

ATTACHMENT 4

MEDICAL COMPLICATIONS REPORTING FORM

**Colorectal Cancer Screening Demonstration Program (CRCSDP)
Medical Complications Reporting Form**

Public reporting burden of this collection of information is estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-XXXX).

Instructions

Please complete this Medical Complications Reporting Form for any medical complications experienced by clients who receive a sigmoidoscopy, colonoscopy, or double contrast barium enema for screening or diagnostic purposes through the CRCSDP. This form should be completed for any medical complication occurring either **during the procedure or within 30 days following the procedure.**

For Medical Complications Requiring Hospitalization

For clients hospitalized due to a medical complication, the following protocol should be followed:

- Within 72 hours of the hospitalization, notify your CDC technical assistance team (CDC program and scientific consultants and IMS technical consultant) by e-mail.
- Within 5 days of the hospitalization, complete and submit the Medical complications Reporting Form to your CDC technical assistance team (listed above). It may be helpful for you to obtain a copy of the endoscopy report (you do not need to send CDC the endoscopy).
- Communicate regularly by e-mail and/or your routine monthly telephone calls with your CDC technical assistance team to provide updates regarding the client's medical status.
- Re-submit the form monthly or more frequently as the client's status changes to your CDC technical assistance team until resolution. On the resubmission, you need to only fill out the record id, client id, date form completed, examination date and last two questions completed.
- Complete all fields of the CCDE record on this client per usual and submit when due.

For Medical Complications NOT Requiring Hospitalization

For clients experiencing a medical complication that does **not** require hospitalization, the following protocol should be followed:

- Complete the Medical Complications Reporting Form and submit by e-mail with any new or updated Medical Complications Reporting Forms quarterly to your CDC technical assistance team (listed above) on September 1, December 1, March 1, or June 1.
- If the medical complication was not resolved by the quarterly submission date, re-submit at subsequent quarterly submissions until resolution.
- Complete all fields of the CCDE record on this client per usual and submit when due.

Medical Complications Reporting Form

1. Today's date: / / (mm/dd/yyyy)

2. Program:

- Baltimore, MD
- St. Louis, MO
- State of Nebraska
- Stony Brook, NY
- Seattle and King County, WA

3. CCDE Client Identification Number:

4. CCDE Record Identification Number:

5. For which examination are you reporting an medical complication?

- Sigmoidoscopy
- Colonoscopy
- Double Contrast Barium Enema

6. What was the indication for the examination?

- Screening
- Surveillance after a positive colonoscopy (done outside program or during prior cycle)
- Follow-up to positive FOBT in this cycle
- Follow-up to positive DCBE in this cycle
- Follow-up to positive sigmoidoscopy in this cycle
- Unknown

7. Examination date: / / (mm/dd/yyyy)

8. Results of examination (*check all that apply*):

- Normal/negative
- Diverticulosis
- Hemorrhoids
- Other finding not suggestive of cancer/polyp(s)
- Polyp(s)/suspicious for cancer/presumed cancer
- No findings/inconclusive
- Pending
- Unknown

9. Was the bowel preparation considered adequate by the clinician performing the examination?

- Yes
- No
- Unknown

10. If sigmoidoscopy or colonoscopy, segment reached:

- Rectum
- Rectosigmoid junction

- Sigmoid colon
- Descending colon
- Splenic flexure
- Transverse colon
- Hepatic flexure
- Ascending colon
- Cecum
- Appendix
- Overlapping lesions
- Unknown

11. Was the examination noted to be difficult?

- Yes *(please describe)*
- No
- Unknown

12. Was a biopsy/polypectomy performed?

- Yes
- No
- Unknown

13. Were any of these procedures performed? (report all that apply)

- Snare polypectomy
- Hot biopsy forceps or cautery
- Cold biopsy
- Ablation
- Submucosal injection
- Control of bleeding
- Unknown
- Other, specify

14. a. What was the nature of the medical complication? (check all that apply and describe)

- Bleeding
- Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc)
- Complications related to anesthesia
- Possible perforation
- Excessive abdominal pain
- Emergency room visit
- Death (please provide cause of death)
- Other _____

14. b. Please describe the medical complication:

15. Client medications (prescription and OTC) if available:

- Aspirin
- H2 blockers
- NSAIDs
- Anticoagulants

- Inhaled corticosteroids
- Oral corticosteroids
- Proton pump inhibitor
- None
- Other, _____

16. Did this outpatient examination lead to a hospital admission?

- Yes - *please notify CDC within 72 hours of hospital admission*
- No

17. Current status of client (*please include date completing form, current patient status, and length of hospitalization with admission and discharge date included*):

18. Interventions to address medical complications with pertinent dates included: