Pharmacy Name: _____

Pharmacy Permit Number: _____

COLORECTAL CANCER (CRC) SCREENING PROTOCOL

v2

Approved 3/18/2026

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to provide education and information specific to Colorectal Cancer and when appropriate, initiate colorectal cancer (CRC) screening using fecal immunochemical test (FIT), stool DNA test (e.g., sDNA-FIT), or blood-based cell-free DNA testing (bb-cfDNA).

PHARMACIST EDUCATION AND TRAINING

Prior to initiating CRC screening under this protocol, pharmacist(s) shall have received education and training in CRC screening, including review of the most recent: 1) Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement,[1] 2) the American Cancer Society's Colorectal Cancer Screening Guideline for Average-Risk Adults[2] and 3) the National Comprehensive Cancer Network (NCCN) Guidelines for Colorectal Cancer Screening[3] from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

CRITERIA

Pharmacist(s) authorized to initiate the dispensing or ordering of CRC screening methods shall follow the most current ACS, USPSTF, or NCCN Guidelines for CRC screening.[1,2,3]

Inclusion criteria (All criteria must be met):

- Patient is between 45 and 85 years of age
    - For patients 76 through 85 years of age the decision to be screened shall be based on a person's preference, life expectancy, overall health, and prior screening history using shared decision making between the pharmacist and the patient.

- Patient is at average risk for colorectal cancer (CRC) as defined by inclusion and exclusion criteria
- Patient is able and willing to undergo a screening completion colonoscopy if positive results are obtained from the screening test.

Exclusion criteria:

- A person with active signs or symptoms of CRC including, but not limited to rectal bleeding, unexplained bowel habit changes (diarrhea or constipation), unexplained abdominal pain, unexplained anemias, or unexplained recent weight loss.
- A personal history of colorectal cancer or adenomatous colon polyps
- A family history of colorectal cancer in first or 2nd degree relatives
- A personal history of inflammatory bowel disease (IBD, e.g. ulcerative colitis or Crohn's disease)
- A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC)
- A personal history of getting radiation to the abdomen (belly) or pelvic area to treat a prior cancer
- Patient is not due for colorectal cancer screening based on guidelines for CRC screening
    - Patient has had a colonoscopy in the last 10 years
    - Patient has had CT-colonography or flexible sigmoidoscopy (flex sig) in the last 5 years
    - Patient has received a FOBT, or FIT test in the past year
    - Patient has received sDNA-FIT or bb-cfDNA in the past 3 years
- Patient has been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-associated Polyposis (MAP), Garner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis

PROCEDURES FOR DISPENSING, MONITORING AND FOLLOW UP

Upon initiation of the protocol, the pharmacist will initiate the appropriate test according to the Guidelines (See Appendix 1).

In the case when results from screening tests are received by the initiating pharmacists, pharmacists shall report the results, positive or negative, to the patient's designated primary care provider. The pharmacist shall follow up with patients within two (2) business days to provide results and direct the patient to their primary care provider as needed. In the case

of any positive results, patients shall be directed to their primary care provider for follow up and timely scheduling of a screening completion colonoscopy.

When it is determined that the patient meets criteria for colonoscopy-based CRC screening, the pharmacist shall notify the patient and the primary care provider for a screening colonoscopy.

In the case the patient has signs or symptoms of CRC, the pharmacist shall direct the patient urgently to their primary care provider or endoscopy provider to evaluate for a colonoscopy.

In the case where the patient has attested that they do not have a primary care provider, the patient shall be directed to the authorizing prescriber for follow-up as indicated above.

In the case when results from screening tests are received by the authorizing prescriber and not the initiating pharmacist, no specific follow up procedures for the initiating pharmacist are required.

EDUCATION REQUIREMENTS

Individuals, or their guardian/caregiver, receiving a CRC screening under the protocol shall receive education regarding:

- Directions regarding how to complete the specific screening ordered or dispensed
- Information regarding need for follow-up screening completion colonoscopy in the case of positive screening test results

DOCUMENTATION

Pharmacist(s) shall document via prescription record with each person who receives a CRC screening under this protocol including:

(a) Prescription documentation as required in 201 KAR 2:171
(b) Documentation that the individual receiving CRC screening was provided with required education pursuant to this administrative regulation.
(c) Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and referral.

NOTIFICATION

Pharmacist(s) shall ask all persons receiving CRC screening under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the screening modality ordered or dispensed under the protocol to the identified primary care provider within two (2) business days. Once screening results are obtained, pharmacist(s) shall notify the patient’s primary care provider of the screening results within two (2) business days of receipt.

In the case when results from screening tests are received by the authorizing

prescriber and not the initiating pharmacist, no specific notification procedures for the initiating pharmacist are required.

Any individual affirmatively stating that the individual does not have a primary care provider may still receive CRC screening under this protocol provided all other applicable requirements of the protocol are met. In this circumstance, pharmacist(s) shall notify the authorizing prescriber of the screening results within two (2) business days of receipt.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving CRC screening under this protocol within 7 days]

TERMS
This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____
Prescriber Name Date

_____
Prescriber Kentucky License Number

_____
Prescriber Signature

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled : _____ and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Appendix 1
Recommended CRC Screening Modalities

	Recommendations	USPSTF 2021	ACS 2018	NCCN 2025
	Choice of Test	Screening for CRC with several different methods can accurately detect early-stage CRC and adenomatous polyps	High-sensitivity stool-based test or a structural (visual) exam, depending on patient preference and test availability; all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy	Shared decision-making with patients regarding the choice of screening method based on risk stratification, administration, and eligibility.
Direct Visual Exam	Colonoscopy	Every 10 years	Every 10 years	Every 10 years
	CT colonography	Every 5 years	Every 5 years	Every 5 years
	Flexible sigmoidoscopy	Every 5 years	Every 5 years	Every 5-10 years
	FS with FIT	FS every 10 years with annual FIT	–	–
Stool-based noninvasive	gFOBT or hs-gFOBT	Annual gFOBT	Annual hs-gFOBT	Annual hs-gFOBT
	Fecal immunochemical test (FIT)	Annual	Annual	Annual
	mt-sDNA (Cologuard)	Every 1 to 3 years	Every 3 years	Every 3 years
Blood-based noninvasive	bb-cfDNA	–	–	Every 3 years

References:

1. Davidson KW, Barry MJ, Mangione CM, et al. Screening for Colorectal Cancer: US Preventive Services Task Force

Recommendation Statement. *JAMA.* 2021;325(19):1965-1977. doi:10.1001/jama.2021.6238
2. Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2018;68(4):250-281.
3. NCCN guidelines:National Comprehensive Cancer Network. 2025. Colorectal Cancer Screening (02.2025). https://www.nccn.org

Additional Resources

Cologuard HCP Resources https://www.cologuardhcp.com/resources
Link to NEJM Pivotal Study (DeeP-C)