ATTACHMENT 3c. CCDE Data Users Manual

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Colorectal Clinical Data Elements (CCDE)

DATA USER'S MANUAL

for the

Colorectal Cancer Control Program (CRCCP)

CCDE Version 1.00 March 2010

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

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Introduction

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

The intended audience for this manual is the grantee staff responsible for the collection and aggregation of the CCDE data. It is divided into 4 chapters as follows:

Chapter 1 Data Submission

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

Chapter 2 Colorectal Cancer Clinical Data Elements (CCDEs)

This chapter includes a general introduction to the CCDEs and detailed information about each CCDE data item.

Chapter 3 Registry Linkage

This chapter provides variable definition tables that outline each of the collaborative stage variables collected in the CCDEs.

Chapter 4 References

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

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CHAPTER 1

CCDE Data Submission

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

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

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

Inclusion of records:

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

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

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

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

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

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

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

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

YP -> Your Program's abbreviation (e.g. AL = Alabama)

MM -> Month of submission due date, with leading zeroes (09 = September)

YY -> Year of submission due date (10 = 2010)

VVV -> CCDE version number (100 = CCDE version 1.00)

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

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

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

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

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

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

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

YPMMYY-NARRATIVE

YP = Your Program's abbreviation (e.g. AL = Alabama)

MM = Month of submission due date, with leading zeroes (09 = September)

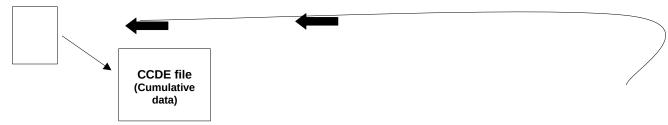
YY = Year of submission due date (10 = 2010)

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

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

Semi-annual CCDE Data Submission Process

Grantees



 $\begin{subarray}{c} \begin{subarray}{c} \beg$

| • | CCDE | | | ubmission Process National and | | |
|---------------------------|---|--|---|--|---|---------------------|
| Sexpicatini | ual Timeline | www.crccp.org Web site | - | Validation a Steps Analysis | - | Grantee Specific |
| March September Narrative | | file and Su | Grantee programs prepare and submit a CCD file and Submission Narrative on March 15 and September 15. | | | |
| May | November Reports, da | ata reviews, Cand Col | IMS creates an analysis file that is provided to the Carlo within a specified times frame, for review and approval. | | | |
| June | December | reviewed a | IMS generates feedback reports which are reviewed and posted to the www.crccp.org Web site within a specified time frame. | | | |
| July . | January | approximate feedback realities IMS Techn | CCDE Data Review Calls are held within approximately one month of the posting of the feedback reports. Data Notes, prepared by the IMS Technical Consultant, are posted three business days in advance of the scheduled call. | | | |
| July | January | The IMS Clinical Data Consultant sends Action Items requiring investigation or response to the Program Consultant and the Grantee within 5 business days after a data call. The CDC Program Consultant communicates a summary of the data review in a letter to the Grantee. | | | sponse to the see within 5 ne CDC s a summary of | |
| August | The Grantee invector completes responsion Narra next CCDE submi | | | nses in Secti ative and sub | ons I | and II of the |

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

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

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

CHAPTER 2

Colorectal Cancer Clinical Data Elements (CCDEs)

Introduction to the CCDE Chapter

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

Understanding the CCDE data

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

CCDE Field Descriptions

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

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

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

Understanding the CCDE Data

Colorectal Cancer Clinical Data Elements

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

CCDE Cycle Definition

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

Tracking Screening Adherence

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

Structure of the CCDEs

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

Section 1: Client and Record Identification

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

Section 2: Demographic Information

This section contains demographic information about clients. The information collected in this section must be self-reported by the clients. This information must be completed for each client and each CCDE record for that client.

Section 3: Screening History

This section contains information regarding previous colorectal screening tests. The information collected in this section can be self-reported by the client, or can come from information documented in the client's medical record. Medical record information is preferred if available. This information must be completed for each client and each CCDE record for that client.

Section 4: Assessed Risk

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

Section 5: Screening Adherence

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

<u>Section 6: Screening and Diagnostic Tests Performed</u>

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

Section 7: Pathology from all Endoscopy Tests Performed

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

Section 8: Diagnosis Information for Surgeries Performed to Complete Diagnosis

This section contains data regarding the date of surgery and histology from the surgical resection. This section should be completed anytime the client has "surgery recommended to complete the final diagnosis" after one of the tests in Section 6.

Section 9: Final Diagnosis

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

Section 10: Treatment Information

This section collects treatment information for clients with a final diagnosis of cancer.

Section 11: Registry Information for Cancer/High Grade Dysplasia

This section collects staging information obtained after linking with the central cancer registry for diagnoses of cancer and high grade dysplasia.

Section 12: Record Information

This section includes the CCDE version for data reported and an end of record mark.

Race and Hispanic Origin

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

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

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

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

Unique Client Identifier

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

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

Data Conventions

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

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

Alphanumeric Fields: Alphanumeric or character data must be left-justified. In a left-justified field, the field value is placed so that the first character of the value is in the first position of the field. For example, Item 1.2 (Client Identifier) is left-justified in the CCDE file. The starting and ending positions are columns 4 through 18. If the Client Identifier is 1234, then "1234" should be placed in columns 4 through 7 and columns 8 through 18 would be filled with blanks as shown here: "1234".

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

Blank Filled Fields: A blank filled field is filled with blank characters. If the field has a length of six and it is appropriate to blank fill the field, then it should contain six blank characters. It is only appropriate to blank fill a field when it is indicated in the item description. A blank field should not be used as a substitute for an "unknown" response if a valid "unknown" code exists.

CCDE Field Descriptions

ITEM NO / NAME: 1.1: Program

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

LENGTH: 3

FIELD LOCATION: 1-3

TYPE: Numeric – right justify. Include leading zeroes.

SKIP PATTERN: This field should always be completed.

CONTENTS: 001 = Alabama (AL)

004 = Arizona (AZ) 006 = California (CA) 008 = Colorado (CO) 009 = Connecticut (CT) 010 = Delaware (DE) 012 = Florida (FL) 019 = Iowa (IA) 023 = Maine (ME)

024 = Maryland (MD) 025 = Massachusetts (MA) 027 = Minnesota (MN) 030 = Montana (MT) 031 = Nebraska (NE)

033 = New Hampshire (NH) 035 = New Mexico (NM) 036 = New York (NY) 041 = Oregon (OR) 042 = Pennsylvania (PA) 046 = South Dakota (SD)

049 = Utah (UT)

053 = Washington (WA)

Tribal Program Codes 090 = Arctic Slope (AC)

092 = Southcentral Foundation (SO)

098 = South Puget Intertribal Planning Agency (SP) 099 = Alaska Native Tribal Health Consortium (AN)

EXPLANATION: The state FIPS codes are the Federal Information Processing

Standard codes developed by the National Bureau of Standards. The tribal program codes are codes assigned by the CDC to be

used by the tribal programs in lieu of state FIPS codes.

EXAMPLE: For Arizona: 004

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

ITEM NO / NAME: 1.2: Client identifier

PURPOSE: To indicate a system-generated identification number for each

client that will be consistent for the client throughout the database.

LENGTH: 15

FIELD LOCATION: 4-18

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

SKIP PATTERN: This field should always be completed.

CONTENTS: A fifteen-digit alphanumeric code. The client identifier must be

unique and constant for each client in your database in order to track each client over time. A client identifier that is unique only to a specific clinic or location is not acceptable because it cannot track the client between locations. Completely numeric client identifiers are preferred; however, the CCDEs allow the use of alphanumeric client identifiers if you find it necessary. If alphabetic characters are

included in the Client identifier field, they must be entered consistently in uppercase or lowercase for all records for each

client.

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

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

Number, 123-45-6789 is as follows:

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

EXAMPLE: Client identifier is 001000002357901: 001000002357901

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

ITEM NO / NAME: 1.3: Record identifier

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

LENGTH: 6

FIELD LOCATION: 19-24

TYPE: Numeric – right justify

SKIP PATTERN: This field should always be completed.

CONTENTS: A six-digit numeric code. This field will be used to identify one

unique record among many for a client. For example, the record

identifier can be a visit date or a sequential record number.

EXPLANATION: A screening cycle begins with either an initial colorectal cancer test

or the distribution of a fecal kit, continues through any additional tests required for diagnostic evaluation following an abnormal or incomplete test, and ends when a final diagnosis is reached and

treatment is initiated, when required.

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

number (e.g. 1 = first cycle, 2 = second cycle, etc).

Grantees are asked to be consistent in the method used for

creating a record identifier.

EXAMPLE: Using a date of 4/1/2010: <u>040110</u>

Using a cycle number of 1: 000001 or ____1

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

ITEM NO / NAME: 2.1: Date of birth

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

LENGTH: 8

FIELD LOCATION: 25-32

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the

month of birth from 01 to 12, DD is the day of birth from 01 to 31, and YYYY is the year of birth, including the century. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01 1955). At a

minimum, the year of birth must be reported.

EXPLANATION: Date of birth must be self-reported by the client. This field is used

to compute age values and is vital to various analyses. It is, therefore, important to provide as complete a date as possible.

EXAMPLE: For a client born on May 1, 1953: <u>05011953</u>

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

ITEM NO / NAME: 2.2: Gender

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

LENGTH: 1

FIELD LOCATION: 33

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Male

2 = Female

9 = Other/unknown

EXPLANATION: Gender must be self-reported by the client. A response of 9

(Other/unknown) in the context of this question could mean that the client was not asked, the client's answer was not recorded, the client self-identified with a gender other than male or female, or the

client refused to answer the question.

EXAMPLE: Client is female: 2

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

ITEM NO / NAME: 2.3 Hispanic or Latino origin

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

LENGTH: 1

FIELD LOCATION: 34

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

2 = No

9 = Unknown/missing

EXPLANATION: The method of identifying Hispanic or Latino Origin must be self-

identification by the client. Consider placing this field prior to race on the data form for better completion of the race/ethnicity data.

Hispanic Origin or Latino should be collected as a separate data field from race. If Hispanic or Latino Origin is not collected separately from race on your forms and a client reports race as Hispanic, then Item 2.3 (Hispanic or Latino origin) should be reported as 1 (Yes) and Item 2.4.1 (Race 1) should be reported as

9 (Unknown). If Hispanic or Latino Origin is not collected separately and a client reports race as something other than "Hispanic" or "Latino", then Item 2.3 (Hispanic or Latino Origin) should be reported as 9 (Unknown/missing). If Hispanic or Latino Origin is not asked of the client, the answer is not recorded, the client doesn't know or the client refuses to answer, then report 9

(Unknown/missing).

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

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

ITEM NO / NAME: 2.4.1: Race 1

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

LENGTH: 1

FIELD LOCATION: 35

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

9 = Unknown

EXPLANATION:

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

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

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

A Race and Ethnicity Code Set is provided at the end of this chapter (Chapter 2) in <u>Appendix B</u>. 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.

Section 2 - Demographic Information

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

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

ITEM NO / NAME: 2.4.2: Race 2

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

LENGTH: 1

FIELD LOCATION: 36

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than one race is self-

reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the

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

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

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

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

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

ITEM NO / NAME: 2.4.3: Race 3

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

LENGTH: 1

FIELD LOCATION: 37

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than two races are self-

reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the

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

in the Race 1 field.

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

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

EXAMPLE: If a client identifies as Asian, White and African American: Race 1

= 3; Race 2 = 1; and Race 3 = 2

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

ITEM NO / NAME: 2.4.4: Race 4

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

LENGTH: 1

FIELD LOCATION: 38

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than three races are

self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the

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

in the Race 1 field.

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

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

the CCDEs.

EXAMPLE: If a client identifies as Asian, White, African American and Alaska

Native: Race $1 = \underline{3}$; Race $2 = \underline{1}$; Race $3 = \underline{2}$; and Race $4 = \underline{5}$

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

ITEM NO / NAME: 2.4.5: Race 5

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

LENGTH: 1

FIELD LOCATION: 39

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than four races are self-

reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the

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

reported in the Race 1 field.

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

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

the CCDEs.

EXAMPLE: If a client identifies as Asian, White, African American, Alaskan

Native and Hawaiian: Race 1 = 3; Race 2 = 1; Race 3 = 2;

Race 4 = 5; and Race 5 = 4

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

ITEM NO / NAME: 2.5: State of residence

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

LENGTH: 2

FIELD LOCATION: 40-41

TYPE: Numeric - right justify

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

CONTENTS: A 2-digit numeric code.

EXPLANATION: State of residence must be self-reported by the client. The state

Federal Information Processing Standard (FIPS) codes are

developed by the National Institute of Standards and Technology

(NIST) and are available at

http://www.itl.nist.gov/fipspubs/fip5-2.htm. There is a code for each

state and territory.

EXAMPLE: Client's state of residence is Maryland: <u>24</u>

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|--------------|------------------|------------------|
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: 2.6 County of residence

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

LENGTH: 3

FIELD LOCATION: 42-44

TYPE: Numeric - right justify

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

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

Item 2.5.

EXPLANATION: County of residence must be self-reported by the client. The

county FIPS codes are the Federal Information Processing Standard codes developed by the National Institute of Standards

and Technology (NIST) and are available at

http://www.itl.nist.gov/fipspubs/co-codes/states.htm. There is a 3-digit code for each county in a state or territory. If the state or territory where the client lives does not have counties, enter 999.

EXAMPLE: Client's county of residence is Frontier, Nebraska: <u>063</u>

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

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

PURPOSE: To indicate if a client has previously received any of the following

colorectal screening tests: take-home FOBT, take-home FIT, sigmoidoscopy, colonoscopy, DCBE, CTC (virtual colonoscopy) or

stool DNA.

LENGTH: 1

FIELD LOCATION: 45

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This information can be self-reported by the client, or can come

from information documented in the client's medical record. Medical record information is preferred, if available. Fecal tests done by a provider in an office are not acceptable and should not

be recorded in this field.

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

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

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

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

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

precancerous polyps

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

cancer or adenomatous/pre-cancerous polyps.

LENGTH: 1

FIELD LOCATION: 46

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

If Item 4.1 (Personal history of CRC (colorectal cancer) or

precancerous polyps) = 1 (Yes), then Item 6.0 (Indication for test 1)

should $\underline{not} = 1$ (Screening).

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This field is used to indicate if a client has ever been diagnosed

with colorectal cancer, which is cancer of the colon or rectum.

Other possible terms for CRC include colon cancer, rectal cancer, cancer of the large intestine, cancer of the large bowel, and bowel cancer. Anal cancer, or cancer of the anus, should not be reported

in this field.

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

be reported as 1 (Screening).

This information can be self-reported by the client, or can come from information documented in the client's medical record. Medical record information is preferred, if available. If the client indicates that he/she has been previously diagnosed with CRC or had a precancerous polyp, then this field should be completed as 1 (Yes). If the client has never been diagnosed with CRC or a pre-

cancerous polyp prior to the visit, then complete this field as 2 (No).

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

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

ITEM NO / NAME: 4.2: Family history of CRC

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

LENGTH: 1

FIELD LOCATION: 47

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This information should be self-reported by the client, or can come

from information documented in the client's medical record. Medical

record information is preferred, if available.

The information reported in this field may include family history of

either CRC or adenomatous polyps.

Each grantee, in conjunction with the Medical Advisory Board, will determine criteria and type of screening test offered for clients at

determine criteria and type of screening test offered for clients at increased risk for CRC due to family history of CRC or

adenomatous polyps. These criteria should be consistent with

available guidelines.

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

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

ITEM NO / NAME: 4.3: Currently experiencing CRC symptoms

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

symptoms.

LENGTH: 1

FIELD LOCATION: 48

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This information can be self-reported by the client, or can come

from information documented in the client's medical record. Medical

record information is preferred, if available.

Each grantee should work with its Medical Advisory Board to define a list of symptoms requiring medical evaluation. The list may

include, but may not be limited to:

- Rectal bleeding, bloody diarrhea, or blood in the stool within the past 6 months (bleeding that is known or suspected to be due to hemorrhoids after clinical evaluation would not prevent a client from receiving CRC screening services).
- Prolonged change in bowel habits (e.g., diarrhea or constipation for more than two weeks that has not been clinically evaluated).
- Persistent abdominal pain.
- Symptoms of bowel obstruction (e.g., abdominal distension, nausea, vomiting, severe constipation).
- Significant unintentional weight loss of 10% or more of starting body weight.

If the response is 1 (Yes), then the client is clinically ineligible for CRCCP funded testing, and will need to be referred out of the program for the appropriate medical care or evaluation.

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If a clinically ineligible client is subsequently evaluated and cleared for screening, they may be enrolled for CRCCP funded testing with Item 4.3 updated from 1 (Yes) to 2 (No).

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

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

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

PURPOSE: To indicate the date testing was initiated for a client based on date

of FOBT/FIT kit distribution or the initial appointment date for the

first test recommended within this cycle.

LENGTH: 8

FIELD LOCATION: 49 - 56

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is a value

from 01 to 12, DD is a value from 01 to 31, and YYYY is the year, including the century. No part of this date field may be left blank.

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

EXPLANATION: If the initial test was a take-home FOBT or take-home FIT, then

indicate the date that the fecal kit was distributed to the client. Otherwise, indicate the initial appointment date scheduled for the

first test.

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

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

ITEM NO / NAME: 5.2: Screening adherence

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

LENGTH: 1

FIELD LOCATION: 57

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

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

CONTENTS: 1 = Test Performed

2 = Test Pending

3 = No test performed, FOBT/FIT card not returned

4 = No test performed, appointment not kept

EXPLANATION: Each grantee will need to establish guidelines to determine when a

fecal kit is considered unreturned, how much time can elapse or the number of appointments rescheduled before a client is considered

an appointment no show.

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

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

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

If, once the established timeframe has been reached, and the appointment for the initial test has not been kept, indicate 4 (No test performed, appointment not kept). The CCDE cycle should be

considered closed. This does not mean that attempts to get the client in for testing should stop. If the client does return for an initial test, a new CCDE cycle should be created.

EXAMPLE: If the client returns their FOBT kit: 1

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

ITEM NO / NAME: 6.0: Indication for test 1

PURPOSE: To report the indication or purpose for the first test provided to the

client, reported in Item 6.1.01 (Test 1 performed).

LENGTH: 1

FIELD LOCATION: 58

TYPE: Numeric

SKIP PATTERN: This field should be completed when 5.2 (Screening Adherence = 1

(Test Performed).

If Item 4.1 (Personal history of CRC (colorectal cancer) or

precancerous polyps) = 1 (Yes), then Item 6.0 (Indication for test 1)

should not = 1 (Screening).

CONTENTS: 1 = Screening

2 = Surveillance 3 = Diagnostic 9 = Unknown

EXPLANATION: A screening test (1) is a test provided for a client who has no

colorectal cancer symptoms, may have never been screened for colorectal cancer, or may have had a previous screening test without significant findings and is due for routine rescreening.

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

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

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

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

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|--------------|------------------|------------------|
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: 6.1.01: Test 1 performed

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

cycle.

LENGTH: 1

FIELD LOCATION: 59

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

If Item 6.0 (Indication for test 1) = 1 (Screening), then Item 6.1.01

should $\underline{not} = 5$ (DCBE).

If Item 6.0 (Indication for test 1) = 3 (Diagnostic), then Item 6.1.01

should only = 4 or 5.

CONTENTS: 1 = Take-home Fecal Occult Blood Test (FOBT)

2 = Take-home Fecal Immunochemical Test (FIT)

3 = Sigmoidoscopy 4 = Colonoscopy

5 = Double-contrast Barium Enema (DCBE)

7 = Other

EXPLANATION: This field should be reported with the first test received by the client

within the current cycle.

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

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|--------------|------------------|------------------|
| 1.00 | 12/02/2009 | Add new |

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

PURPOSE: To specify the type of "other" test indicated in Item 6.1.01 (Test 1

performed).

LENGTH: 40

FIELD LOCATION: 60 - 99

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.1.01 (Test 1

performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.1.01.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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|--------------|------------------|------------------|
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: 6.1.03: Date of test 1

PURPOSE: To specify the date of the first test.

LENGTH: 8

FIELD LOCATION: 100 - 107

TYPE: Date

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the

month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. <u>08 2010</u>). This field should not be left

completely blank if a first test was performed.

EXPLANATION: This field captures the date that test 1 is performed. If the test is a

take-home FOBT or FIT, then report the date that the kit was

processed.

If a test was recommended, but the appointment was not kept, or the FOBT/FIT kit was not returned, then this information should be reported in Item 5.1 (Initial test appointment date, or date fecal kit distributed) and Item 5.2 (Screening adherence). Items in Section

6 (Screening and Diagnostic Tests Performed) are limited to

reporting data on tests that were completed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: <u>08012010</u>

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

ITEM NO / NAME: 6.1.04: Provider specialty

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

LENGTH: 2

FIELD LOCATION: 108 - 109

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

CONTENTS: 1 = General practitioner

2 = Internist

3 = Family practitioner
4 = Gastroenterologist
5 = General surgeon
6 = Colorectal surgeon

7 = Licensed practical nurse

8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant

11 = Administrator, if FOBT/FIT mailed by non-clinician

12 = Radiologist

13 = Obstetrician/Gynecologist (OB/GYN)

99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the

provider who performed or provided the first test reported in Item

6.1.01.

If the first test is an FOBT/FIT, capture the specialty of the

individual that made the assessment that a FOBT/FIT should be

provided to the client.

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

provided to the client.

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

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

ITEM NO / NAME: 6.1.05: Result of test 1

PURPOSE: To specify the result of test 1.

LENGTH: 1

FIELD LOCATION: 110

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

If Item 6.1.01 (Test 1 performed) = 1 (Take-home FOBT) or 2

(Take-home FIT), then Item 6.1.05 must = 5, 6, 7 or 9.

If Item 6.1.01 (Test 1 performed) = 3 (Sigmoidoscopy), 4

(Colonoscopy) or 5 (DCBE), then Item 6.1.05 must = 1-4, 7 or 9.

If Item 6.1.01 (Test 1 performed) = 7 (Other), then Item 6.1.05 must

be reported using the result that is appropriate for the test

performed and specified in Item 6.1.02 (Test 1 performed – other

specify).

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids

2 = Other finding not suggestive of cancer or polyp(s)

3 = Polyp(s), or Lesion(s) suspicious for cancer

4 = Inadequate/Incomplete test with no findings

5 = FOBT/FIT/Other Test Performed Negative

6 = FOBT/FIT/Other Test Performed Positive

7 = Pending

9 = Unknown

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

the most severe.

For take-home FOBT, take-home FIT or other similar stool tests, if the medical chart records any gradation of positive (e.g. "weakly positive" or "slightly positive"), then Item 6.1.05 should be recorded

as 6 (FOBT/FIT/Other Test Performed Positive).

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

Examples of Other findings may include:

- Colitis (inflammation of the bowel wall)
- Arteriovenous malformation

- Ulcerative colitis
- Crohn's colitis

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

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

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

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

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

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

endoscopy?

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

sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 111

TYPE: Numeric

SKIP PATTERN: If Item 6.1.06 = 1 (Yes), then Item 7.1 (Histology of most severe

polyp/lesion) must be completed.

Leave blank if Item 6.1.01 (Test 1 performed) = 1 (Take-home

FOBT), 2 (Take-home FIT), 5 (DCBE) or 7 (Other).

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This field should only be completed if the first test provided is either

a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most

severe polyp/lesion) must be completed.

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

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

ITEM NO / NAME: 6.1.07: Was the bowel preparation considered adequate by the

clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a

sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 112

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 (Test 1 performed) = 3

(Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other);

otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the

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

(Unknown).

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

(Unknown).

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

adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: <u>1</u>

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

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

PURPOSE: To indicate whether or not the procedure report notes that the

cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 113

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 (Test 1 performed) = 4

(Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was

reached or not reached during the colonoscopy in order to report 1

(Yes) or 2 (No); otherwise, report 9 (Unknown).

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

(Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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

ITEM NO / NAME: 6.1.09: Test 1 outcome

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

LENGTH: 1

FIELD LOCATION: 114

TYPE: Numeric

SKIP PATTERN: If Item 6.1.05 (Result of test 1) = 5 (FOBT/FIT/Other Test

Performed Negative) or 6 (FOBT/FIT/Other Test Performed

Positive), then Item 6.1.09 should = 1 (Complete).

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

If Item 6.1.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.1.09

should = 2 (Incomplete/Inadequate).

If Item 6.1.08 (Cecum reached) = 2 (No), then Item 6.1.09 should =

2 (Incomplete/Inadequate).

CONTENTS: 1 = Complete

2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in

Item 6.1.05 (Result of test 1). If the test was completed

satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached during colonoscopy, then

report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose

not to remove the smaller polyps. In these instances, the Test

Outcome would be considered 1 (Complete). If the

recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication

then that procedure would begin a new cycle where the in

(Item 6.0) would be reported as 2 (Surveillance).

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

tests needed) as Test 2.

EXAMPLE: If the colonoscopy is considered complete: $\underline{1}$

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

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

cycle.

PURPOSE: To indicate the next recommended procedure following the

completion of Test 1 needed to complete this cycle. (This should

not be confused with Item 9.04 to report the next test

recommended for re-screening or surveillance.)

1 LENGTH:

FIELD LOCATION: 115

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence = 1 (Test Performed).

CONTENTS: 1 = Sigmoidoscopy

2 = Colonoscopy

3 = DCBE

4 = Surgery to complete diagnosis

7 = Other

8 = None (cycle is complete)

Once test 1 is completed, the next recommended procedure within **EXPLANATION:**

the screening cycle should be reported. The next recommended test within the screening cycle should either be a diagnostic test to follow-up a positive initial screening test or another screening test where the first screening test was incomplete or inconclusive.

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

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

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

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

EXAMPLE: If a DCBE is recommended as the next procedure within this

client's "cycle": 3

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

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

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

LENGTH: 40

FIELD LOCATION: 116 - 155

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.1.10 (Recommended

next follow-up procedure within this cycle) is reported as 7 (Other);

otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.1.10.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: <u>virtual</u>

colonoscopy

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

ITEM NO / NAME: 6.2.01: Test 2 performed

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

cycle.

LENGTH: 1

FIELD LOCATION: 156

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

CONTENTS: 0 = None

3 = Sigmoidoscopy 4 = Colonoscopy

5 = Double-contrast Barium Enema (DCBE)

7 = Other

EXPLANATION: This field should be reported with the second test received by the

client within the current cycle.

EXAMPLE: If the second test provided to the client is a DCBE: <u>5</u>

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

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

PURPOSE: To specify the type of "other" test indicated in Item 6.2.01 (Test 2

performed).

LENGTH: 40

FIELD LOCATION: 157 - 196

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2

performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.2.01.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: <u>virtual colonoscopy</u>

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

ITEM NO / NAME: 6.2.03: Date of Test 2

PURPOSE: To specify the date of the second test.

LENGTH: 8

FIELD LOCATION: 197 - 204

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2

performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month

from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. <u>08 2010</u>). This field should not be left completely

blank if a second test was performed.

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

EXAMPLE: If a colonoscopy is performed on August 1, 2010: <u>08012010</u>

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

ITEM NO / NAME: 6.2.04: Provider specialty

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

LENGTH: 2

FIELD LOCATION: 205 - 206

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2

performed) is not = 0 (None).

CONTENTS: 1 = General practitioner

2 = Internist

3 = Family practitioner 4 = Gastroenterologist 5 = General surgeon 6 = Colorectal surgeon

7 = Licensed practical nurse

8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant

12 = Radiologist

13 = Obstetrician/Gynecologist (OB/GYN)

99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the

provider who performed or provided the first test reported in Item

6.2.01.

EXAMPLE: If the provider specialty for the second test is a general surgeon: $\underline{5}$

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

ITEM NO / NAME: 6.2.05: Result of Test 2

PURPOSE: To specify the results of Test 2.

LENGTH: 1

FIELD LOCATION: 207

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2

performed) is not = 0 (None).

If Item 6.2.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE),

then Item 6.2.05 must = 1 - 4, 7 or 9.

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

Item 6.2.02

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids

2 = Other finding not suggestive of cancer or polyp(s)

3 = Polyp(s), or Lesion(s) suspicious for cancer

4 = Inadequate/Incomplete test with no findings

5 = FOBT/FIT/Other Test Performed Negative

6 = FOBT/FIT/Other Test Performed Positive

7 = Pending

9 = Unknown

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

the most severe.

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

finding, but the finding is not a cancerous lesion or a polyp.

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

Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician

fatigue.

If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the

observations and be reported using response options 1, 2 or 3.

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

EXAMPLE: If result of the colonoscopy is normal: $\underline{1}$

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

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

endoscopy?

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

sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 208

TYPE: Numeric

SKIP PATTERN: If Item 6.2.06 = 1 (Yes), then Item 7.1 (Histology of most severe

polyp/lesion) must be completed.

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

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This field should only be completed if the second test provided is

either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most

severe polyp/lesion) must be completed.

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

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

ITEM NO / NAME: 6.2.07: Was the bowel preparation considered adequate by the

clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a

sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 209

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 (Test 2 performed) = 3

(Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other);

otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the

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

(Unknown).

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

(Unknown).

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

adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: <u>1</u>

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

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

PURPOSE: To indicate whether or not the procedure notes report that the

cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 210

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 (Test 2 performed) = 4

(Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was

reached or not reached during the colonoscopy in order to report 1

(Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.2.08 is 2 (No), then Item 6.2.09 (Test 2 outcome) should

be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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

ITEM NO / NAME: 6.2.09: Test 2 outcome

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

LENGTH: 1

FIELD LOCATION: 211

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2

performed) is not 0 = (None).

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

If Item 6.2.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed

Positive), then Item 6.2.09 should = 1 (Complete).

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

should = 2 (Incomplete).

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

2 (Incomplete).

CONTENTS: 1 = Complete

2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in

Item 6.2.05. If the test was completed satisfactorily, report 1

(Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel

periorned satisfactority such as all obstruction, inadequate

prep, or the cecum was not reached, then report 2

(Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are

extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test

Outcome would be considered 1 (Complete). If the

recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication

(Item 6.0) would be reported as 2 (Surveillance).

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

EXAMPLE: If the colonoscopy is considered complete: 1

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

ITEM NO / NAME: 6.2.10: Recommended next follow-up procedure within this

cycle after test 2.

PURPOSE: To indicate the next recommended procedure following the

completion of Test 2.

LENGTH: 1

FIELD LOCATION: 212

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2

performed) is not = 0 (None).

CONTENTS: 1 = Sigmoidoscopy

2 = Colonoscopy

3 = DCBE

4 = Surgery to complete diagnosis

7 = Other

8 = None (cycle is complete)

EXPLANATION: Once Test 2 is completed, the next recommended procedure within

the screening cycle should be reported. The next recommended test within the screening cycle should either be a diagnostic test to follow-up a positive initial screening test or another screening test where the first and second screening tests were incomplete or

inconclusive.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable. No further procedures (Items 6.3.01 or 6.4.01) should be reported. Items 6.3.01 and 6.4.01

should be completed with 0 (None).

If Test 2 is normal and the recommended screening or surveillance test for the next cycle is FOBT or FIT, then indicate 8 (None). The screening cycle should be considered complete and the next FOBT or FIT should begin a new CCDE record. Items 6.3.01 and 6.4.01

should be completed with 0 (None).

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

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

EXAMPLE:

If a DCBE is recommended as the next procedure within this clients "cycle": $\underline{3}$

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

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

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

LENGTH: 40

FIELD LOCATION: 213 - 252

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.2.10 is reported as 7

(Other); otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.2.10.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: <u>virtual</u>

colonoscopy

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

ITEM NO / NAME: 6.3.01: Test 3 performed

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

cycle.

LENGTH: 1

FIELD LOCATION: 253

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

CONTENTS: 0 = None

3 = Sigmoidoscopy 4 = Colonoscopy

5 = Double-contrast Barium Enema (DCBE)

7 = Other

EXPLANATION: This field should be reported with the third test received by the

client within the current cycle.

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

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

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

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

LENGTH: 40

FIELD LOCATION: 254 - 293

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3

performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.3.01.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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

ITEM NO / NAME: 6.3.03: Date of Test 3

PURPOSE: To specify the date of the third test.

LENGTH: 8

FIELD LOCATION: 294 - 301

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3

performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month

from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. <u>08</u> 2010). This field should not be left completely

blank if a second test was performed.

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

EXAMPLE: If a colonoscopy is performed on August 1, 2010: <u>08012010</u>

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

ITEM NO / NAME: 6.3.04: Provider specialty

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

LENGTH: 2

FIELD LOCATION: 302 - 303

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3

performed) is not = 0 (None).

CONTENTS: 1 = General practitioner

2 = Internist

3 = Family practitioner4 = Gastroenterologist5 = General surgeon6 = Colorectal surgeon

7 = Licensed practical nurse

8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant

12 = Radiologist

13 = Obstetrician/Gynecologist (OB/GYN)

99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the

provider who performed or provided the first test reported in Item

6.3.01.

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

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

ITEM NO / NAME: 6.3.05: Result of Test 3

PURPOSE: To specify the results of Test 3.

LENGTH: 1

FIELD LOCATION: 304

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3

performed) is not = 0 (None).

If Item 6.3.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE),

then Item 6.3.05 must = 1 - 4, 7 or 9.

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

Item 6.3.02.

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids

2 = Other finding not suggestive of cancer or polyp(s)

3 = Polyp(s), or Lesion(s) suspicious for cancer 4 = Inadequate/Incomplete test with no findings

5 = FOBT/FIT/Other Test Performed Negative

6 = FOBT/FIT/Other Test Performed Positive

7 = Pending

9 = Unknown

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

the most severe.

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

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

bowel was not adequately cleared of fecal material) or physician

fatigue.

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

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

EXAMPLE: If result of the colonoscopy is normal: $\underline{1}$

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

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

endoscopy?

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

sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 305

TYPE: Numeric

SKIP PATTERN: If Item 6.3.06 = 1 (Yes), then Item 7.1 (Histology of most severe

polyp/lesion) must be completed.

Leave blank if 6.3.01 = 0, 5 or 7.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This field should only be completed if the third test provided is

either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most

severe polyp/lesion) must be completed.

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

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

ITEM NO / NAME: 6.3.07: Was the bowel preparation considered adequate by the

clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a

sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 306

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 (Test 3 performed) = 3

(Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other);

otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the

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

(Unknown).

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

(Unknown).

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

adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: <u>1</u>

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

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

PURPOSE: To indicate whether or not the procedure notes report that the

cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 307

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 (Test 3 performed) = 4

(Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was

reached or not reached during the colonoscopy in order to report 1

(Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.3.08 is 2 (No), then Item 6.3.09 (Test 3 outcome) should

be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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

ITEM NO / NAME: 6.3.09: Test 3 outcome

PURPOSE: To indicate if the third test was complete.

LENGTH: 1

FIELD LOCATION: 308

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3

performed) is not = 0 (None).

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

If Item 6.3.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed

Positive), then Item 6.3.09 should = 1 (Complete).

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

should = 2 (Incomplete).

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

2 (Incomplete).

CONTENTS: 1 = Complete

2 = Incomplete/Inadequate

Each test provided should have a specific result that is reported in **EXPLANATION:**

Item 6.3.05. If the test was completed satisfactorily, report 1

(Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel

prep, or the cecum was not reached, then report 2

(Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are

extremely small (< 5mm), it is acceptable for the provider to choose

not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the

recommendation of a repeat colonoscopy in 3-6 months is made,

then that procedure would begin a new cycle where the indication

(Item 6.0) would be reported as 2 (Surveillance).

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

EXAMPLE: If the colonoscopy is considered complete: 1

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

ITEM NO / NAME: 6.3.10: Recommended next follow-up procedure within this

cycle after test 3.

PURPOSE: To indicate the next recommended procedure following the

completion of Test 3.

LENGTH: 1

FIELD LOCATION: 309

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3

performed) is not = 0 (None).

CONTENTS: 1 = Sigmoidoscopy

2 = Colonoscopy

3 = DCBE

4 = Surgery to complete diagnosis

7 = Other

8 = None (cycle is complete)

EXPLANATION: Once Test 3 is completed, the next recommended procedure within

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

inconclusive.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable. No further procedures (Item 6.4.01) should be reported. Item 6.4.01 will be completed with 0

(None).

If Test 3 is normal and the recommended screening or surveillance test for the next cycle is FOBT or FIT, then indicate 8 (None). The screening cycle should be considered complete and the next FOBT or FIT should begin a new CCDE record. Item 6.4.01 should be

completed with 0 (None).

There may be rare instances in which it is appropriate for an FOBT or FIT to be reported as Test 4. In these instances Item 6.3.10 should be reported as 7 (Other). Item 6.3.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

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

EXAMPLE:

If a DCBE is recommended as the next procedure within this clients "cycle": $\underline{3}$

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

ITEM NO / NAME: 6.3.11: Other recommended test, specify

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

LENGTH: 40

FIELD LOCATION: 310 - 349

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.3.10 is reported as 7

(Other). Otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.3.10.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: <u>virtual</u>

colonoscopy

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

ITEM NO / NAME: 6.4.01: Test 4 performed

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

cycle.

LENGTH: 1

FIELD LOCATION: 350

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

Adherence) = 1 (Test Performed).

CONTENTS: 0 = None

3 = Sigmoidoscopy 4 = Colonoscopy

5 = Double-contrast Barium Enema (DCBE)

7 = Other

EXPLANATION: This field should be reported with the fourth test received by the

client within the current cycle.

EXAMPLE: If the fourth test provided to the client is a DCBE: <u>5</u>

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

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

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

LENGTH: 40

FIELD LOCATION: 351 - 390

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4

performed) = 7 (Other). Otherwise, leave blank.

EXPLANATION: This field captures the type of "other" test indicated in Item 6.4.01.

Use this item appropriately. Reclaiming inappropriate "other"

responses is time consuming and could potentially result in the loss

of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

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

ITEM NO / NAME: 6.4.03: Date of Test 4

PURPOSE: To specify the date of the fourth test.

LENGTH: 8

FIELD LOCATION: 391 - 398

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4

performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month

from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. <u>08</u> <u>2010</u>). This field should not be left completely

blank if a second test was performed.

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

EXAMPLE: If a colonoscopy is performed on August 1, 2010: <u>08012010</u>

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

ITEM NO / NAME: 6.4.04: Provider specialty

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

LENGTH: 2

FIELD LOCATION: 399 - 400

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4

performed) is not = 0 (None).

CONTENTS: 1 = General practitioner

2 = Internist

3 = Family practitioner4 = Gastroenterologist5 = General surgeon6 = Colorectal surgeon

7 = Licensed practical nurse

8 = Registered nurse 9 = Nurse practitioner 10 = Physician assistant

12 = Radiologist

13 = Obstetrician/Gynecologist (OB/GYN)

99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the

provider who performed or provided the first test reported in Item

6.4.01.

EXAMPLE: If the provider specialty for the fourth test is a general surgeon: $\underline{5}$

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

ITEM NO / NAME: 6.4.05: Result of Test 4

PURPOSE: To specify the results of Test 4.

LENGTH: 1

FIELD LOCATION: 401

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4

performed) is not = 0 (None).

If Item 6.4.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE),

then Item 6.4.05 must = 1 - 4, 7 or 9.

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

Item 6.4.02.

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids

2 = Other finding not suggestive of cancer or polyp(s)

3 = Polyp(s), or Lesion(s) suspicious for cancer

4 = Inadequate/Incomplete test with no findings

5 = FOBT/FIT/Other Test Performed Negative

6 = FOBT/FIT/Other Test Performed Positive

7 = Pending

9 = Unknown

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

the most severe.

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

finding, but the finding is not a cancerous lesion or a polyp.

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

fatigue.

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

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

EXAMPLE: If result of the colonoscopy is normal: $\underline{1}$

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

ITEM NO / NAME: 6.4.06: Was a biopsy/polypectomy performed during the

endoscopy?

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

sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 402

TYPE: Numeric

SKIP PATTERN: If Item 6.4.06 = 1 (Yes), then Item 7.1 (Histology of most severe

polyp/lesion) must be completed.

Leave blank if 6.4.01 = 0, 5 or 7.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: This field should only be completed if the fourth test provided is

either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most

severe polyp/lesion) must be completed.

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

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

ITEM NO / NAME: 6.4.07: Was the bowel preparation considered adequate by the

clinician performing the endoscopy or DCBE?

PURPOSE: To indicate the adequacy of the bowel preparation for a

sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 403

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 (Test 4 performed) = 3

(Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other);

otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the

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

(Unknown).

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

(Unknown).

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

adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

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

ITEM NO / NAME: 6.4.08: Was the cecum reached during the colonoscopy?

PURPOSE: To indicate whether or not the procedure notes report that the

cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 404

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 (Test 4 performed) = 4

(Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was

reached or not reached during the colonoscopy in order to report 1

(Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.4.08 is 2 (No), then Item 6.4.09 (Test 4 outcome) should

be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

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

ITEM NO / NAME: 6.4.09: Test 4 outcome

PURPOSE: To indicate if the fourth test was complete.

LENGTH: 1

FIELD LOCATION: 405

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4

performed) is not = 0 (None).

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

If Item 6.4.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed

Positive), then Item 6.4.09 should = 1 (Complete).

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

should = 2 (Incomplete).

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

2 (Incomplete).

CONTENTS: 1 = Complete

2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in

Item 6.4.05. If the test was completed satisfactorily, report 1

(Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel

prep, or the cecum was not reached, then report 2

(Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are

extremely small (< 5mm), it is acceptable for the provider to choose

not to remove the smaller polyps. In these instances, the Test

Outcome would be considered 1 (Complete). If the

recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication

(Item 6.0) would be reported as 2 (Surveillance).

Section 6 – Screening and Diagnostic Tests Performed

EXAMPLE: If the colonoscopy is considered complete: 1

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

ITEM NO / NAME: 6.4.10: Recommended next follow-up procedure within this

cycle after test 4.

PURPOSE: To indicate the next recommended procedure following the

completion of Test 4.

LENGTH: 1

FIELD LOCATION: 406

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4

performed) is not = 0 (None).

CONTENTS: 4 = Surgery to complete diagnosis

8 = None (cycle is complete)

EXPLANATION: Once Test 4 is completed, the next recommended procedure within

the screening cycle should be reported.

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

treatment data where applicable.

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

record.

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

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

ITEM NO / NAME: 7.1: Histology of the most severe polyp or lesion

PURPOSE: Report the worst histology of all biopsies and polypectomies

performed during this cycle.

LENGTH: 2

FIELD LOCATION: 407 - 408

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed if a biopsy or polypectomy was

performed during any of Test 1 - 4 [Item 6.x.06 = 1 (Yes)].

CONTENTS: 1 = Normal or other non-polyp histology

2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.)

3 = Hyperplastic polyp

4 = Adenoma, NOS (no high grade dysplasia noted)

5 = Adenoma, tubular (no high grade dysplasia noted)

6 = Adenoma, mixed tubular villous (no high grade dysplasia

noted)

7 = Adenoma, villous (no high grade dysplasia noted)

8 = Adenoma, serrated (no high grade dysplasia noted)

9 = Adenoma with high grade dysplasia (includes in situ

carcinoma)

10 = Adenocarcinoma, invasive

11 = Cancer, other

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

EXPLANATION: Report the most severe histology result found across all pathology

for Test 1 through Test 4 when a biopsy or polypectomy was

performed during endoscopy. Do not include histology results from

surgical resection. Histology from surgical resection should be

reported in Item 8.1.

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

polyp with high grade dyspiasia is determined to be cancer during a

subsequent surgery.

If the worst histology includes any of the adenoma diagnoses (4-

11), then Items 7.2 and 7.3 must be completed.

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

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

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

| CCDE Colorectal Histology Categories | International Classification of Disease for Oncology, 3 rd 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 |
| | Adenocarcinoma in situ in |
| | 8210/2 adenomatous polyp |
| | Adenocarcinoma in situ in villous |
| | 8261/2 adenoma |
| | Adenocarcinoma in situ in |
| 40.44 | 8263/2 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 |

| | des and | 3 rd Edition, Acceptable Morphology Terminology from Common Codes |
|---|------------------|---|
| | 8214/3 | |
| | 8220/3 | Adenocarcinoma in adenomatous polyposis coli |
| 1 | 8221/3 | Adenocarcinoma in multiple adenomatous polyps |
| | 8260/3 | Papillary adenocarcinoma, NOS |
| | 8261/3 | Adenocarcinoma in villous adenoma |
| 1 | 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 |
| 1 | 8571/3 | Adenocarcinoma with cartilaginous and osseous metaplasia |
| | 8940/3 | Mixed tumor, malignant, NOS |
| : | 8941/3 | Carcinoma in pleomorphic adenoma |
| | | 148-8159, 8163-8179, 8222-8249, |
| | | 511-8519, 8551-8559, 8561-8569, |
| | | 942-9989 (with behavior codes of /3) |
| | | Tumor cells, malignant |
| | 8002/3 | Malignant tumor, small cell type |
| | 8004/3 8005/3 | Malignant tumor, spindle cell type |
| | 8050/3 | Malignant tumor, clear cell type Papillary carcinoma, NOS |
| | 8070/3 | Squamous cell carcinoma, NOS. |
| | 8240/3 | Carcinoid tumor, NOS |
| | 8249/3 | Atypical carcinoid tumor |

ITEM NO / NAME: 7.2: Total number of adenomatous polyps/lesions

PURPOSE: To indicate the total number of adenomatous polyps/lesions

removed or biopsied through all endoscopy procedures during the client's "cycle". Do not report specimens from surgical resections.

LENGTH: 2

FIELD LOCATION: 409 - 410

TYPE: Numeric - right justify

SKIP PATTERN: If Item 7.1 (Histology of most severe polyp/lesion) is an adenoma or

cancer (4-11), then Item 7.2 should be completed; otherwise, leave

blank.

CONTENTS: 01 = One adenomatous polyp/lesion removed or biopsied

02 = Two adenomatous polyps/lesions removed or biopsied

• • •

97 = ≥ Ninety-seven adenomatous polyps/lesions removed or

biopsied

98 = At least one adenomatous polyp/lesion removed or biopsied,

exact number not known

99 = Unknown

EXPLANATION: The actual number of adenomatous polyps or lesions removed

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

and report in Item 7.2.

When more than 97 adenomatous polyps or lesions are removed or

biopsied during endoscopy, report 97 (≥ 97 polyps/lesions).

If the report indicates adenomatous polyps or lesions were removed or biopsied, but no definite account of the number removed is available, indicate 98 (At least one polyp/lesion, exact

number not known).

If it is unknown whether any adenomatous polyps or lesions were

removed or biopsied, code 99 (Unknown).

Section 7 – Pathology from All Endoscopy Tests Performed

EXAMPLE: If 8 adenomatous polyps/lesions are noted: <u>08</u>

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

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

PURPOSE: To report the size of the largest adenomatous polyp or lesion

reported across all endoscopy procedures performed within the

cycle. Do not report specimens from surgical resections.

LENGTH: 1

FIELD LOCATION: 411

TYPE: Numeric – right justify

SKIP PATTERN: If Item 7.1 (Histology of most severe polyp/lesion) is an adenoma or

cancer (4-11), then Item 7.3 should be completed; otherwise, leave

blank.

CONTENTS: 1 = < 1 cm

 $2 = \ge 1 \text{ cm}$ 9 = Unknown

EXPLANATION: Report the diameter of the polyp/lesion in centimeters (cm) or the

longest dimension of the polyp/lesion. This should be the size of the actual polyp and not the size of the biopsy specimen submitted

for pathology. Do not include information from any surgical

resection.

There may be instances when a lesion is biopsied, but not removed during endoscopy. The size of such lesions should also be taken

into consideration when reporting the size of the largest

adenomatous polyp or lesion.

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

size from the pathology report.

EXAMPLE: If the size of the lesion is 2 cm: $\underline{2}$

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

ITEM NO / NAME: 8.1: Histology from surgical resection

PURPOSE: To report the worst histopathology from the surgical resection

reported in Item 6.x.10 (where x is either the 1st, 2nd, 3rd or 4th test reported in Section 6) if the client underwent surgery to complete

the diagnosis.

LENGTH: 2

FIELD LOCATION: 412 - 413

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.10 is 4 (Surgery to complete diagnosis), then this field

should be completed; otherwise, leave blank.

CONTENTS: 0 = Surgery recommended but not performed

1 = Normal or other non-polyp histology

2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.)

3 = Hyperplastic polyp

4 = Adenoma, NOS (no high grade dysplasia noted)

5 = Adenoma, tubular (no high grade dysplasia noted)

6 = Adenoma, mixed tubular villous (no high grade dysplasia noted)

7 = Adenoma, villous (no high grade dysplasia noted)

8 = Adenoma, serrated (no high grade dysplasia noted)

9 = Adenoma with high grade dysplasia (includes in situ

carcinoma)

10 = Adenocarcinoma, invasive

11 = Cancer, other

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

NOTE: For guidance on converting ICD-O morphology to CCDE histology from surgical resection, refer to the table following Item

7.1 (Histology of most severe polyp/lesion).

EXPLANATION: Most often, if a polyp is detected during endoscopy, it can be

removed during the endoscopy and the client will not need surgery to complete the diagnosis. On some occasions, if the polyp is large or the lesion is suspicious for cancer, a biopsy will be taken, but the lesion will not be removed in its entirety during the endoscopy.

Instead, it will be removed during a subsequent surgery to complete

the diagnosis.

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

considered when determining the worst histopathological diagnosis.

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

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

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

EXAMPLE:

If the histology for the polyp/lesion removed is cancer, other: 11

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

ITEM NO / NAME: 8.2: Date surgery performed

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

diagnosis.

LENGTH: 8

FIELD LOCATION: 414 - 421

TYPE: Date

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

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the

month of surgery from 01 to 12, DD is the day of surgery from 01 to 31, and YYYY is the year of the surgery, including the century. If just the year is known, blank fill the month and day. If just the year

and month are known, blank fill the day (e.g. 08 2010).

EXPLANATION: This field captures the date that the surgery to complete diagnosis

was performed. If more than one surgical resection was performed to obtain a final diagnosis, then report the date of the surgery which

provided the final diagnosis (Item 9.02).

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

If Item 8.1 = 0 (Surgery recommended but not performed), then this

field should be left blank.

EXAMPLE: If a surgery was performed on August 1, 2010: <u>08012010</u>

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

ITEM NO / NAME: 9.01: Status of final diagnosis

PURPOSE: To specify the status of final diagnosis for a cycle after all screening

and diagnostic tests are performed/offered to the client.

LENGTH: 1

FIELD LOCATION: 422

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening

adherence) is reported as 1 (performed); otherwise, leave blank.

CONTENTS: 1 = Complete (final diagnosis determined)

2 = Pending final diagnosis

3 = Client refused diagnostic follow-up

4 = Client lost to follow-up before final diagnosis was made

5 = Irreconcilable.

EXPLANATION: Report the status of the client's care after all screening and

diagnostic tests are performed/offered to the client.

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

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

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

A status of 4 (Client lost to follow-up) should be reported if prior to the completion of all recommended tests, a client moves to a location beyond the Program's range of service delivery, or the client can no longer be located by the grantee. A status of 4 (Lost to Follow-up) should also be reported if a client dies prior to the

completion of all recommended tests. Lost to follow-up should be reported when tracking efforts have been attempted in accordance with the grantee's written protocol, but were unsuccessful. Again, while such cases are simply reported to the CDC as 4 (Lost to Follow-up) in the CCDE file, grantees should track more detailed information about each "lost" case.

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

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

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

EXAMPLE:

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

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

ITEM NO / NAME: 9.02: Final diagnosis

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

LENGTH: 1

FIELD LOCATION: 423

TYPE: Numeric

SKIP PATTERN: If Item 9.01 (Status of final diagnosis) is 1 (Complete), then this

field should be completed; otherwise, leave blank.

CONTENTS: 1 = Normal/Negative

2 = Hyperplastic polyps

3 = Adenomatous polyp, no high grade dysplasia 4 = Adenomatous polyp with high grade dysplasia

5 = Cancer

EXPLANATION: After all screening and diagnostic tests are performed or offered to

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

the final diagnosis.

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

(Normal/Negative).

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

Section 11 (Registry Information for Cancer/High Grade Dysplasia)

should be completed if Item 9.02 (Final Diagnosis) = 4

(Adenomatous polyp with high grade dysplasia) or 5 (Cancer).

EXAMPLE: If the final diagnosis is Normal: 1

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

ITEM NO / NAME: 9.03: Date of final diagnosis

PURPOSE: To specify the date of final diagnosis.

LENGTH: 8

FIELD LOCATION: 424 - 431

TYPE: Date

SKIP PATTERN: This field should be completed if Item 9.01 (Status of final

diagnosis) is 1 (Complete), 3 (Refused), 4 (Lost to follow-up) or 5

(Irreconcilable); otherwise, it should be blank.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the

month of diagnosis from 01 to 12, DD is the day of diagnosis from 01 to 31, and YYYY is the year of diagnosis. If any part of the date is unknown, blank-fill only that part. For example, if the month and year of diagnosis are known, but the day is not, then blank-fill the

day (e.g. <u>08 2010</u>).

EXPLANATION: This field should indicate the date of the procedure that provided

the final diagnosis (which may include the date of the "normal" screening test). If more than one procedure was performed to obtain a final diagnosis, report the date of the procedure which provided the worst histologic diagnosis. In some cases the first of

multiple tests may provide the date of final diagnosis.

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

diagnosis.

EXAMPLE: If the date of the final pathology report is July 15, 2010: <u>07152010</u>

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

Section 9 – Final Diagnosis

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

cycle

PURPOSE: To indicate the next recommended test for the client at the end of

the "cycle".

LENGTH: 1

FIELD LOCATION: 432

TYPE: Numeric

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

CONTENTS: 1 = Take-home FOBT

2 = Take-home FIT 3 = Sigmoidoscopy 4 = Colonoscopy

5 = DCBE 8 = None 9 = Unknown

EXPLANATION: Report the next screening or surveillance test recommended to the

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

following a normal/negative test.

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

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

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

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

cycle

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

LENGTH: 1

FIELD LOCATION: 433

TYPE: Numeric

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

(Complete).

Leave blank if Item 9.04 (Recommended screening or surveillance

test for next cycle) = 8 (None) or 9 (Unknown).

CONTENTS: 1 = Screening

2 = Surveillance after a positive colonoscopy and/or surgery

EXPLANATION: If a test was recommended in Item 9.04, then the indication for the

test (screening vs. surveillance) should be reported.

Grantees should encourage their providers to make re-screening and surveillance frequency recommendations based on published

guidelines, when available.

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

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

Section 9 – Final Diagnosis

ITEM NO / NAME: 9.06: Number of months before screening or surveillance test

for next cycle.

PURPOSE: To indicate the recommended interval between Item 9.03 (Date of

final diagnosis) and the next recommended screening/surveillance

test.

LENGTH: 3

FIELD LOCATION: 434 - 436

TYPE: Numeric - right justify

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

Leave blank if Item 9.04 (Recommended screening or surveillance

test for next cycle) = 8 (None) or 9 (Unknown).

CONTENTS: 12 = Twelve months

13 = Thirteen months

. . .

180 = One hundred eighty months

999 = Unknown

EXPLANATION: If a test was recommended in Item 9.04, then the report the interval

between the final diagnosis and the next test date. If Item 9.04 is reported as 8 (None) or 9 (Unknown), this field should be left blank.

EXAMPLE: If the recommended interval before the next test is two years: <u>24</u>

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

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

observation or treatment

PURPOSE: To indicate if there was a complication that occurred due to a

DCBE or endoscopy procedure.

LENGTH: 2

FIELD LOCATION: 437 - 438

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.01 (Test Performed) was 3 (Sigmoidoscopy), 4

(Colonoscopy), 5 (DCBE) or 7 (Other) then this field should be

completed; otherwise, leave blank.

CONTENTS: 0 = No complications reported

1 = Bleeding requiring transfusion

2 = Bleeding not requiring transfusion

3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia,

etc.)

4 = Complications related to anesthesia

5 = Bowel perforation

6 = Post-polypectomy syndrome/excessive abdominal pain

7 = Death8 = Other

99 = Unknown

EXPLANATION: Grantees may report the worst of up to two distinct serious

complications occurring within 30 days of the test date and resulting

in an emergency room visit, hospitalization or death. One

complication should be reported in Item 9.07, and the other in Item

9.08.

If there were no complications reported by the client or clinician, report 0 (No complications reported) in both Items 9.07 and 9.08. If

the client only experienced one complication, report that

complication in Item 9.07 and then report 0 (No complications

reported) in Item 9.08.

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

EXAMPLE: If the client experienced bleeding, but did not require a transfusion:

2

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

ITEM NO / NAME: 9.08: Complications (2) of endoscopy or DCBE requiring

observation or treatment

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

endoscopy procedure.

LENGTH: 2

FIELD LOCATION: 439 - 440

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.01 (Test Performed) was 3 (Sigmoidoscopy), 4

(Colonoscopy), 5 (DCBE) or 7 (Other) then this field should be

completed. Otherwise, leave blank.

CONTENTS: 0 = N/A - no 2nd complication reported

1 = Bleeding requiring transfusion

2 = Bleeding not requiring transfusion

3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia,

etc.)

4 = Complications related to anesthesia

5 = Bowel perforation

6 = Post-polypectomy syndrome/excessive abdominal pain

7 = Death

8 = Other

99 = Unknown

EXPLANATION: Grantees may report the worst of up to two distinct serious

complications occurring within 30 days of the test date and resulting

in an emergency room visit, hospitalization or death. One

complication should be reported in Item 9.07, and the other in Item

9.08.

If there were no complications reported by the client or clinician, report 0 (No complications reported) in both Items 9.07 and 9.08. If

the client only experienced one complication, report that

complication in Item 9.07 and then report 0 (No complications

reported) in Item 9.08.

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

EXAMPLE: If the client experienced bleeding, but did not require a transfusion:

2

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

ITEM NO / NAME: 9.09: Complications of endoscopy or DCBE – Other specify

PURPOSE: To specify the type of "other" complication reported in Item 9.07 or

Item 9.08.

LENGTH: 40

FIELD LOCATION: 441 - 480

TYPE: Free text

SKIP PATTERN: If Item 9.07 or Item 9.08 = 8 (Other), then this field should be

completed; otherwise, leave blank.

EXPLANATION: This field captures the type of "other" complication indicated in Item

9.07 and/or Item 9.08. Try to use this item appropriately.

Reclaiming inappropriate "other" responses is time consuming and could potentially result in the loss of valuable data. Acceptable other complications would include infection (bacteremia or abscess)

or allergic reaction to sedative.

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

EXAMPLE: If the client experienced an infection: Infection

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

Section 9 – Final Diagnosis

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

PURPOSE: To indicate if CRCCP funds were used to pay for any of the

screening or diagnostic tests reported in 6.x.01.

LENGTH: 1

FIELD LOCATION: 481

TYPE: Numeric

SKIP PATTERN: If at least one test was completed, then this field should be

completed; otherwise, leave blank.

CONTENTS: 1 = Yes

2 = No

9 = Unknown

EXPLANATION: If the funding source for the screening or diagnostic test is

documented, then a response of 1 (Yes) or 2 (No) should be reported. If the funding source cannot be determined, then a

response of 3 (Unknown) should be reported.

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

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

TEM NO / NAME: 10.1: Recurrent cancers

PURPOSE: Indicate if the cancer reported in Item 9.02 (Final Diagnosis) is a

new primary, a recurrent cancer, or a non-CRC primary cancer.

LENGTH: 1

FIELD LOCATION: 482

TYPE: Numeric

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

completed; otherwise, leave blank.

CONTENTS: 1 = New CRC primary

2 = Recurrent CRC

3 = Non-CRC primary (metastasis from another organ)

9 = Unknown

EXPLANATION: If the cancer reported in Item 9.02 is a new primary colorectal

cancer, report 1 (New CRC primary). If the cancer is a metastasis of a non-colorectal primary, then report it as 3 (Non-CRC primary).

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

This should occur rarely.

Grantees will need to work with their Cancer Registry to determine

if a cancer is a new CRC primary, a non-CRC primary or a

recurrent CRC cancer.

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

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

ITEM NO / NAME: 10.2: Status of treatment

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

diagnosed.

LENGTH: 1

FIELD LOCATION: 483

TYPE: Numeric

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

completed.

If Item 9.02 = 4 (Adenomatous polyp with high grade dysplasia), then this field may be completed; however, Item 10.2 may $\underline{not} = 3$ (Treatment not indicated due to polypectomy), 4 (Treatment not

recommended) or 9 (Unknown).

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

CONTENTS: 1 = Treatment started and/or completed

2 = Treatment pending

3 = Treatment not indicated due to polypectomy

4 = Treatment not recommended

5 = Treatment refused 6 = Lost to follow-up

9 = Unknown

EXPLANATION: For the purpose of this program, the CDC requires the reporting of

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

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

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

Endoscopy can often achieve screening and treatment simultaneously, by detecting and removing a polyp. A complete polypectomy would be considered both diagnostic and the only

required treatment. In this case, the procedure should be reported in the Screening and Diagnostic Tests Performed section (Item 6.x.01), Treatment should be reported as 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the polypectomy. In this instance, Item 9.03 (Date of final diagnosis) and Item 10.3 (Date of treatment) would be the same.

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

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

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

EXAMPLE: If client refused treatment: <u>5</u>

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

ITEM NO / NAME: 10.3: Date of treatment

PURPOSE: To report the date treatment began.

LENGTH: 8

FIELD LOCATION: 484 - 491

TYPE: Date

SKIP PATTERN: If Item 10.2 (Status of treatment) = 2 (Treatment pending) or 9

(Unknown), this field must be blank; otherwise it must be

completed.

If Item 10.2 (Status of treatment) = 1 (Treatment started and/or completed), 3 (Treatment not indicated due to polypectomy), 4 (Treatment not recommended), 5 (Treatment refused) or 6 (Lost to

follow-up), then this item should be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the

month of treatment from 01 to 12, DD is the day of treatment from 01 to 31, and YYYY is the year of treatment, including the century. If any part of the date is unknown, blank-fill only that part. For example, if the month and year of treatment are known, but the day

is not, then blank-fill the day (e.g. <u>08 2010</u>).

EXPLANATION: If Item 10.2 (Status of Treatment) is 1 (Started), then complete with

the date the treatment began.

The fact that a client is referred for standard treatment is <u>not</u> sufficient confirmation that treatment has been started. A client should be classified as having started treatment only when the grantee has confirmed that a plan for standard treatment has been developed and actually started. The date when standard treatment

began refers to the client's actual start of therapy.

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

diagnosis) and Item 10.3 (Date of Treatment) would be the same.

In the circumstance that surgical removal of a polyp or cancer (to complete a diagnosis) is complete, with no evidence of spread, the surgery would also be considered both diagnostic and the only

required treatment. In this case, the date of surgery should be reported in Item 8.2 (Date of Surgery), Treatment should be 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the surgery.

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

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

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

EXAMPLE:

Client began chemotherapy on December 15, 2010: 12152010

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

ITEM NO / NAME: 11.01: Registry linkage status

To indicate if the record for the client reported in Item 9.02 (Final PURPOSE:

Diagnosis) has been linked to the state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 492

TYPE: Numeric

This field should only be completed if Item 9.02 (Final Diagnosis) SKIP PATTERN:

was reported as 4 (Adenomatous Polyp with high grade dysplasia)

or 5 (Cancer); otherwise, leave blank.

1 = Pending linkage CONTENTS:

> 2 = Linked, matched 3 = Linked, not matched

EXPLANATION: At the time of each CCDE submission, this field should be updated

to indicate if the record has been linked to the state/central cancer

registry or not.

If your Program has not linked a record with the Cancer Registry at

the time of the CCDE submission, report this item as 1 (Pending

linkage).

If your Program has successfully matched a record with the Cancer

Registry at the time of the CCDE submission, report this item as 2

(Linked, matched).

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

not matched).

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

registry: 2

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

ITEM NO / NAME: 11.02: Registry Date of Diagnosis

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

cancer registry.

LENGTH: 8

FIELD LOCATION: 493 - 500

TYPE: Date - MMDDYYYY format

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: An 8-digit date item of the form MMDDYYYY, where MM (month) is

the month of diagnosis from 01 to 12, DD (day) is the day of diagnosis from 01 to 31, and YYYY is the year of the diagnosis, including the century. If any part of the date is unknown, blank fill only that part. For example, if the month and year of diagnosis are known, but the day is not, then blank fill the day (e.g. <u>08 2010</u>).

EXPLANATION: This item should indicate the date of diagnosis [NAACCR data item

390] obtained from the state/central cancer registry.

Please note that Item 9.03 (the Date of Final Diagnosis) and Item

11.02 may differ in many instances.

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

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

ITEM NO / NAME: 11.03: Registry Histologic Type

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

registry.

LENGTH: 4

FIELD LOCATION: 501 - 504

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: Values for Item 11.03 (Registry Histologic Type) fall within the

range of 8000 to 9989.

NOTE: See Chapter 3 (Registry Linkage) for a list of the most common histology/behavior codes and their definitions as reported

in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked,

matched), then report the Registry Histologic Type [NAACCR data

item # 522] obtained from the state/central cancer registry

database.

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

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

ITEM NO / NAME: 11.04: Registry Behavior

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

cancer registry.

LENGTH: 1

FIELD LOCATION: 505

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: 0 = Benign

1 = Uncertain whether benign or malignant/Borderline malignancy

2 = Carcinoma, In Situ

3 = Malignant

NOTE: See Chapter 3 (Registry Linkage) for a list of the most common histology/behavior codes and their definitions as reported

in the Collaborative Staging Manual Coding Instructions.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked,

matched), then report the Registry Behavior type [NAACCR data

item # 523] obtained from the state/central cancer registry

database.

EXAMPLE: If the Registry Behavior indicates "Malignant": 3

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

ITEM NO / NAME: 11.05: Registry primary site

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

registry.

LENGTH: 4

FIELD LOCATION: 506 - 509

TYPE: Alphanumeric - left justify

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: C000 through C999. The "C" must be included as part of the

variable response.

Chapter 3 (Registry Linkage) contains documentation which provides a table of available <u>primary site codes</u> as listed in the topography section of the *International Classification of Diseases*

for Oncology, Third Edition (ICD-O-3).

EXPLANATION: If Item 11.1 (Registry linkage status) is reported as 2 (Linked,

matched), the primary site [NAACCR data item #400] obtained from

the cancer registry should be reported.

EXAMPLE: If the primary site is cecum: <u>C180</u>

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

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

PURPOSE: To report the derived summary stage obtained from the

state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 510

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: 0 = In situ

1 = Localized

2 = Regional, direct extension only

3 = Regional, regional lymph nodes only

4 = Regional, extension and nodes

5 = Regional, NOS

7 = Distant

8 = Not applicable

9 = Unknown/unstaged

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked,

matched), then report the collaborative stage (CS)-derived

summary stage 2001 [NAACCR data item #3020] obtained from the

cancer registry database. Please refer to the Web site

www.cancerstaging.org for general instructions provided to cancer

registry sites on reporting this information.

Chapter 3 (Registry Linkage) has additional information for this

item.

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

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

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

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

state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 511 – 513 TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS-derived AJCC stage include: 000, 010, 020,

100, 110, 120, 130, 140, 121, 150, 160, 170, 151, 180, 190, 230, 240, 200, 210, 220, 300, 310, 320, 321, 322, 323, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 500, 510, 520, 530, 540, 541, 542, 550, 560, 570, 580, 590, 600, 610, 620, 630, 700, 710,

720, 721, 722, 730, 740, 888, 900, 999.

NOTE: See Chapter 3 (Registry Linkage) for a complete list of all

<u>available codes</u> and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked,

matched), then report the collaborative stage (CS)-derived AJCC stage [NAACCR data item #3000] obtained from the cancer registry

database.

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

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

ITEM NO / NAME: 11.08: Registry CS extension

PURPOSE: To indicate the extension of disease, as reported by the

state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 514 - 516

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS extension include: 000, 050, 100, 110, 120,

130, 140, 150, 160, 170, 200, 300, 400, 410, 420, 450, 460, 490, 500, 550, 560, 570, 600, 650, 660, 700, 750, 800, 850, 900, 950,

999.

NOTE: See Chapter 3 (Registry Linkage) for a complete list of all

<u>available codes</u> and their definitions as reported in the *Collaborative Staging Manual Coding Instructions*.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked,

matched), then report the collaborative stage (CS)-derived extension [NAACCR data item #2810] obtained from the cancer

registry database.

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

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

ITEM NO / NAME: 11.09: Registry CS lymph nodes

PURPOSE: To indicate the lymph node involvement, as reported by the

state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 517 – 519

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS lymph nodes are 000, 050, 100, 200, 300, 400,

410, 420, 450, 460, 470, 800, 999.

NOTE: See Chapter 3 (Registry Linkage) for a complete list of all

<u>available codes</u> and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked.

matched), then report the collaborative stage (CS) lymph node involvement [NAACCR data item #2830] obtained from the cancer

registry database.

EXAMPLE: If the primary site is colon, and the lymph nodes involvement

reported is "Regional lymph node(s) for ascending colon: 200

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

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

PURPOSE: To indicate any distant metastases at the time of diagnosis, as

reported by the state/central cancer registry.

LENGTH: 2

FIELD LOCATION: 520 - 521

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

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

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

used infrequently.

NOTE: See Chapter 3 (Registry Linkage) for a complete list of all

<u>available codes</u> and their definitions as reported in the *Collaborative Staging Manual Coding Instructions*.

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked,

matched), then report the CS mets at diagnosis [NAACCR data

item #2850] obtained from the cancer registry database.

EXAMPLE: If the mets at diagnosis are reported as "None": <u>00</u>

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

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

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

registry.

LENGTH: 3

FIELD LOCATION: 522 - 524

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending

linkage) or 3 (Linked, not matched).

CONTENTS: 001-988 Exact size in millimeters

989 = ≥ 989 millimeters

990 = Microscopic focus or foci only; no size of focus is given

991 = Described as less than 1 cm

992 = Described as between 1 cm and 2 cm 993 = Described as between 2 cm and 3 cm 994 = Described as between 3 cm and 4 cm 995 = Described as between 4 cm and 5 cm

998 = Familial/multiple polyposis 999 = Unknown; size not stated

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked.

matched), then report the Collaborative Stage (CS) Tumor Size [NAACCR data item # 2800] obtained from the state/central cancer

registry database.

Not all cancer registries collect this information. If this field is blank

in the Cancer Registry, report 999 (Unknown).

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

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

ITEM NO / NAME: 12.1: CCDE version

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

in.

LENGTH: 3

FIELD LOCATION: 525 - 527

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

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

EXPLANATION: As the program begins to evaluate data collected, some variables

may be dropped, new variables may be added, or additional options may be added to variable responses. As these changes

occur, the CCDE version number will change.

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

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

CHAPTER 3

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

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

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

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

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

11.04 Registry Behavior (alone)

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

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

| Histology Description | Histology | Histology/ Behavior | Histology/Behavior Description |
|----------------------------------|-----------|------------------------|--|
| | | 8050/3 | Papillary carcinoma, NOS |
| | | 8051/3 | Verrucous carcinoma, NOS |
| | | 8052/2 | Papillary squamous cell carcinoma, non-invasive |
| | | 8052/3 | Papillary squamous cell carcinoma |
| SQUAMOUS CELL CARCINOMA, NOS | 807 | 8070/2 | Squamous cell carcinoma in situ, NOS |
| | | 8070/3 | Squamous cell carcinoma, NOS |
| | | 8071/3 | Sq. cell carcinoma, keratinizing, NOS |
| | | 8072/3 | Sq. cell carcinoma, lg. cell, non-ker. |
| | | 8073/3 | Sq. cell carcinoma, sm. cell, non-ker. |
| | | 8074/3 | Sq. cell carcinoma, spindle cell |
| | | 8075/3 | Squamous cell carcinoma, adenoid |
| | | 8076/2 | Sq. cell carc. in situ with question. stromal invas. |
| | | 8076/3 | Sq. cell carcinoma, micro-invasive |
| | | 8078/3 | Squamous cell carcinoma with horn formation |
| TRANSITIONAL CELL CARCINOMA, NOS | 812 | 8120/2 | Transitional cell carcinoma in situ |
| | | 8120/3 | Transitional cell carcinoma, NOS |
| | | 8121/3 | Schneiderian carcinoma |
| | | 8122/3 | Trans. cell carcinoma, spindle cell |
| | | 8123/3 | Basaloid carcinoma |
| | | 8124/3 | Cloacogenic carcinoma |
| ADENOCARCINOMA, NOS | 814 | 8140/2 | Adenocarcinoma in situ |
| | | 8140/3 | Adenocarcinoma, NOS |
| | | 8141/3 | Scirrhous adenocarcinoma |
| 1 | | 1 | 1 |
| ADENOCARCINOMA, NOS (cont'd) | 814 | 8143/3 | Superficial spreading adenocarcinoma |
| | | 8145/3 | Carcinoma, diffuse type |

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

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

| Histology Description | Histology | Histology/ Behavior | Histology/Behavior Description |
|--------------------------------|-----------|------------------------|--|
| EPITHELIOID CELL MELANOMA | 877 | 8770/3 | Mixed epithel. & spindle cell melanoma |
| | | 8771/3 | Epithelioid cell melanoma |
| | | 8772/3 | Spindle cell melanoma, NOS |
| SARCOMA, NOS | 880 | 8800/3 | Sarcoma, NOS |
| | | 8801/3 | Spindle cell sarcoma |
| | | 8802/3 | Giant cell sarcoma |
| | | 8803/3 | Small cell sarcoma |
| | | 8804/3 | Epithelioid sarcoma |
| | | 8805/3 | Undifferentiated sarcoma |
| | | 8806/3 | Desmoplastic small round cell tumor |
| FIBROMATOUS NEOPLASMS | 881 | 8810/3 | Fibrosarcoma, NOS |
| | | 8811/3 | Fibromyxosarcoma |
| | | 8813/3 | Fascial fibrosarcoma |
| | | 8814/3 | Infantile fibrosarcoma |
| | | 8815/3 | Solitary fibrous tumor, malignant |
| LIPOSARCOMA NEOPLASMS | 885 | 8850/3 | Liposarcoma, NOS |
| | | 8851/3 | Liposarcoma, well differentiated |
| | | 8852/3 | Myxoid liposarcoma |
| | | 8853/3 | Round cell liposarcoma |
| | | 8854/3 | Pleomorphic liposarcoma |
| | | | |
| LIPOSARCOMA NEOPLASMS (cont'd) | 885 | 8855/3 | Mixed type liposarcoma |
| | | 8857/3 | Fibroblastic liposarcoma |
| | | 8858/3 | Dedifferentiated liposarcoma |
| MYOMATOUS NEOPLASMS | 889 | 8890/3 | Leiomyosarcoma, NOS |

8891/3

Epithelioid leiomyosarcoma

| Histology Description | Histology | Histology <i>l</i> Behavior | Histology/Behavior Description |
|-------------------------------|-----------|--------------------------------|---|
| | | 8894/3 | Angiomyosarcoma |
| | | 8895/3 | Myosarcoma |
| | | 8896/3 | Myxoid leiomyosarcoma |
| STROMAL SARCOMA | 893 | 8934/3 | Carcinofibroma |
| | | 8935/3 | Stromal sarcoma, NOS |
| | | 8936/3 | Gastrointestinal stromal sarcoma |
| CARCINOSARCOMA, NOS | 898 | 8980/3 | Carcinosarcoma, NOS |
| | | 8981/3 | Carcinosarcoma, embryonal type |
| | | 8982/3 | Malignant myoepithelioma |
| MALIGNANT LYMPHOMA, NOS | 959 | 9590/3 | Malignant lymphoma, NOS |
| | | 9591/3 | Malignant lymphoma, non-Hodgkin |
| | | 9596/3 | Composite Hodgkin and non-Hodgkin lymphoma |
| HODGKIN LYMPHOMA | 965 | 9650/3 | Hodgkin lymphoma, NOS |
| | | 9651/3 | Hodgkin lymphoma, lymphocyte-rich |
| | | 9652/3 | Hodgkin lymphoma, mixed cellularity, NOS |
| | | 9653/3 | Hodgkin lymphoma, lymphocytic deplet., NOS |
| | | 9654/3 | Hodgkin lymphoma, lymphocytic deplet., diffuse fibrosis |
| | | 9655/3 | Hodgkin lymphoma, lymphocyt. deplet., reticular |
| | | 9659/3 | Hodgkin lymph., nodular lymphocyte predom. |
| | | T | |
| HODGKIN LYMPHOMA, NOD. SCLER. | 966 | 9661/3 | Hodgkin granuloma [obs] |
| | | 9662/3 | Hodgkin sarcoma [obs] |
| | | 9663/3 | Hodgkin lymphoma, nodular sclerosis, NOS |
| | | 9664/3 | Hodgkin lymphoma, nod. scler., cellular phase |
| | | 9665/3 | Hodgkin lymphoma, nod. scler., grade 1 |
| | | 9667/3 | Hodgkin lymphoma, nod. scler., grade 2 |

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

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

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

CCDE Item 11.05: Registry primary site

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

| C170 = Duodenum | C318 = Overlap of accessory sinuses |
|--|--|
| C171 = Jejunum | C319 = Accessory sinus, NOS |
| C172 = Ileum | C320 = Glottis |
| C173 = Meckel's diverticulum | C321 = Supraglottis |
| C178 = Overlapping of small intestine | C322 = Subglottis |
| C179 = Small intestine, NOS | C323 = Laryngeal cartilage |
| C180 = Cecum | C328 = Overlapping of larynx |
| C181 = Appendix | C329 = Larynx, NOS |
| C182 = Ascending colon | C339 = Trachea |
| C183 = Hepatic flexure of colon | C340 = Main bronchus |
| C184 = Transverse colon | C341 = Upper lobe, lung |
| C185 = Splenic flexure of colon | C342 = Middle lobe, lung |
| C186 = Descending colon | C342 = Ivilidate lobe, lung |
| C187 = Sigmoid colon | C348 = Overlapping of lung |
| | C348 – Overlapping of lung C349 = Lung, NOS |
| C188 = Overlapping of colon | 3 . |
| C189 = Colon, NOS | C379 = Thymus C380 = Heart |
| C199 = Rectosigmoid junction | |
| C209 = Rectum, NOS | C381 = Anterior mediastinum |
| C210 = Anus, NOS | C382 = Posterior mediastinum |
| C211 = Anal canal | C384 = Mediastinum, NOS |
| C212 = Cloacogenic zone | C384 = Pleura, NOS |
| C218 = Overlap of rectum, anus, etc. | C388 = Ovr. heart, mediastinum, pleura |
| C220 = Liver | C390 = Upper respiratory tract, NOS |
| C221 = Intrahepatic bile duct | C398 = Overlap of respiratory system |
| C239 = Gallbladder | C399 = Ill-defined sites of resp sys |
| C240 = Extrahepatic bile duct | C400 = Long bones: upper limb, scapula |
| C241 = Ampulla of Vater | C401 = Short bones: upper limb |
| C248 = Overlapping of biliary tract | C402 = Long bones: lower limb |
| C249 = Biliary tract, NOS | C403 = Short bones: lower limb |
| C250 = Head of pancreas | C408 = Overlap of bones, etc. of limbs |
| C251 = Body of pancreas | C409 = Bone of limb, NOS |
| C252 = Tail of pancreas | C410 = Bones of skull and face |
| C253 = Pancreatic duct | C411 = Mandible |
| C254 = Islets of Langerhans | C412 = Vertebral column |
| C257 = Other spec pancreas | C413 = Rib, Sternum, Clavicle |
| C258 = Overlapping of pancreas | C414 = Pelvic bones, Sacrum, Coccyx |
| C259 = Pancreas, NOS | C418 = Overlap bones, etc. |
| C260 = Intestinal tract, NOS | C419 = Bone, NOS |
| C268 = Overlapping of digestive system | C420 = Blood |
| C269 = Gastrointestinal tract, NOS | C421 = Bone marrow |
| C300 = Nasal cavity | C422 = Spleen |
| C301 = Middle ear | C423 = Reticuloendothelial system, NOS |
| C310 = Maxillary sinus | C424 = Hematopoietic system, NOS |
| C311 = Ethmoid sinus | C440 = Skin of lip, NOS |
| C312 = Frontal sinus | C441 = Eyelid |
| C313 = Sphenoid sinus | C442 = External ear |
| | |

| C443 = Skin other/unspec parts of face C444 = Skin of scalp and neck C445 = Skin of trunk | C538 = Overlapping of cervix uteri C539 = Cervix uteri C540 = Isthmus uteri |
|---|---|
| C446 = Skin of upper limb and shoulder | C541 = Endometrium |
| C447 = Skin of lower limb and hip | C542 = Myometrium |
| C448 = Overlapping of skin | C543 = Fundus uteri |
| C449 = Skin, NOS | C548 = Overlapping of corpus uteri |
| C470 = Periph nerves: head, face, neck | C549 = Corpus uteri |
| C471 = Peri nerves: upr limb, shoulder | C559 = Uterus, NOS |
| C472 = Periph nerves: lower limb, hip | C569 = Ovary |
| C473 = Periph nerves: thorax | C570 = Fallopian tube |
| C474 = Periph nerves: abdomen | C571 = Broad ligament |
| C475 = Periph nerves: pelvis | C572 = Round ligament |
| C476 = Periph nerves: trunk, NOS | C573 = Parametrium |
| C478 = Overlap of peripheral nerves | C574 = Uterine adnexa |
| C479 = Autonomic nervous system, NOS | C577 = Other spec fem genital organs |
| C480 = Retroperitoneum | C578 = Overlap of fem genital organs |
| C481 = Specified parts of peritoneum | C579 = Female genital tract, NOS |
| C482 = Peritoneum, NOS | C589 = Placenta |
| C488 = Overlap retroper & peritoneum | C600 = Prepuce |
| C490 = Conn tissues: head, face, neck | C601 = Glans penis |
| C491 = Conn tissues: upr limb, shoulder | C602 = Body of penis |
| C492 = Conn tissues: lower limb, hip | C608 = Overlapping of penis |
| C493 = Conn tissues: thorax | C609 = Penis, NOS |
| C494 = Conn tissues: abdomen | C619 = Prostate gland |
| C495 = Conn tissues: pelvis | C620 = Undescended testis |
| C496 = Conn tissues: trunk, NOS | C621 = Descended testis |
| C498 = Overlapping conn tissues | C629 = Testis, NOS |
| C499 = Conn tissues, NOS | C630 = Epididymis |
| C500 = Nipple | C631 = Spermatic cord |
| C501 = Central portion of breast | C632 = Scrotum, NOS |
| C502 = Upper-inner quadrant of breast | C637 = Other spec male genital organs |
| C503 = Lower-inner quadrant of breast | C638 = Overlap male genital organs |
| C504 = Upper-outer quadrant of breast | C639 = Male genital organs, NOS |
| C505 = Lower-outer quadrant of breast | C649 = Kidney, NOS |
| C506 = Axillary tail of breast | C659 = Renal pelvis |
| C508 = Overlapping of breast | C669 = Ureter |
| C509 = Breast, NOS | C670 = Trigone of bladder |
| C510 = Labium majus | C671 = Dome of bladder |
| C511 = Labium minus | C672 = Lateral wall of bladder |
| C512 = Clitoris | C673 = Anterior wall of bladder |
| C518 = Overlapping of vulva | C674 = Posterior wall of bladder |
| C519 = Vulva, NOS | C675 = Bladder neck |
| C529 = Vagina, NOS | C676 = Ureteric orifice |
| C530 = Endocervix | C677 = Urachus |
| C531 = Exocervix | C678 = Overlapping of bladder |

| C679 = Bladder, NOS | C725 = Cranial nerve, NOS |
|--------------------------------------|---|
| C680 = Urethra | C728 = Overlap of brain & CNS |
| C681 = Paraurethral gland | C729 = Nervous system, NOS |
| C688 = Overlapping of urinary organs | C739 = Thyroid gland |
| C689 = Urinary system, NOS | C740 = Cortex of adrenal gland |
| C690 = Conjunctiva | C741 = Medulla of adrenal gland |
| C691 = Cornea, NOS | C749 = Adrenal gland, NOS |
| C692 = Retina | C750 = Parathyroid gland |
| C693 = Choroid | C751 = Pituitary gland |
| C694 = Ciliary body | C752 = Craniopharyngeal duct |
| C695 = Lacrimal gland | C753 = Pineal gland |
| C696 = Orbit, NOS | C754 = Carotid body |
| C698 = Overlapping of eye and adnexa | C755 = Aortic body & other paraganglia |
| C699 = Eye, NOS | C758 = Overlapping of endocrine glands |
| C700 = Cerebral meninges | C759 = Endocrine gland, NOS |
| C701 = Spinal meninges | C760 = Head, face or neck, NOS |
| C709 = Meninges, NOS | C761 = Thorax, NOS |
| C710 = Cerebrum | C762 = Abdomen, NOS |
| C711 = Frontal lobe | C763 = Pelvis, NOS |
| C712 = Temporal lobe | C764 = Upper limb, NOS |
| C713 = Parietal lobe | C765 = Lower limb, NOS |
| C714 = Occipital lobe | C767 = Other ill-defined sites |
| C715 = Ventricle, NOS | C768 = Overlap of ill-defined sites |
| C716 = Cerebellum, NOS | C770 = Lymph nodes: head, face & neck |
| C717 = Brain stem | C771 = Intrathoracic lymph nodes |
| C718 = Overlapping of brain | C772 = Intra-abdominal lymph nodes |
| C719 = Brain, NOS | C773 = Lymph nodes of axilla or arm |
| C720 = Spinal cord | C774 = Lymph nodes:inguinal region or leg |
| C721 = Cauda equina | C775 = Pelvic lymph nodes |
| C722 = Olfactory nerve | C778 = Lymph nodes of multiple regions |
| C723 = Optic nerve | C779 = Lymph node, NOS |
| C724 = Acoustic nerve | C809 = Unknown primary site |
| | |

CCDE Item 11.06: Registry CS-derived SS2000

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

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

CCDE Item 11.07: Registry CS-derived AJCC stage group

550

560

570

300

310

320

Stage II NOS

Stage IIA

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

| Value | Description | Value | Description | Value | Description |
|-------|---------------------------|-------|--|----------|---|
| 000 | Stage 0 | 322 | Stage IIA1 | 590 | Stage IIISB (lymphoma only) |
| 010 | Stage 0a | 323 | Stage IIA2 | 600 | Stage IIIS (lymphoma only) |
| | | | | ! | 1 |
| 020 | Stage 0is | 330 | Stage IIB | 610 | Stage IIIESA (lymphoma only) |
| 100 | Stage I | 340 | Stage IIC | 620 | Stage IIIESB (lymphoma only) |
| 110 | Stage I NOS | 350 | Stage IIEA (lymphoma only) | 630 | Stage IIIES (lymphoma only) |
| 120 | Stage IA | 360 | Stage IIEB (lymphoma only) | 700 | Stage IV |
| 121 | Stage IA NOS | 370 | Stage IIE (lymphoma only) | 710 | Stage IV NOS |
| 130 | Stage IA1 | 380 | Stage IISA (lymphoma only) | 720 | Stage IVA |
| 140 | Stage IA2 | 390 | Stage IISB (lymphoma only) | 721 | Stage IVA1 |
| 150 | Stage IB | 400 | Stage IIS (lymphoma only) | 722 | Stage IVA2 |
| 151 | Stage IB NOS | 410 | Stage IIESA (lymphoma only) | 730 | Stage IVB |
| 160 | Stage IB1 | 420 | Stage IIESB (lymphoma only) | 740 | Stage IVC |
| 170 | Stage IB2 | 430 | Stage IIES (lymphoma only) | 888 | Not applicable |
| 180 | Stage IC | 500 | Stage III | 900 | Stage Occult |
| 190 | Stage IS | 510 | Stage III NOS | 999 | Stage Unknown |
| 230 | Stage ISA (lymphoma only) | 520 | Stage IIIA | | |
| 240 | Stage ISB (lymphoma only) | 530 | Stage IIIB | | |
| 200 | Stage IEA (lymphoma only) | 540 | Stage IIIC | | |
| 210 | Stage IEB (lymphoma only) | 541 | Stage IIIC1 | | |
| 220 | Stage IE (lymphoma only) | 542 | Stage IIIC2 | | |
| | | | | П | |

Stage IIIEA (lymphoma only)

Stage IIIEB (lymphoma only)

Stage IIIE (lymphoma only)

CCDE Item 11.08: Registry CS extension

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

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

| Value | Description for Colon | Description for Rectum | TNM 7 | TNM 6 | SS77 | SS2000 |
|-------|---|--|-------|-------|------|--------|
| 200 | Muscularis propria invaded Stated as T2[NOS] with no other information on extension | Muscularis propria invaded Stated as T2[NOS] with no other information on extenision | T2 | T2 | L | L |
| 300 | Localized, NOS Confined to colon, NOS | Localized, NOS Confined to rectum, NOS | T1 | T1 | L | L |
| 400 | Extension through wall, NOS Invasion through muscularis propria or muscularis, NOS Non-peritonealized pericolic tissues invaded Perimuscular tissue invaded Subserosal tissue/(sub)serosal fat invaded Transmural, NOS | Extension through wall, NOS Invasion through muscularis propria or muscularis, NOS Perimuscular tissue invaded Subserosal tissue/(sub)serosal fat invaded Non-peritonealized pericolic tissues invaded Transmural, NOS | Т3 | Т3 | L | L |
| 410 | Stated as T2[NOS] with no other information on extension | Stated as T2[NOS] with no other information on extension | Т3 | Т3 | L | L |
| 420 | Fat, NOS | Fat, NOS | Т3 | Т3 | RE | RE |
| 450 | Extension to: All colon sites: Adjacent tissue(s), NOS Connective tissue Mesenteric fat Mesentery Mesocolon Pericolic fat Ascending and descending colon Retroperitoneal fat Transverse colon/flexures Gastrocolic ligament Greater omentum | Adjacent (connective) tissue: For all sites: Perirectal fat For rectosigmoid: Mesentery (including mesenteric fat, mesocolon) Pericolic fat For rectum: Extension to anus Rectovaginal septum | Т3 | Т3 | RE | RE |

| Value | Description for Colon | Description for Rectum | TNM 7 | TNM 6 | SS77 | SS2000 |
|-------|---|--|-------|-------|------|--------|
| 460 | Adherent to other organs or structures, but no microscopic tumor found in adhesion(s) | Adherent to other organs or structures but no tumor found in adhesion(s) | Т3 | Т3 | RE | RE |
| 490 | | Stated as T4[NOS] with no other information on extension | T4NOS | T4 | RE | RE |
| 500 | Invasion of/through serosa (mesothelium) (visceral peritoneum) | Invasion of/through serosa (mesothelium) (visceral peritoneum) | T4a | T4 | RE | RE |
| 550 | Any of [(420) to (450)] + (500) | (500) with [(420) or (450)] | T4a | T4 | RE | RE |
| 560 | Stated as T4a with no other information on extension | Stated as T4a with no other information on extension | T4a | T4 | RE | RE |
| 570 | Adherent to other organs or structures, NOS | Adherent to other organs or structures, NOS | T4b | T4 | RE | RE |

| Value | Description for Colon | Description for Rectum | TNM 7 | TNM 6 | SS77 | SS2000 |
|-------|--|---|-------|-------|------|--------|
| 600 | All colon sites: Small intestine Cecum and appendix: Greater omentum Ascending colon: Greater omentum Liver, right lobe Transverse colon and flexures: Gallbladder/bile ducts Kidney Liver Pancreas Spleen Stomach Descending colon: Greater omentum Pelvic wall Spleen Sigmoid colon: Greater omentum Pelvic wall | Rectosigmoid: Cul de sac (rectouterine pouch) Pelvic wall Small intestine Rectum: Bladder for males only Cul de sac (rectouterine pouch) Ductus deferens Pelvic wall Prostate Rectovesical fascia for male only Seminal vesicle(s) Skeletal muscle of pelvic floor Vagina | T4b | T4 | RE | RE |
| 650 | All colon sites: Abdominal wall Retroperitoneum (excluding fat) | | T4b | Т4 | RE | RE |
| 660 | Ascending colon: Right kidney Right ureter Descending colon: Left kidney Left ureter | | T4b | T4 | RE | RE |

| Value | Description for Colon | Description for Rectum | TNM 7 | TNM 6 | SS77 | SS2000 |
|-------|--|--|-------|-------|------|--------|
| 700 | Cecum, ascending, descending and sigmoid colon: Fallopian tube Ovary Uterus | Rectosigmoid: Bladder Colon via serosa Fallopian tube(s) Ovary(ies) Prostate Ureter(s) Uterus Rectum: Bladder for female only Bone(s) of pelvis Urethra Uterus | T4b | T4 | D | D |
| 750 | All colon sites unless otherwise stated above: Adrenal (suprarenal) gland Bladder Diaphragm Fistula to skin Gallbladder Other segment(s) of colon via serosa | | T4b | Т4 | D | D |
| 800 | Further contiguous extension: Cecum and appendix: Kidney Liver Ureter Transverse colon and flexures: Ureter Sigmoid colon: Cul de sac (rectouterine pouch) Ureter Other contiguous extension | Further contiguous extension | T4b | Т4 | D | D |

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

CCDE Item 11.09: Registry CS lymph nodes

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

| Value | Description for Colon | Description for Rectum | TNM 7 | TNM 6 | SS77 | SS2000 |
|-------|--|--|-------|-------|------|--------|
| 000 | None; no regional lymph node involvement | None; no regional lymph node involvement | N0 | N0 | None | None |
| 050 | Tumor deposit(s) in the subserosa, or non- peritonealized pericolic or perirectal tissues without regional nodal metastasis | Tumor deposit(s) in the subserosa, or non- peritonealized pericolic or perirectal tissues without regional nodal metastasis | N1c | N1 | RN | RN |
| 100 | Regional lymph node(s) for all colon sites: Colic (NOS) Epicolic (adjacent to bowel wall) Mesocolic (NOS) Paracolic/pericolic | Regional lymph node(s): Rectosigmoid: Paracolic/pericolic Perirectal Rectal Nodule(s) or foci in pericolic fat/adjacent mesentery/mesocolic fat Rectum: Perirectal Rectal, NOS Nodule(s) or foci in perirectal fat | ۸ | * | RN | RN |
| 200 | Regional lymph node(s), for specific subsites: Cecum: Cecal: anterior (prececal), posterior (retrocecal); NOS Ileocolic Right colic Ascending colon: Ileocolic Middle colic Right colic Transverse colon and flexures: | Regional lymph node(s): Rectosigmoid: Colic, NOS Left colic Hemorrhoidal, superior or middle Inferior mesenteric Middle rectal Sigmoidal (sigmoid mesenteric) Superior rectal Rectum: Hemorrhoidal, superior, middle or inferior | ۸ | * | RN | RN |

| Value | Description for Colon | Description for Rectum | TNM 7 | TNM 6 | SS77 | SS2000 |
|-------|---|---|-------|-------|------|--------|
| | Inferior mesenteric for splenic flexure only Left colic for splenic flexure only Middle colic Right colic for hepatic flexure only Descending colon: Inferior mesenteric Left colic Sigmoid Sigmoid colon: Inferior mesenteric Sigmoidal (sigmoid mesenteric) Superior hemorrhoidal Superior rectal | Inferior mesenteric Internal iliac (hypogastric) Obturator Rectal, superior, middle, or inferior Sacral, NOS Lateral (laterosacral) Middle (promontorial) (Gerota's node) Presacral Sacral promotory Sigmoidal (sigmoid mesenteric) | | | | |
| 300 | Regional lymph node(s) for all colon sites: Mesenteric, NOS Regional lymph node(s), NOS | Mesenteric, NOS Regional lymph node(s), NOS | ^ | * | RN | RN |
| 400 | Stated as N1 pathologic | Stated as N1 pathologic | N1NOS | N1 | RN | RN |
| 410 | Stated as N1a pathologic | Stated as N1a pathologic | N1a | N1 | RN | RN |
| 420 | Stated as N1b pathologic | Stated as N1b pathologic | N1b | N1 | RN | RN |
| 450 | Stated as N2 pathologic | Stated as N2 pathologic | N2NOS | N2 | RN | RN |
| 460 | Stated as N2a pathologic | Stated as N2a pathologic | N2a | N2 | RN | RN |
| 470 | Stated as N2b pathologic | Stated as N2b pathologic | N2b | N2 | RN | RN |
| 800 | Lymph nodes, NOS | Lymph nodes, NOS | ^ | * | RN | RN |
| 999 | Unknown; not stated Regional lymph node(s) cannot be assessed | Unknown; not stated Regional lymph node(s) cannot be assessed | NX | NX | U | U |

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

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

CCDE Item 11.10: Registry CS mets at diagnosis

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

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

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

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

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

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

CHAPTER 4

References

Appendix A

CCDE Submission Narrative Guidelines

CCDE Submission Narrative Guidelines January 1, 2010

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

The submission narrative is comprised of two sections:

- The first section should include written responses to any action items that were identified in the previous data submission. Following the review and discussion of the grantee's CCDE data file by the CDC Program Consultant, CDC Scientific Consultant and IMS Clinical Data Technical Consultant and grantee staff, an Action Plan will be developed. The CDC Program Consultant will provide this information to the appropriate staff at the program. Each action item should be addressed by the grantee in this first section.
- II. The second section should address the following questions. If the question is not applicable to your program at this time, please indicate "N/A":
 - 1. Summarize reasons for any significant data issues identified by the program but not resolved prior to submitting the CCDE file to the CDC.
 - 2. Identify any modifications made to the software which generates the CCDE file that would cause significant changes in the distribution of the values for individual data items.
 - 3. Identify any batch recoding of records in the CCDE file that would cause significant changes in the distribution of the values for individual data items.
 - 4. Identify any data management staffing, system, or procedural changes that would affect the data management capacity. Examples of these include staff turnover, revision of data collection forms, revision of data entry screens, a change in the data collection model (i.e. centralized to decentralized), etc.
 - 5. Identify any plans to significantly upgrade existing data management software, or to develop and migrate the client database to a new data management system.

SAMPLE

CCDE Submission Narrative for Your Program September 2010 Submission

Part 1. Action Item Responses

Standard Quality Indicator Guide (SQIG)

Item 8: There are several records where Status of Final Diagnosis = Complete, but the Final Diagnosis and Date of Final Diagnosis are missing.

**RESPONSE: We used the CCDE Edit program to identify 20 records with

incomplete data. These records were reviewed and corrected.

Item 10: The CDC provides a recommendation that at least 80% of clients should take less than 60 days from the beginning of screening until final diagnosis. Your program does not meet this recommendation. Please discuss causes for the delay between screening and diagnosis.

RESPONSE: While reviewing the cases we have discovered some reporting issues. At the time of submission, we continue to evaluate all the causes for the delay in timeliness. We will report on any findings as soon as possible.

Part 2: Address the following questions:

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

Please see response to SQIG Item 10.

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

Not applicable.

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

We modified how our export program creates the record ID. The record ID has been changed for all records reported in this submission.

4. Identify any data management staffing, system, or procedural changes that would affect the data management capacity.

Not applicable.

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



APPENDIX B

CDC RACE AND ETHNICITY CODE SET

Version 1.0 (03/2000)

Modified from original: http://www.cdc.gov/phin/vocabulary/race.html

TABLE 1 - RACE CONCEPTS AND CODES

| CCDE CATEGORY | CONCEPT |
|---------------------|--|
| 1. White | EUROPEAN (which may include:) |
| | Armenian |
| | English |
| | French |
| | German |
| | Irish |
| | Italian |
| | Polish |
| | Scottish |
| | MIDDLE EASTERN OR NORTH AFRICAN (which may include:) |
| | Assyrian |
| | Egyptian |
| | Iranian |
| | Iraqi |
| | Lebanese |
| | Palestinian |
| | Syrian |
| | Afghanistani |
| | Israeli |
| | ARAB |
| | |
| 2. Black or African | |
| American | BLACK |
| | AFRICAN AMERICAN |
| | AFRICAN (which may include:) |
| | Botswanan |
| | Ethiopian |
| | Liberian |
| | Namibian |
| | Nigerian |
| | Zairian |
| | Bahamian |
| | Barbadian |
| | Dominican |
| | Dominican Islander |
| | Haitian |
| | Jamaican |

| ı | O District | l I |
|---|---------------------|-----|
| | 2. Black or African | |

Version 1.0 (03/2000)

Modified from original: http://www.cdc.gov/phin/vocabulary/race.html

| CCDE CATEGORY | CONCEPT | | |
|---|----------------------------------|--|--|
| American (cont'd) | Tobagoan | | |
| | Trinidadian | | |
| | West Indian | | |
| | | | |
| 3. Asian | Asian Indian | | |
| | Bangladeshi | | |
| | Bhutanese | | |
| | Burmese | | |
| | Cambodian | | |
| | Chinese | | |
| | Taiwanese | | |
| | Filipino | | |
| | Hmong | | |
| | Indonesian | | |
| | Japanese | | |
| | Korean | | |
| | Laotian | | |
| | Malaysian | | |
| | Okinawan | | |
| | Pakistani | | |
| | Sri Lankan | | |
| | Thai | | |
| | Vietnamese | | |
| | lwo Jiman | | |
| | Maldivian | | |
| | Nepalese | | |
| | Singaporean | | |
| | Madagascar | | |
| | | | |
| Native Hawaiian or Other Pacific Islander | POLYNESIAN (which may include:) | | |
| | Native Hawaiian | | |
| | Samoan | | |
| | Tahitian | | |
| | Tongan | | |
| | Tokelauan | | |
| | MICRONESIAN (which may include:) | | |
| | Guamanian | | |
| | Chamorro | | |
| | Mariana Islander | | |
| | Marshallese | | |
| 4. Native Hawaiian or | maionaiooo | | |
| T. HALIVE HAVVAIIAH OI | | | |

Version 1.0 (03/2000)

Modified from original: http://www.cdc.gov/phin/vocabulary/race.html

| CCDE CATEGORY | CONCEPT |
|---------------------------------------|---|
| Other Pacific Islander (Cont'd) | Palauan |
| \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | Carolinian |
| | Kosraean |
| | Pohnpeian |
| | Yapese |
| | Saipanese |
| | Kiribati |
| | Chuukese |
| | MELANESIAN (which may include:) |
| | Fijian |
| | Papua New Guinean |
| | Solomon Islander |
| | New Hebrides |
| | OTHER PACIFIC ISLANDER |
| | |
| 5. American Indian or | |
| Alaskan Native | AMERICAN INDIAN |
| | CANADIAN AND LATIN AMERICAN INDIAN (which |
| | may include:) |
| | Canadian Indian Central American Indian |
| | |
| | French American Indian Mexican American Indian |
| | South American Indian |
| | |
| | Spanish American Indian ALASKAN NATIVE (which may include:) |
| | Alaskan Indian |
| | |
| | 1113113 |
| | Inuit Aleut |

Version 1.0 (03/2000)

Modified from original: http://www.cdc.gov/phin/vocabulary/race.html

TABLE 2 - ETHNICITY CONCEPTS AND CODES

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

APPENDIX C CCDE DATA DEFINITION TABLE

APPENDIX D GLOSSARY OF TERMS

References

ACS: http://www.cancer.org

Adenomatous polyp See "Polyp". More likely to develop into cancer than a

non-adenomatous polyp. Also known as "adenoma".

CDC CRCCP Home Page: http://www.cdc.gov/cancer/crccp/

CO-RADS Colonoscopy Reporting and Data System (CO-RADS),

a standardized colonoscopy reporting and data

system. CO-RADS specifies the elements that should be included in all colonoscopy reports and presents a

standard method for reporting them.

Colonoscope: A flexible, lighted instrument with a built-in tiny camera

used to view the inside of the entire colon and rectum.

Colonoscopy: An examination in which the doctor looks at the

internal walls of the entire colon through a flexible, lighted instrument called a colonoscope. The doctor may collect samples of tissue or cells for closer examination. The doctor may also remove polyps

during colonoscopy.

Colorectal: Related to the colon, rectum or both.

CRCCP Resource Web Site: www.CRCCP.org

CS Coding Manual: www.cancerstaging.org

Double-Contrast Barium

Enema

A series of x-rays of the colon and rectum. The x-rays are taken after the patient is given an enema, followed

by an injection of air. The barium outlines the intestines on the x-rays, allowing many abnormal

growths to be visible.

Fecal Immunochemical Test

(FIT)

Like a fecal occult blood test (FOBT), an FIT also detects hidden blood in the stool using a different

technique than guaiac based FOBT. FIT is effectively done the same way as an FOBT, but it may be more specific or more sensitive than a guaiac based FOBT.

Fecal Occult Blood Test

(FOBT)

A quaiac based test to check for hidden blood in stool.

Fecal refers to stool. Occult means hidden.

Sometimes called "F.O.B.T.".

References

Flexible Sigmoidoscopy A procedure in which the doctor looks inside the

rectum and the lower portion of the colon (sigmoid colon) through a flexible, lighted tube called a sigmoidoscope. The doctor may collect samples of tissue or cells for closer examination and remove

some polyps within view.

Gastroenterologist A doctor who specializes in diagnosing and treating

disorders of the digestive system (which includes the esophagus, stomach, pancreas, intestines, and liver).

Polyp An abnormal, often precancerous growth of tissue

(colorectal polyps are growths of tissue inside the

intestine).

Rectum The last 8 to 10 inches of the large intestine. The

rectum stores solid waste until it leaves the body

through the anus.

Screening Test "Screening tests" are tests used to check, or screen,

for disease when there are no symptoms. Screening tests for colorectal cancer include: fecal occult blood test, flexible sigmoidoscopy, colonoscopy, and double contrast barium enema. (When a test is performed to find out why symptoms exist, it is called a "diagnostic"

test).

SEER Coding Manual: www.seer.cancer.gov

Sigmoidoscope A flexible, lighted instrument with a built-in tiny camera

that allows the doctor to view the lining of the rectum

and lower portion of the colon.

Stool DNA A stool DNA test looks for traces of DNA (genetic

material) shed by polyps and/or colorectal tumors.

Virtual Colonoscopy A screening examination of the colon in which x-rays

obtained by CAT scan are used to generate

computerized three-dimensional images of the colonic

mucosa.