138	1 = Yes 2 = No 9 = Unknown	Range check.
4.4.2	**Previous DCBE test date** *Most recent date for previous DCBE indicated in 4.4.1.*	6	139	144	MMYYYY *If just the year is known, blank fill the month (e.g., 2006).*	If 4.4.1 = 1, then "MMYYYY" or "YYYY". Leave blank if 4.4.1 = 2, 9
4.4.3	**Result of previous DCBE** *Result of most recent previous DCBE indicated in 4.4.1.*	1	145	145	1 = Normal/negative/results other than polyp(s), tumor(s), or cancer 2 = Polyp(s)/tumor(s)/cancer 3 = Incomplete 9 = Unknown	Range check. Leave blank if 4.4.1 = 2, 9
	Reserved for future use	10	146	155		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
5. Colorectal Cancer Risk Factors – Complete for each CCDE record. This information can be self-reported, or can come from information documented in the client's medical record (preferred).						
5.1.1	**Personal history of CRC** *Has client ever been diagnosed with colorectal cancer?*	1	156	156	1 = Yes 2 = No 9 = Unknown	Range check.
5.1.2	**Year CRC diagnosed** *Year (most recent occurrence) that CRC was diagnosed.*	4	157	160	YYYY	If 5.1.1 = 1, then "YYYY". Leave blank if 5.1.1 = 2,9
5.2.1	**Personal history of polyp(s)** *Has client ever been diagnosed with colorectal polyp(s)?*	1	161	161	1 = Yes 2 = No 9 = Unknown	Range check.
5.2.2	**Largest number of polyps diagnosed during a single procedure**	2	162	163	1 – 49 = Number of polyps 50 = ≥ 50 polyps 91 = < 10 polyps (if exact number not known) 92 = ≥ 10 polyps (if exact number not known) 99 = Unknown **Right justify**	Range check. Leave blank if 5.2.1 = 2, 9
5.2.3	**Were any of these polyps adenomatous?**	1	164	164	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 5.2.1 = 2, 9
5.3	**High risk due to family history of CRC** *Is this client considered to be at high-risk because of a family history of CRC?** ***Each program will have their own documented definition of high-risk due to family history of CRC.*	1	165	165	1 = Yes 2 = No 9 = Unknown	Range check.
	Reserved for future use	10	166	175		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6. Screening and Diagnostic Tests Provided – Complete for each CCDE record						
6.0	**Initial test recommended** *The initial test recommended to the individual by the program.*	1	176	176	1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 9 = Unknown	Range check.
6.1.0	**Indication for 1st test provided** *This is the indication for the actual test provided reported in 6.1.01. "Provided = Paid For" (i.e. could be a screening FOBT mailed, but not returned).*	1	177	177	1 = Screening 2 = Surveillance after a positive colonoscopy 9 = Unknown	Range check.
6.1.01	**1st test provided** *The actual first test provided through the program. "Provided = Paid For" (i.e. could be a screening FOBT mailed, but not returned).*	1	178	178	1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE	Range check.
6.1.02	**Date of 1st test** *Either the date of the procedure, the date that the take-home FOBT/FIT test was processed, or the date the FOBT/FIT results were received.*	8	179	186	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
6.1.03	**Provider specialty** *The specialty of the clinician providing the 1st test.*	2	187	188	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 99 = Unknown **Right justify**	Range check.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.1.04	**Clinical practice site** *The type of clinical practice where the 1st test was provided.*	1	189	189	1 = Doctor's office 2 = Ambulatory endoscopy/surgery center 3 = Hospital 4 = Health clinic 5 = Administrator, if FOBT/FIT mailed by non-clinician 9 = Unknown	Range check.
6.1.05	**Results of take-home FOBT/FIT** *This question is answered if 6.1.01 was a take-home FOBT or FIT.*	1	190	190	1 = Normal/negative 2 = Positive 3 = Refused 4 = Did not return card 5 = Pending 9 = Unknown	Range check. Leave blank if 6.1.01 = 3, 4, 5
6.1.06	**Results of endoscopy or DCBE** *This question is answered if 6.1.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	191	191	1 = Normal/negative/diverticulosis/hemorrhoids 2 = Other finding not suggestive of cancer/polyp(s) 3 = Polyp(s)/suspicious for cancer/presumed cancer 4 = No findings/inconclusive 5 = Pending 9 = Unknown *NOTE: If more than one result, report the worst.*	Range check. Leave blank if 6.1.01 = 1, 2
6.1.07	**Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?** *This question is answered if 6.1.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	192	192	1 = Yes* 2 = No 9 = Unknown *Adequacy will be determined by the clinician performing the test.* **Procedure report must explicitly state that the bowel prep was adequate, otherwise report 9 (Unknown).*	Range check. Leave blank if 6.1.01 = 1, 2
6.1.08	**Was the cecum reached during the initial colonoscopy?** *This question is answered if 6.1.01 was a colonoscopy.*	1	193	193	1 = Yes* 2 = No 9 = Unknown **Procedure report must explicitly state that the cecum was reached, otherwise report 9 (Unknown).*	Range check. Leave blank if 6.1.01 = 1, 2, 3, 5
6.1.09	**Complications of endoscopy or DCBE** *This question is answered if 6.1.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	194	194	1 = Yes 2 = No/unknown	Range check. Leave blank if 6.1.01 = 1, 2

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.1.10	**Was a biopsy/polypectomy performed during the endoscopy?** *This question is answered if 6.1.01 was a colonoscopy or a sigmoidoscopy.*	1	195	195	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.1.01 = 1, 2, 5
6.1.11	**Number of specimens sent to pathology (from endoscopy)** *This question is answered if 6.1.01 was a colonoscopy or a sigmoidoscopy, and a biopsy/polypectomy was performed.* *Includes samples removed entirely or in part. If a single polyp is removed piecemeal you would report the number of specimens (not the number of polyps).*	2	196	197	0 = Biopsy performed, no specimens sent 1 - 97 = Number of specimens 98 = ≥ 98 specimens 99 = Unknown **Right justify**	Range check. Leave blank if 6.1.01 = 1, 2, 5 Leave blank if 6.1.10 = 2, 9
6.1.12	**Completeness of polyp removal (from colonoscopy)** *Were all the polyps completely removed during 1st test if it was a colonoscopy?*	1	198	198	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.1.01 = 1, 2, 3, 5 Leave blank if 6.1.06 ≠ 3, 4
6.1.13	**Recommended next follow-up procedure within this cycle after 1st test** *The next follow-up procedure recommended to the client (within the cycle). This can be a diagnostic follow-up test following a positive initial test, or surgery to complete diagnosis.*	1	199	199	1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 8 = None (cycle is complete) * ***Diagnosis Information for Surgeries Performed to Complete Diagnosis*** *section must be completed if surgery is recommended.*	Range check. If response = 4 or 8, then 6.2.01, 6.3.01 and 6.4.01 should = 0 (None).

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.2.01	**2nd test provided within this cycle** *The actual second test provided through the program.* *"Provided = Paid For"*	1	200	200	0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE NOTE: FOBT/FIT can not be a second, third or fourth test in a "cycle".	Range check. If response = 0 (None), then 6.2.02 through 6.2.13 should be blank.
6.2.02	**Date of 2nd test** *The date of the procedure.*	8	201	208	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
6.2.03	**Provider specialty** *The specialty of the clinician providing the 2nd test.*	2	209	210	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 99 = Unknown **Right justify**	Range check.
6.2.04	**Clinical practice site** *The type of clinical practice where the 2nd test was provided.*	1	211	211	1 = Doctor's office 2 = Ambulatory endoscopy/surgery center 3 = Hospital 4 = Health clinic 9 = Unknown	Range check.
6.2.05	(Item not used for 2nd test in "cycle")					
6.2.06	**Results of endoscopy or DCBE** *This question is answered if 6.2.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	212	212	1 = Normal/negative/diverticulosis/hemorrhoids 2 = Other finding not suggestive of cancer/polyp(s) 3 = Polyp(s)/suspicious for cancer/presumed cancer 4 = No findings/inconclusive 5 = Pending 9 = Unknown *NOTE: If more than one result, report the worst.*	Range check.

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.2.07	**Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?** *This question is answered if 6.2.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	213	213	1 = Yes* 2 = No 9 = Unknown *Adequacy will be determined by the clinician performing the test.* **Procedure report must explicitly state that the bowel prep was adequate, otherwise report 9 (Unknown).*	Range check.
6.2.08	**Was the cecum reached during the colonoscopy?** *This question is answered if 6.2.01 was a colonoscopy.*	1	214	214	1 = Yes* 2 = No 9 = Unknown **Procedure report must explicitly state that the cecum was reached, otherwise report 9 (Unknown).*	Range check. Leave blank if 6.2.01 = 3, 5
6.2.09	**Complications of endoscopy or DCBE** *This question is answered if 6.2.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	215	215	1 = Yes 2 = No/unknown	Range check.
6.2.10	**Was a biopsy/polypectomy performed during the endoscopy?** *This question is answered if 6.2.01 was a colonoscopy or a sigmoidoscopy.*	1	216	216	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.2.01 = 5
6.2.11	**Number of specimens sent to pathology (from endoscopy)** *This question is answered if 6.2.01 was a colonoscopy or a sigmoidoscopy, and a biopsy/polypectomy was performed.* *Includes samples removed entirely or in part. If a single polyp is removed piecemeal you would report the number of specimens (not the number of polyps).*	2	217	218	0 = Biopsy performed, no specimens sent 1 - 97 = Number of specimens 98 = ≥ 98 specimens 99 = Unknown **Right justify**	Range check. Leave blank if 6.2.01 = 5 Leave blank if 6.2.10 = 2, 9

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.2.12	**Completeness of polyp removal (from colonoscopy)** *Were all the polyps completely removed during 2nd test if it was a colonoscopy?*	1	219	219	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.2.01 = 3, 5 Leave blank if 6.2.06 ≠ 3, 4
6.2.13	**Recommended next follow-up procedure within this cycle after 2nd test.** *The next follow-up procedure recommended to the client (within the cycle). This can be another diagnostic follow-up test or surgery to complete diagnosis.*	1	220	220	1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 8 = None (cycle is complete) * ***Diagnosis Information for Surgeries Performed to Complete Diagnosis*** *section must be completed if surgery is recommended.*	Range check. If response = 4 or 8, then 6.3.01 and 6.4.01 should = 0 (None).

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.3.01	**3rd test provided within this cycle** *The actual third test provided through the program.* *"Provided = Paid For"*	1	221	221	0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE NOTE: FOBT/FIT can not be a second, third or fourth test in a "cycle".	Range check. If response = 0 (None), then 6.3.02 through 6.3.13 should be blank.
6.3.02	**Date of 3rd test** *The date of the procedure.*	8	222	229	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
6.3.03	**Provider specialty** *The specialty of the clinician providing the 3rd test.*	2	230	231	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 99 = Unknown **Right justify**	Range check.
6.3.04	**Clinical practice site** *The type of clinical practice where the 3rd test was provided.*	1	232	232	1 = Doctor's office 2 = Ambulatory endoscopy/surgery center 3 = Hospital 4 = Health clinic 9 = Unknown	Range check.
6.3.05	(Item not used for 3rd test in "cycle")					
6.3.06	**Results of endoscopy or DCBE** *This question is answered if 6.3.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	233	233	1 = Normal/negative/diverticulosis/hemorrhoids 2 = Other finding not suggestive of cancer/polyp(s) 3 = Polyp(s)/suspicious for cancer/presumed cancer 4 = No findings/inconclusive 5 = Pending 9 = Unknown *NOTE: If more than one result, report the worst.*	Range check.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.3.07	**Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?** *This question is answered if 6.3.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	234	234	1 = Yes* 2 = No 9 = Unknown *Adequacy will be determined by the clinician performing the test.* **Procedure report must explicitly state that the bowel prep was adequate, otherwise report 9 (Unknown).*	Range check.
6.3.08	**Was the cecum reached during the colonoscopy?** *This question is answered if 6.3.01 was a colonoscopy.*	1	235	235	1 = Yes* 2 = No 9 = Unknown **Procedure report must explicitly state that the cecum was reached, otherwise report 9 (Unknown).*	Range check. Leave blank if 6.3.0 1 = 3, 5
6.3.09	**Complications of endoscopy or DCBE** *This question is answered if 6.3.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	236	236	1 = Yes 2 = No/unknown	Range check.
6.3.10	**Was a biopsy/polypectomy performed during the endoscopy?** *This question is answered if 6.3.01 was a colonoscopy or a sigmoidoscopy.*	1	237	237	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.3.01 = 5
6.3.11	**Number of specimens sent to pathology (from endoscopy)** *This question is answered if 6.3.01 was a colonoscopy or a sigmoidoscopy, and a biopsy/polypectomy was performed.* *Includes samples removed entirely or in part. If a single polyp is removed piecemeal you would report the number of specimens (not the number of polyps).*	2	238	239	0 = Biopsy performed, no specimens sent 1 - 97 = Number of specimens 98 = ≥ 98 specimens 99 = Unknown **Right justify**	Range check. Leave blank if 6.3.01 = 5 Leave blank if 6.3.10 = 2, 9

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.3.12	**Completeness of polyp removal (from colonoscopy)** *Were all the polyps completely removed during 3rd test if it was a colonoscopy?*	1	240	240	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.3.01 = 3, 5 Leave blank if 6.3.06 ≠ 3, 4
6.3.13	**Recommended next follow-up procedure within this cycle after 3rd test.** *The next follow-up procedure recommended to the client (within the cycle). This can be another diagnostic follow-up test or surgery to complete diagnosis.*	1	241	241	1 = Sigmoidoscopy 2 = Colonoscopy 3 = DCBE 4 = Surgery to complete diagnosis* 8 = None (cycle is complete) * ***Diagnosis Information for Surgeries Performed to Complete Diagnosis*** *section must be completed if surgery is recommended.*	Range check. If response = 4 or 8, then 6.4.01 should = 0 (None).

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.4.01	**4th test provided within this cycle** *The actual fourth test provided through the program.* *"Provided = Paid For".*	1	242	242	0 = None 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE NOTE: FOBT/FIT can not be a second, third or fourth test in a "cycle".	Range check. If response = 0 (None), then 6.4.02 through 6.4.13 should be blank.
6.4.02	**Date of 4th test** *The date of the procedure.*	8	243	250	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY" or "YYYY", but not blank.
6.4.03	**Provider specialty** *The specialty of the clinician providing the 4th test.*	2	251	252	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 99 = Unknown **Right justify**	Range check.
6.4.04	**Clinical practice site** *The type of clinical practice where the 4th test was provided.*	1	253	253	1 = Doctor's office 2 = Ambulatory endoscopy/surgery center 3 = Hospital 4 = Health clinic 9 = Unknown	Range check.
6.4.05	(Item not used for 4th test in "cycle")					
6.4.06	**Results of endoscopy or DCBE** *This question is answered if 6.4.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	254	254	1 = Normal/negative/diverticulosis/hemorrhoids 2 = Other finding not suggestive of cancer/polyp(s) 3 = Polyp(s)/suspicious for cancer/presumed cancer 4 = No findings/inconclusive 5 = Pending 9 = Unknown *NOTE: If more than one result, report the worst.*	Range check.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.4.07	**Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?** *This question is answered if 6.4.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	255	255	1 = Yes* 2 = No 9 = Unknown *Adequacy will be determined by the clinician performing the test.* **Procedure report must explicitly state that the bowel prep was adequate, otherwise report 9 (Unknown).*	Range check.
6.4.08	**Was the cecum reached during the colonoscopy?** *This question is answered if 6.4.01 was a colonoscopy.*	1	256	256	1 = Yes* 2 = No 9 = Unknown **Procedure report must explicitly state that the cecum was reached, otherwise report 9 (Unknown).*	Range check. Leave blank if 6.4.01 = 3, 5
6.4.09	**Complications of endoscopy or DCBE** *This question is answered if 6.4.01 was a colonoscopy, a sigmoidoscopy or a DCBE.*	1	257	257	1 = Yes 2 = No/unknown	Range check.
6.4.10	**Was a biopsy/polypectomy performed during the endoscopy?** *This question is answered if 6.4.01 was a colonoscopy or a sigmoidoscopy.*	1	258	258	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.4.01 = 5
6.4.11	**Number of specimens sent to pathology (from endoscopy)** *This question is answered if 6.4.01 was a colonoscopy or a sigmoidoscopy, and a biopsy/polypectomy was performed.* *Includes samples removed entirely or in part. If a single polyp is removed piecemeal you would report the number of specimens (not the number of polyps).*	2	259	260	0 = Biopsy performed, no specimens sent 1 - 97 = Number of specimens 98 = ≥ 98 specimens 99 = Unknown **Right justify**	Range check. Leave blank if 6.4.01 = 5 Leave blank if 6.4.10 = 2, 9

Data Definition Table

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
6.4.12	**Completeness of polyp removal (from colonoscopy)** *Were all the polyps completely removed during 4th test if it was a colonoscopy?*	1	261	261	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 6.4.01 = 3, 5 Leave blank if 6.4.06 ≠ 3, 4
6.4.13	**Recommended next follow-up procedure after 4th test.** *The next follow-up procedure recommended to the client. This can be another diagnostic follow-up test or surgery to complete diagnosis.*	1	262	262	4 = Surgery to complete diagnosis* 8 = None (cycle is complete) * ***Diagnosis Information for Surgeries Performed to Complete Diagnosis*** *section must be completed if surgery is recommended.*	Range check.
	Reserved for future use	10	263	272		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7. Diagnosis Information for All Polyps/Lesions – Complete for each CCDE record						
7.0	**Total number of polyps/lesions** *Total number of unique polyps/lesions identified through all colonoscopies and/or sigmoidoscopies during the client's "cycle".*	2	273	274	0 = No polyps/lesions 1 – 96 = Number of polyps/lesions 97 = ≥ 97 polyps/lesions 98 = At least one polyp/lesion, exact number not known 99 = Unknown *Specimens from surgical resections do not belong in this section.* **Right justify**	Range check.
7.01.1	**Location of 1st polyp/lesion** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	275	276	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.01.2	**Size of 1st polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	277	278	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.01.3.1	**Procedure for removal of 1st polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	279	279	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.01.3.2	**Procedure for removal of 1st polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	280	280	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.01.3.3	**Procedure for removal of 1st polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	281	281	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.01.4	**Was 1st polyp/lesion completely removed?**	1	282	282	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.01.5	**Histology of 1st polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	283	284	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.02.1	**Location of 2nd polyp/lesion** *Complete only if more than one polyp/lesion was removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	285	286	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.02.2	**Size of 2nd polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	287	288	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.02.3.1	**Procedure for removal of 2nd polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	289	289	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.02.3.2	**Procedure for removal of 2nd polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	290	290	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.02.3.3	**Procedure for removal of 2nd polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	291	291	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.02.4	**Was 2nd polyp/lesion completely removed?**	1	292	292	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.02.5	**Histology of 2nd polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	293	294	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.03.1	**Location of 3rd polyp/lesion** *Complete only if more than two polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	295	296	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.03.2	**Size of 3rd polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	297	298	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.03.3.1	**Procedure for removal of 3rd polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	299	299	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.03.3.2	**Procedure for removal of 3rd polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	300	300	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.03.3.3	**Procedure for removal of 3rd polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	301	301	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.03.4	**Was 3rd polyp/lesion completely removed?**	1	302	302	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.03.5	**Histology of 3rd polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	303	304	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.04.1	**Location of 4th polyp/lesion** *Complete only if more than three polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	305	306	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.04.2	**Size of 4th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	307	308	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.04.3.1	**Procedure for removal of 4th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	309	309	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.04.3.2	**Procedure for removal of 4th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	310	310	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.04.3.3	**Procedure for removal of 4th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	311	311	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.04.4	**Was 4th polyp/lesion completely removed?**	1	312	312	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.04.5	**Histology of 4th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	313	314	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.05.1	**Location of 5th polyp/lesion** *Complete only if more than four polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.* *Location will generally be found on the endoscopy report.*	2	315	316	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown **Right justify**	Range check. Leave blank if 7.0 = 0
7.05.2	**Size of 5th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	317	318	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.05.3.1	**Procedure for removal of 5th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	319	319	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.05.3.2	**Procedure for removal of 5th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	320	320	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.05.3.3	**Procedure for removal of 5th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	321	321	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.05.4	**Was 5th polyp/lesion completely removed?**	1	322	322	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.05.5	**Histology of 5th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	323	324	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.06.1	**Location of 6th polyp/lesion** *Complete only if more than five polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	325	326	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.06.2	**Size of 6th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	327	328	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.06.3.1	**Procedure for removal of 6th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	329	329	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.06.3.2	**Procedure for removal of 6th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	330	330	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.06.3.3	**Procedure for removal of 6th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	331	331	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.06.4	**Was 6th polyp/lesion completely removed?**	1	332	332	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.06.5	**Histology of 6th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	333	334	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.07.1	**Location of 7th polyp/lesion** *Complete only if more than six polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	335	336	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.07.2	**Size of 7th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	337	338	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.07.3.1	**Procedure for removal of 7th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	339	339	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.07.3.2	**Procedure for removal of 7th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	340	340	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.07.3.3	**Procedure for removal of 7th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	341	341	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.07.4	**Was 7th polyp/lesion completely removed?**	1	342	342	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.07.5	**Histology of 7th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	343	344	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.08.1	**Location of 8th polyp/lesion** *Complete only if more than seven polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	345	346	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.08.2	**Size of 8th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	347	348	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.08.3.1	**Procedure for removal of 8th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	349	349	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.08.3.2	**Procedure for removal of 8th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	350	350	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.08.3.3	**Procedure for removal of 8th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	351	351	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.08.4	**Was 8th polyp/lesion completely removed?**	1	352	352	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.08.5	**Histology of 8th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	353	354	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.09.1	**Location of 9th polyp/lesion** *Complete only if more than eight polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	355	356	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.09.2	**Size of 9th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	357	358	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.09.3.1	**Procedure for removal of 9th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	359	359	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.09.3.2	**Procedure for removal of 9th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	360	360	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.09.3.3	**Procedure for removal of 9th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	361	361	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.09.4	**Was 9th polyp/lesion completely removed?**	1	362	362	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.09.5	**Histology of 9th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	363	364	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.10.1	**Location of 10th polyp/lesion** *Complete only if more than nine polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	365	366	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.10.2	**Size of 10th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	367	368	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.10.3.1	**Procedure for removal of 10th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	369	369	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.10.3.2	**Procedure for removal of 10th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	370	370	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.10.3.3	**Procedure for removal of 10th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	371	371	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.10.4	**Was 10th polyp/lesion completely removed?**	1	372	372	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.10.5	**Histology of 10th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	373	374	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.11.1	**Location of 11th polyp/lesion** *Complete only if more than ten polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	375	376	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.11.2	**Size of 11th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	377	378	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.11.3.1	**Procedure for removal of 11th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	379	379	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.11.3.2	**Procedure for removal of 11th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	380	380	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.11.3.3	**Procedure for removal of 11th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	381	381	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.11.4	**Was 11th polyp/lesion completely removed?**	1	382	382	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.11.5	**Histology of 11th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	383	384	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.12.1	**Location of 12th polyp/lesion** *Complete only if more than eleven polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	385	386	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.12.2	**Size of 12th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	387	388	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.12.3.1	**Procedure for removal of 12th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	389	389	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.12.3.2	**Procedure for removal of 12th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	390	390	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.12.3.3	**Procedure for removal of 12th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	391	391	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.12.4	**Was 12th polyp/lesion completely removed?**	1	392	392	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.12.5	**Histology of 12th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	393	394	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.13.1	**Location of 13th polyp/lesion** *Complete only if more than twelve polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	395	396	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.13.2	**Size of 13th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	397	398	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.13.3.1	**Procedure for removal of 13th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	399	399	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.13.3.2	**Procedure for removal of 13th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	400	400	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.13.3.3	**Procedure for removal of 13th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	401	401	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.13.4	**Was 13th polyp/lesion completely removed?**	1	402	402	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.13.5	**Histology of 13th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	403	404	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.14.1	**Location of 14th polyp/lesion** *Complete only if more than thirteen polyps/lesions were removed*. *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	405	406	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.14.2	**Size of 14th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	407	408	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.14.3.1	**Procedure for removal of 14th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	409	409	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.14.3.2	**Procedure for removal of 14th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	410	410	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.14.3.3	**Procedure for removal of 14th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	411	411	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.14.4	**Was 14th polyp/lesion completely removed?**	1	412	412	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.14.5	**Histology of 14th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	413	414	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.15.1	**Location of 15th polyp/lesion** *Complete only if more than fourteen polyps/lesions were removed.* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps.*	2	415	416	1 = Rectum 2 = Rectosigmoid junction 3 = Sigmoid 4 = Descending 5 = Splenic flexure 6 = Transverse 7 = Hepatic flexure 8 = Ascending 9 = Cecum 10 = Appendix 11 = Overlapping lesions 99 = Unknown *Location will generally be found on the endoscopy report.* **Right justify**	Range check. Leave blank if 7.0 = 0
7.15.2	**Size of 15th polyp/lesion** *This is the diameter of the polyp/lesion in millimeters (mm) or the longest dimension of the polyp/lesion if asymmetric.* *NOTE: This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology.*	2	417	418	0 = < 1 mm 1 – 97 = Size of polyp/lesion in mm 98 = ≥ 98 mm 99 = Unknown **Right justify** *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy report and pathology report in order to "match up" the correct polyps. 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.*	Range check. Leave blank if 7.0 = 0
7.15.3.1	**Procedure for removal of 15th polyp/lesion (1)** *This is the first procedure performed during removal/biopsy of the polyp/lesion.*	1	419	419	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 7 = Not biopsied or removed 9 = Unknown	Range check. Leave blank if 7.0 = 0

Item	Variable Name	Column Length	Column Begin	Column End	Codes / Format / Comments	Edit Checks / Skip Patterns
7.15.3.2	**Procedure for removal of 15th polyp/lesion (2)** *This is the second procedure performed during removal/biopsy of the polyp/lesion.*	1	420	420	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than one procedure was performed during the polyp/lesion removal.*
7.15.3.3	**Procedure for removal of 15th polyp/lesion (3)** *This is the third procedure performed during removal/biopsy of the polyp/lesion.*	1	421	421	1 = Snare polypectomy 2 = Hot biopsy forceps or cautery 3 = Cold biopsy 4 = Ablation 5 = Submucosal injection 6 = Control of bleeding 9 = Unknown	Range check. Leave blank if 7.0 = 0 *NOTE: This field should only be completed if more than two procedures were performed during the polyp/lesion removal.*
7.15.4	**Was 15th polyp/lesion completely removed?**	1	422	422	1 = Yes 2 = No 9 = Unknown	Range check. Leave blank if 7.0 = 0
7.15.5	**Histology of 15th polyp/lesion** *This is the histology of the polyp/lesion. If polyp was submitted to pathology as piecemeal fragments and more than one histological diagnosis was reported, report the worst (the response options are listed in general order of severity).* *NOTE: The individual translating clinical data into the CCDEs will need to carefully compare the endoscopy and pathology reports in order to "match up" the correct lesions.*	2	423	424	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed ***Histologies for all polyps/lesions should be reviewed and a final diagnosis recorded in Item 9.2.*** **Right justify**	Range check. Leave blank if 7.0 = 0 Do not update/change this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.
	Reserved for future use	30	425	454		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
8. Diagnosis Information for Surgeries Performed to Complete Diagnosis						
8.1	**Histology from surgical resection** *This is the worst histopathological diagnosis made from surgical resection (the response options are listed in general order of severity).*	2	455	456	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 = Carcinoma, other 99 = Unknown/other lesions ablated, not retrieved or confirmed *Use histology from surgical resection in conjunction with all of the polyp/lesion histologies in the **Diagnosis Information for All Polyps/Lesions** section, to report the "Final diagnosis" (9.2).* **Right justify**	Range check. If surgery was recommended in 6.1.13, 6.2.13, 6.3.13 or 6.4.13 but was not completed, code 0 (Surgery recommended but not performed). If no surgery was recommended in 6.1.13, 6.2.13, 6.3.13 or 6.4.13, leave blank.
8.2	**Date surgery performed** *The date of the surgical procedure used to complete diagnosis (recommended in 6.1.13, 6.2.13, 6.3.13 or 6.4.13).*	8	457	464	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	"MMDDYYYY", "MM YYYY", or "YYYY". If 6.1.13, 6.2.13, 6.3.13 or 6.4.13 = 4 (Surgery to complete diagnosis), then date must be completed. If no surgery was recommended in 6.1.13, 6.2.13, 6.3.13 or 6.4.13, then leave blank. If 8.1 = 0, then leave blank.
	Reserved for future use	10	465	474		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
9. Final Diagnosis – Completed for all CCDE records						
9.1	**Status of diagnosis** *After all screening and diagnostic tests were performed /offered to the client, what is the status of the client's care?*	1	475	475	1 = Complete (final diagnosis made) 2 = Pending final diagnosis 3 = Verbal/written refusal for any test needed to obtain a final diagnosis*[Ŧ] 4 = Client moved before final diagnosis was made[Ŧ] 5 = Client died before final diagnosis was made[Ŧ] 6 = Lost to follow-up*[Ŧ] 9 = Unknown *Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up. [Ŧ]These items should have an administrative close-out date reported in 9.3 "Date of diagnosis".	Range check. If a client receives a single screening test which is normal/negative, then complete this field as 1 (Complete).
9.2	**Final diagnosis** *This is the final diagnosis after all procedures have been completed (including surgery, if done) that will determine the re-screening or surveillance test recommendation.*	1	476	476	1 = Normal/negative 2 = Polyp, no high grade dysplasia[2] 3 = Polyp with high grade dysplasia[1,2] 4 = Cancer[1,2] [1]***Diagnosis Information for Cancer/High Grade Dysplasia*** *section must be completed if 9.2 "Final diagnosis" = 3, 4.* [2]*Treatment section must be completed if 9.2 "Final diagnosis" = 2, 3, 4.*	Range check. If the only test performed in cycle was FOBT or FIT, then complete this field as 1 (Normal/negative).
9.3	**Date of diagnosis** *This can be the date of the final pathology report, the date of the 'normal' screening test, or when the client refused or was determined to be lost to follow-up.*	8	477	484	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	If 9.1 = 1, 3-6, then "MMDDYYYY", "MM YYYY" or "YYYY". If 9.1 = 3-6, then an administrative close-out date will be necessary. Leave blank if 9.1 = 2, 9

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
9.4	**Recommended screening or surveillance test for next cycle** *The next screening or surveillance test recommended to the client at the end of the cycle. This can be 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.*	1	485	485	1 = Take-home FOBT 2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy 5 = DCBE 6 = None 9 = Unknown	Range check. If client is terminally ill or for other reasons no further tests are recommended, then code this as 6 (None). Leave blank if 9.1 ≠ 1
9.5	**Indication for screening or surveillance test for next cycle** *The indication for the next screening or surveillance test recommended to the client.*	1	486	486	1 = Screening 2 = Surveillance after a positive colonoscopy and/or surgery	Range check. Leave blank if 9.1 ≠ 1 Leave blank if 9.4 = 6, 9
9.6	**Number of months before screening or surveillance test for next cycle** *The number of months recommended between Date of diagnosis (9.3) and next recommended screening or surveillance test.*	3	487	489	12 – 180 = Actual number of months 999 = Unknown **Right Justify**	Range check. Leave blank if 9.1 ≠ 1 Leave blank if 9.4 = 6, 9
	Reserved for future use	10	490	499		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
10. Diagnosis Information for Cancer/High Grade Dysplasia – Complete this section when Final Diagnosis (9.2) = 3 or 4						
10.1	**Stage at diagnosis/treatment** *AJCC cancer stage used as a basis for clinical decisions. This can be based on clinical and/or pathological information.*	1	500	500	0 = Stage 0 (high grade dysplasia, severe dysplasia, or in situ) 1 = Stage I 2 = Stage II 3 = Stage III 4 = Stage IV 9 = Unknown/unstaged	Range check. If "Final diagnosis" (9.2) = 3 (High grade dysplasia) or 4 (Cancer), then 10.1 must be completed.
10.2	**Recurrent cancers** *Is this cancer a new primary or a recurrent cancer?*	1	501	501	1 = New CRC primary 2 = Recurrent CRC 3 = Non-CRC primary (metastasis from another organ) 9 = Unknown	Range check.
10.3	**Registry linkage status** *Has this record been linked to the state cancer registry?*	1	502	502	1 = Pending linkage 2 = Linked, matched 3 = Linked, not matched	Range check.
10.4	**Registry primary site** *Primary site [NAACCR data item #400] obtained from the central cancer registry.* *See SEER Program Coding and Staging Manual (pg 73):* *http://seer.cancer.gov/manuals/SPM2004.pdf*	4	503	506	C000-C999 *NOTE: The 'C' must be included as part of the variable response in the CCDE file. For example Cecum = C180. A complete list of valid values/labels will be provided for reference in the CCDE User's Manual.* **Alphanumeric, left justify**	Range check. Leave blank if 10.3 = 1, 3
10.5	**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 (pg 67) & SEER Summary Staging Manual:* *http://www.cancerstaging.org/cstage/csmanualpart1.pdf* *http://seer.cancer.gov/tools/ssm/*	1	507	507	0 = In situ 1 = Localized 2 = Regional, direct extension only 3 = Regional, regional lymph nodes only 4 = Regional, extension and nodes 5 = Regional, NOS 7 = Distant 8 = Not applicable 9 = Unknown/unstaged	Range check. Leave blank if 10.3 = 1, 3

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
10.6	**Registry CS-derived AJCC stage group** *Collaborative stage (CS)-derived AJCC stage [NAACCR date Item #3000] obtained from the central cancer registry database WHEN AVAILABLE.* *See CS Staging Manual (pg 65): http://www.cancerstaging.org/cstage/csmanualpart1.pdf*	2	508	509	Range: 00-99 *Valid values for CS-derived AJCC stage include: 00-02, 10-24, 30-43, 50-63, 70-74, 88, 90, 99.* *A complete list of valid values/labels will be provided for reference in the CCDE User's Manual.*	Range check. Leave blank if 10.3 = 1, 3
10.7	**Registry CS extension** *Collaborative stage (CS) extension [NAACCR data item #2810] obtained from the central cancer registry database.* *See CS Staging Manual (pg 272): http://www.cancerstaging.org/cstage/csmanualpart2.pdf*	2	510	511	Range: 00-99 *Valid values for CS extension include: 00, 05, 10-16, 20, 30, 40, 42, 45, 46, 50, 55, 57, 60, 65, 66, 70, 75, 80, 95, 99.* *A complete list of valid values/labels will be provided for reference in the CCDE User's Manual.*	Range check. Leave blank if 10.3 = 1, 3
10.8	**Registry CS lymph nodes** *Collaborative stage (CS) lymph nodes [NAACCR data item #2830] obtained from the central cancer registry database.* *See CS Staging Manual (pg 274): http://www.cancerstaging.org/cstage/csmanualpart2.pdf*	2	512	513	Range: 00-99 *Valid values for CS lymph nodes include: 00, 10, 20, 30, 80, 99.* *A complete list of valid values/labels will be provided for reference in the CCDE User's Manual.*	Range check. Leave blank if 10.3 = 1, 3
10.9	**Registry CS mets at diagnosis** *Collaborative stage (CS) mets at diagnosis [NAACCR data item #2850] obtained from the central cancer registry database.* *See CS Staging Manual (pg 275): http://www.cancerstaging.org/cstage/csmanualpart2.pdf*	2	514	515	Range: 00-99 *Valid values for CS mets at diagnosis include: 00, 08, 10, 40, 50, 99.* *A complete list of valid values/labels will be provided for reference in the CCDE User's Manual.*	Range check. Leave blank if 10.3 = 1, 3
	Reserved for future use	10	516	525		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
11. Treatment Information - Complete this section when Final Diagnosis (9.2) = 2, 3 or 4						
11.1	**Status of treatment** *In some cases, a polypectomy may be considered both diagnostic and treatment. In other cases surgery may be considered both diagnostic and start of treatment.*	1	526	526	1 = Treatment started and/or completed 2 = Treatment pending 3 = Treatment not indicated‡ 4 = Verbal/written refusal of treatment*‡ 5 = Client moved‡ 6 = Deceased‡ 7 = Lost to follow-up*‡ 9 = Unknown *Programs must have a policy in place to define how much time can elapse before the client is deemed refused or lost to follow-up. ‡These items should have an administrative close-out date reported in 11.2 "Date of treatment".	Range check. If "Final diagnosis" (9.2) = 2, 3, 4, then 11.1 must be completed.
11.2	**Date of treatment** *Can be the date treatment began, when the client refused, or was determined to be lost to follow-up. Date that treatment began **may** be the date of one of the tests. For instance, if a polypectomy was done and cancer was found **and removed**, the date that the polyp(s) was removed would also be the date that treatment began.*	8	527	534	MMDDYYYY *If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 04 2006).*	If 11.1 = 1, 3-7, then "MMDDYYYY", "MM YYYY" or "YYYY". If 11.1 = 3-7, then an administrative close-out date will be necessary. Leave blank if 11.1 = 2, 9
11.3	**Who paid for treatment?** *This is the primary source of payment for treatment.*	1	535	535	1 = Medicaid 2 = Other, State 3 = Medicare 4 = Self-Pay (by client) 5 = Charity care/uncompensated 6 = Other 9 = Unknown	Range check. Leave blank if 11.1 ≠ 1 (Treatment started).
	Reserved for future use	10	536	545		Leave blank.

Item	Variable Name	Column Length	Begin	End	Codes / Format / Comments	Edit Checks / Skip Patterns
12. Record Information – Completed for each CCDE record						
12.1	**CCDE version**	3	546	548	100 = For all data currently collected/reported	Range check.
12.2	**End of record mark**	2	549	550	The record ends with a carriage return-line feed (CR-LF).	

APPENDIX D

CDC RACE AND ETHNICITY CODE SET

CDC Race and Ethnicity Code Set – Version 1.0 (03/2000)

Modified from original: http://www.cdc.gov/phin/vocabulary/race.html

TABLE 1 – RACE CONCEPTS AND CODES

MDE 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

MDE CATEGORY	CONCEPT
2. Black or African 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
	Palauan
	Carolinian
	Kosraean

MDE CATEGORY	CONCEPT
4. Native Hawaiian or Other Pacific Islander (Cont'd)	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

CDC Race and Ethnicity Code Set – Version 1.0 (03/2000)

Modified from original: http://www.cdc.gov/phin/vocabulary/race.html

TABLE 2 – ETHNICITY CONCEPTS AND CODES

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

APPENDIX E

ADVERSE EVENTS REPORTING FORM

This appendix is a placeholder for the Adverse Events Reporting Form which can be located in the CRCSDP Policy Manual, Appendix 2.

APPENDIX F

CCDE Revision History

Appendix F
CCDE Revision History

Appendix F contains a detailed history of changes made to each of the variables that comprise the Colorectal Cancer Clinical Data Elements (CCDEs). The CDC will regularly assess the effectiveness of the CCDEs for the purposes of analysis, evaluation and reporting to stakeholders; and changes will be made if necessary. The initial version of the CCDEs, version 1.00, was finalized on February 6, 2006. The following tables list all subsequent revisions to the CCDE variables in detail, grouped by CCDE version number, and then listed in order by item number. The tables in this appendix correspond with the revision history data provided for each item in the CCDE Field Descriptions.

CCDE Version 1.00: 02/06/2006

Item number	Details of modification to item
All CCDE items	Initial version / no revisions

CCDE Version 1.01: 04/26/2006

Item number	Details of modification to item
Item 4.x	Revised to indicate that "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"
Item 5.x	Revised to indicate that "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"
Item 6.x.12	Revised skip pattern to include directions: Leave blank if 6.x.06 ≠ 3, 4
Item 7.xx.3.2	Removed category 7 (Not biopsied or removed). This category can only be used as the first procedure for removal (7.xx.3.1)
Item 7.xx.3.3	Removed category 7 (Not biopsied or removed). This category can only be used as the first procedure for removal (7.xx.3.1)
Item 9.1	Revised to indicate that categories 3 – 6 should have an administrative close-out date reported in Item 9.3 (Date of Diagnosis)
Item 9.5	Revised skip pattern to include directions: Leave blank if 9.1≠ 1.
Item 9.6	Revised skip pattern to include directions: Leave blank if 9.1≠ 1.
Item 11.1	Revised to indicate that categories 3 – 7 should have an administrative close-out date reported in Item 11.2 (Date of Treatment)

CHAPTER 3

Data Quality Assessment

The purpose of this chapter is to emphasize the importance of data quality and to provide examples of how to plan for and assess data quality for this program. A program needs to have computer software to assess data quality. The software used will vary from program to program, but minimally a program should be able to monitor the frequencies of important program variables. A program should have this software available from the start of the program and someone should be designated to assess data quality on an ongoing basis.

It is also very important for your program to have detailed documentation of your computer software system and data quality assessment tools. This is essential in cases of staff turnover or staff absence. This documentation, along with cross-training, will allow the program to continually monitor the quality of the data.

The CDC is currently developing the data quality assessment tools that will be used to monitor and evaluate the CRCSDP data. Therefore, no reports are currently included in this chapter of the Data User's Manual. Updated information for this chapter will be provided in the future.

CHAPTER 4

Registry Linkage

Included in this chapter are tables from the *SEER Program Coding and Staging Manual 2004* (http://seer.cancer.gov/tools/codingmanuals/); and the *Collaborative Staging Manual and Coding Instructions, version 1.0,* 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/cstage/manuals.html).

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 10.4: Registry primary site
- CCDE Item 10.5: Registry CS-derived SS2000
- CCDE Item 10.6: Registry CS-derived AJCC stage group
- CCDE Item 10.7: Registry CS extension
- CCDE Item 10.8: Registry CS lymph nodes
- CCDE Item 10.9: Registry CS mets at diagnosis

In addition, the CDC is currently developing a linkage protocol for this chapter which will contain valuable information to assist programs in the successful linkage of CCDEs with their state cancer registry data. Updated information for this chapter will be provided in the future.

CCDE Item 10.4: Registry primary site

Primary site [NAACCR data item #400] obtained from the central cancer registry database. See the SEER Program Coding and Staging Manual (pg 73) at http://seer.cancer.gov/manuals/SPM2004.pdf

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 10.5: 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 (pg 67) at http://www.cancerstaging.org/cstage/csmanualpart1.pdf and the SEER Summary Staging Manual at http://seer.cancer.gov/tools/ssm/.

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 10.6: 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. See Collaborative stage (CS) Staging Manual (pg 65) at http://www.cancerstaging.org/cstage/csmanualpart1.pdf.

Value	Description	Value	Description	Value	Description
00	Stage 0	35	Stage IIEA (lymphoma only)	70	Stage IV
01	Stage 0a	36	Stage IIEB (lymphoma only)	71	Stage IV NOS
02	Stage 0is	37	Stage IIE (lymphoma only)	72	Stage IVA
10	Stage I	38	Stage IISA (lymphoma only)	73	Stage IVB
11	Stage I NOS	39	Stage IISB (lymphoma only)	74	Stage IVC
12	Stage IA	40	Stage IIS (lymphoma only)	88	Not applicable
13	Stage IA1	41	Stage IIESA (lymphoma only)	90	Stage Occult
14	Stage IA2	42	Stage IESB (lymphoma only)	99	Stage Unknown
15	Stage IB	43	Stage IIES (lymphoma only)		
16	Stage IB1	50	Stage III		
17	Stage IB2	51	Stage III NOS		
18	Stage IC	52	Stage IIIA		
19	Stage IS	53	Stage IIIB		
23	Stage ISA (lymphoma only)	54	Stage IIIC		
24	Stage ISB (lymphoma only)	55	Stage IIIEA (lymphoma only)		
20	Stage IEA (lymphoma only)	56	Stage IIIEB (lymphoma only)		
21	Stage IEB (lymphoma only)	57	Stage IIIE (lymphoma only)		
22	Stage IE (lymphoma only)	58	Stage IIISA (lymphoma only)		
30	Stage II	59	Stage IIISB (lymphoma only)		
31	Stage II NOS	60	Stage IIIS (lymphoma only)		
32	Stage IIA	61	Stage IIIESA (lymphoma only)		
33	Stage IIB	62	Stage IIIESB (lymphoma only)		
34	Stage IIC	63	Stage IIIES (lymphoma only)		

CCDE Item 10.7: Registry CS extension

Collaborative stage (CS) extension [NAACCR data item #2810] obtained from the central cancer registry database. See CS Staging Manual (pg 272) at http://www.cancerstaging.org/cstage/csmanualpart2.pdf.

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
00	In situ; noninvasive; intraepithelial	In situ; noninvasive; intraepithelial	Tis	IS	IS
05	(Adeno)carcinoma in a polyp or adenoma, noninvasive	(Adeno)carcinoma in a polyp or adenoma, noninvasive	Tis	IS	IS
10	Invasive tumor confined to mucosa, NOS, including intramucosal, NOS	Invasive tumor confined to mucosa, NOS, including intramucosal, NOS	Tis	L	L
11	Lamina propria, including lamina propria in the stalk of a polyp	Lamina propria, including lamina propria in the stalk of a polyp	Tis	L	L
12	Muscularis mucosae, including muscularis mucosae in the stalk of a polyp	Muscularis mucosae, including muscularis mucosae in the stalk of a polyp	T1	L	L
13	Confined to head of polyp, NOS	Confined to head of polyp, NOS	T1	L	L
14	Confined to stalk of polyp, NOS	Confined to stalk of polyp, NOS	T1	L	L
15	Invasive tumor in polyp, NOS	Invasive tumor in polyp, NOS	T1	L	L
16	Invades submucosa (superficial invasion), including submucosa in the stalk of a polyp	Submucosa (superficial invasion), including submucosa in the stalk of a polyp	T1	L	L
20	Muscularis propria invaded	Muscularis propria invaded	T2	L	L
30	Localized, NOS Confined to colon, NOS	Localized, NOS Confined to rectum, NOS	T1 (colon) / Tx (rectum)	L	L

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
40	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	L	L
42	Fat, NOS	Fat, NOS	T3	RE	RE
45	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	RE	RE
46	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	RE	RE
50	Invasion of/through serosa (mesothelium) (visceral peritoneum)	Invasion of/through serosa (mesothelium) (visceral peritoneum)	T4	RE	RE
55	Any of [(42) to (45)] + (50)	(50) with [(42) or (45)]	T4	RE	RE
57	Adherent to other organs or structures, NOS	Adherent to other organs or structures, NOS	T4	RE	RE

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
60	All colon sites: Small intestine Cecum and appendix: Greater omentum Ascending colon: Greater omentum Liver, right lobe Tranverse 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	T4	RE	RE
65	All colon sites: Abdominal wall Retroperitoneum (excluding fat)		T4	RE	RE
66	Ascending colon: Right kidney Right ureter Descending colon: Left kidney Left ureter		T4	RE	RE

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
70	Cecum, appendix, 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	T4	D	D
75	All colon sites unless otherwise stated above: Adrenal (suprarenal) gland Bladder Diaphragm Fistula to skin Gallbladder Other segment(s) of colon via serosa		T4	D	D
80	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	T4	D	D

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
95	No evidence of primary tumor	No evidence of primary tumor	T0	U	U
99	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	U	U

CCDE Item 10.8: Registry CS lymph nodes

Collaborative stage (CS) lymph nodes [NAACCR data item #2830] obtained from the central cancer registry database. See CS Staging Manual (page 274) at http://www.cancerstaging.org/cstage/csmanualpart2.pdf.

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
00	None; no regional lymph node involvement	None; no regional lymph node involvement	N0	None	None
10	Regional lymph node(s) for all colon sites: Colic (NOS) Epicolic (adjacent to bowel wall) Mesocolic (NOS) Paracolic/pericolic Nodule(s) or foci in pericolic fat/adjacent mesentery/mesocolic fat	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

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
20	Regional lymph node(s), for specific subsites: Cecum and appendix: Cecal: anterior (prececal), posterior (retrocecal); NOS Ileocolic Right colic Ascending colon: Ileocolic Middle colic Right colic Transverse colon and flexures: 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	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 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)	*	RN	RN
30	Regional lymph node(s) for all colon sites: Mesenteric, NOS Regional lymph node(s), NOS	Mesenteric, NOS Regional lymph node(s), NOS	*	RN	RN
80	Lymph nodes, NOS	Lymph nodes, NOS	*	RN	RN
99	Unknown; not stated Regional lymph node(s) cannot be assessed Not documented in patient record	Unknown; not stated Regional lymph node(s) cannot be assessed Not documented in patient record	NX	U	U

* For codes 10-80 ONLY, the N category is assigned based on the value of Reg LN Pos, using the Lymph Nodes Number Positive Table for this site.

CCDE Item 10.9: 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 (page 275) at http://www.cancerstaging.org/cstage/csmanualpart2.pdf.

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
00	No; none	No; none	M0	None	None
08	Cecum, appendix, ascending, hepatic flexure and transverse colon: Superior mesenteric lymph node(s)		M1	RN	D
10	Distant lymph node(s) other than code 08 For all colon sites: Common iliac Distant lymph node(s), NOS External iliac Para-aortic Retroperitoneal For cecum, appendix, ascending colon, transverse colon, and hepatic flexure: Inferior mesenteric For splenic flexure, descending colon, and sigmoid colon: Superior mesenteric	Distant lymph node(s), NOS	M1	D	D
11		Rectosigmoid: Internal iliac (hypogastric) Obturator	M1	RN	D
12		Other distant lymph node(s), including external iliac or common iliac	M1	D	D

Value	Description for Colon	Description for Rectum	TNM	SS77	SS2000
40	Distant metastases except distant lymph node(s) (codes 08-10) Distant metastasis, NOS Carcinomatosis	Distant metastases except distant lymph node(s) codes 10-12 Distant metastasis, NOS Carcinomatosis	M1	D	D
50	(40) + [(08) or (10)] Distant lymph node(s) plus other distant metastases	(40) + any of [(10) to (12)] Distant lymph node(s) plus other distant metastases	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	MX	U	U

CHAPTER 5

Communications

The purpose of this chapter is to provide a central location to store information provided to the program from the CDC. This chapter can be used as a placeholder for memos from the CDC and IMS regarding the CCDE data and their submission. While these memos will continue to be announced and stored on the www.crcsdp.org Web site, hardcopies may be placed here for quick reference.

CHAPTER 6

Meeting Minutes

This chapter can be used as a placeholder for meeting minutes distributed by the CDC and IMS regarding the CCDE data and their submission. While these memos will continue to be announced and stored on the www.crcsdp.org Web site, hardcopies may be placed here for quick reference.

CHAPTER 7

References

This chapter contains a list of optional reading material related to colorectal cancer screening. These items will be listed in a bibliography type format. In addition, it will include definitions for common abbreviations used by this demonstration program.

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 CRCSDP Home Page:	http://www.cdc.gov/colorectalcancer/
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.
CRCSDP Awardee Contacts:	https://www.crcsdp.org/main/all_contacts
CRCSDP Resource Web Site:	www.crcsdp.org
CS Coding Manual:	http://www.cancerstaging.org/cstage/manuals.html
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 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:	http://seer.cancer.gov/tools/codingmanuals
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.