IOWA | Health and Human Services

Iowa Health and Human Services
Colorectal Cancer Service Entity Agreement

This agreement is entered into between the Iowa Department of Health and Human Services (Agency) and the service provider entity identified in the signature block at the end of this document (Service Entity). The Service Entity's legal name, as it appears on the entity's tax documents, National Provider Identifier (NPI) registration, and related official records, shall be used in this agreement.

I. Purpose

This agreement outlines the responsibilities of both parties to ensure that participants of the Iowa HHS Colorectal Cancer Program (Program) receive timely and appropriate screening, diagnostic, and follow-up services related to colorectal cancer screening abnormalities.

The Program may be supported by federal funds administered by the Centers for Medicare & Medicaid Services (CMS) under the Rural Health Transformation (RHT) Program and/or by the Centers for Disease Control and Prevention (CDC) through the Colorectal Cancer Control Program (CRCCP), as well as state funds. The Agency may, at its discretion, supplement Program funding with other federal or state funds. Such supplementation will not require a formal amendment unless it results in a material change to reimbursement rates, covered services, eligibility, reporting, or compliance obligations.

II. Responsibility of the Service Entity

The Service Entity agrees to:

1. **Adhere to Professional Standards:** Adhere to professional standards and levels of service as set forth in all applicable, local, state, and federal laws, rules, and regulations as well as administrative policies and procedures set forth by the Agency relating to services performed under this agreement.
2. **Assure Civil Rights and Privacy Compliance:** Abide, to the extent required, by the provisions of:
    i. Title VI of the Civil Rights Act of 1964, as amended.
    ii. Section 504 of the Rehabilitation Act of 1973, as well as the Americans with Disabilities Act of 1990 (42 U.S.C. § 12101), and associated regulations (28 C.F.R. §§ 36.101–.999).
    iii. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and associated regulations (45 C.F.R. parts 160 and 164), and all applicable laws protecting the confidentiality of patients and members receiving services through Iowa HHS, Medicaid, and other programs.
3. **Ensure Enrollment of Facilities Providing Services:** This agreement covers all facilities associated to the Tax ID# listed in the signature block.
    a. Provide Tax Information: The Service Entity shall provide a completed IRS Form W-9 upon execution of this agreement or as requested by the Agency. A W-9 form is required only once per Tax ID# associated with this agreement, unless there are changes to the entity's tax information.

b. Individual facilities, providing services authorized by the Program, associated with this Tax ID#, must provide documentation to the Program. To become an approved facility, facilities should follow enrollment procedures on the Iowa HHS website.
    i. Provide NPI information for providers or facilities providing approved services.
    ii. Under the Clinical Laboratory Improvement Amendments (CLIA), any facility that performs even one test on human specimens for diagnosis, prevention, or treatment of disease is considered a laboratory and must have a CLIA certificate. If an individual facility is providing these services, a CLIA certificate is required upon application for enrollment from individual facilities. It is the Service Entities responsibility to ensure individual approved facilities send current CLIA certificates to the Program.
        1. At each renewal, approximately every 2 years, within 5 business days.
        2. If a provider adds a new reference lab or changes test complexity, a new CLIA certificate must be sent to the Program within 5 business days.
        3. Approved facilities must notify the Program within 5 business days of any CLIA suspension, revocation, lapse, or change in certificate type.

4. **Ensure Individual Approved Facilities Comply:** The Service Entity should ensure that individual facilities associated with this Tax ID# and are enrolled and approved by the Program prior to providing services to participants. The Service Entity should ensure approved facilities follow all standards set by this agreement.
5. **Provide Authorized Services:** Deliver services authorized by the Program, which may include, but are not limited to:
    - Fecal Immunochemical Tests (FIT)
    - Screening, follow-up and diagnostic colonoscopies

    All services must align with the Program's approved CPT codes and the current Program fee schedule available on the Iowa HHS website.
6. **Submit Claims for Program Services Performed:** Bill only for services authorized by the Program and performed for eligible Program participants.
7. **Accept Reimbursement at Medicare Part B Rates:** Accept claim reimbursement at Medicare Part B, participating provider rates for Iowa. Services will be reimbursed at the current Medicaid Part B reimbursement rate.
8. **Seek Preauthorization When Required:** Obtain written authorization from the local program before delivering any procedure not already authorized.
    Example: *During a colonoscopy, the endoscopist may proceed with diagnostic evaluation and routine interventions (e.g., biopsy, routine polypectomy, clipping, tattooing) without pre-authorization. If a lesion is identified that requires advanced endoscopic therapy beyond routine polypectomy (e.g., complex EMR/ESD), the endoscopist will schedule a separate, staged procedure and obtain written authorization from the local program before that advanced therapy is performed, unless emergent care is clinically required.*

9. **Assure Timely Claims Submission:** Submit claims within 180 days of the service date. Claims submitted after this period will not be reimbursed by the Agency, and the Service Entity agrees not to bill or seek reimbursement from the participant.

   For services allowable under the CMS Rural Health Transformation (RHT) award, the Program will reimburse in accordance with RHT terms and conditions. The Service Entity must follow RHT billing requirements and attest that no participant balance billing will occur. The Program is restricted to uninsured individuals under CMS Rural Health Transformation (RHT) funding requirements. The Service Entity must make reasonable efforts to verify participant insurance status based on information provided by the participant. If a participant represents themselves as uninsured and the Service Entity later discovers active insurance coverage, the Service Entity shall bill the participant's insurance. In these circumstances, neither the Service Entity nor the local program will be penalized for the participant's inaccurate reporting. In such cases, the Program functions as the payor of last resort, and only the remaining balance, up to the Medicare Part B rate, may be billed to the Program after insurance payment is applied.

   For services not allowable under RHT or when RHT funds are unavailable or exhausted, the Program operates as the payor of last resort. Insurance or other sources of payment must be billed and payment received prior to billing the Program. The Service Entity shall submit the EOB from the other payment source to document any remaining claim amount, up to the Medicare Part B participating provider reimbursement rate for Iowa, requested from the Program.
10. **No Duplication of Payment:** Program reimbursement shall not duplicate payments received from insurance or any other payer.
11. **Agree Not to Bill Participant:** Participants may not be billed for services covered under the Program.
12. **Accept the Program's Reimbursement as Payment in Full:** By entering into this agreement, Service Entity agrees to accept the Program reimbursement rate as payment in full and will not bill the participant for additional costs for the Program services provided.
13. **Maintain Licensure:** Ensure all staff providing Program services are appropriately licensed and practicing within their professional scope.
14. **Maintain Records:** Maintain accurate documentation of all services rendered under the Program. Retain records for six (6) years. Records must be made available to the Agency upon request.
15. **Follow Screening Guidelines:** Adhere to current colorectal cancer screening, diagnostic, and follow-up guidance adopted by the Agency, consistent with the Centers for Disease Control and Prevention's Colorectal Cancer Control Program (CDC-CRCCP) and recommendations of the U.S. Preventive Services Task Force (USPSTF). The Service Entity will also comply with applicable CMS National Coverage Determinations for colorectal cancer screening tests, including NCD 210.3.

16. **Ensure Confidentiality:** Safeguard participant health information in accordance with applicable federal and state privacy laws (i.e. Iowa Code 217.30 and HIPAA regulations, where applicable).

III. Responsibilities of the Agency

The Agency agrees to:

1. **Authorize Services**: Provide authorization for services to Program participants according to Program guidelines.
2. **Reimburse Services:** Reimburse the Service Entity for approved services at Medicare Part B Participating Provider Rates for Iowa, contingent on proper claim submission and available funding.
3. **Provide Support:** Offer technical assistance related to Program implementation.
4. **Monitor Compliance:** Review the Service Entity's adherence to this agreement through audits or record reviews.

IV. Term and Expiration

1. **Effective Date and Duration and Renewal:** This agreement becomes effective on the date signed by the Agency and will remain active for six years from that date unless terminated earlier. It is the Service Entity's responsibility to access the Program's renewal information on the Iowa HHS website and complete the renewal process before the agreement expiration date. All approved facilities associated with this Tax ID# will expire 6 years after the signed date below, regardless of individual facility enrollment.
2. **Termination:** Either party may terminate this agreement with 30 days' written notice. The Agency may terminate immediately in the event of a breach of agreement terms of violation of law, or if state and/or federal funds are de-appropriated, reduced, not allocated, or receipt of funds is delayed, or if any funds or revenues needed by the Agency to make any payment hereunder are insufficient or unavailable for any other reason as determined by the Agency in its sole discretion, or for any other reason that impacts the Agency's ability to carry out its obligations under the agreement.
3. **Funding Authorization and Availability:** Reimbursement under this Agreement is contingent upon authorization and annual funding availability under applicable programs and funding sources. The Agency may utilize any authorized funding source for covered services without amendment and may modify covered services or operational requirements to comply with the directives, terms, or conditions of the applicable funding source. If funds are de-appropriated, reduced, not allocated, or delayed, the Agency may suspend reimbursement, modify covered services, or terminate this Agreement immediately without notice.
4. **Amendments:** Any changes to this agreement must be made in writing and signed by both parties.
5. **Participant Financial Protection upon Termination:** In the event this Agreement is terminated, for any reason, the Service Entity shall not bill or seek reimbursement from any Program participant for any services provided under this Agreement. This includes services delivered prior to termination for which the Program had authorized payment, regardless of whether the Agency later determines not to reimburse due to lack of funds, change in law, or any other

reason. The Service Entity acknowledges and agrees that participants shall bear no financial responsibility for services rendered pursuant to this Agreement.

V. General Provisions

1. **Confidentiality:** The Service Entity must protect participant information in compliance with federal and state privacy laws.
2. **Non-Discrimination:** The Service Entity agrees to comply with all applicable civil rights laws and not discriminate based on race, color, national origin, sex, age, or disability.
3. **Forum, Choice of Law, and Compliance with Law:** Both parties agree to comply with all applicable federal, state, and local laws, rules, and regulations. The laws of the State of Iowa shall govern and determine all matters arising out of or in connection with this Agreement without regard to the conflict of law provisions of Iowa law. All litigation commenced in connection with this Agreement shall be brought and maintained solely in Polk County District Court for the State of Iowa, Des Moines, Iowa, or in the United States District Court for the Southern District of Iowa, Central Division, Des Moines, Iowa, wherever jurisdiction is appropriate. This provision shall not be construed as waiving any immunity to suit or liability including without limitation sovereign immunity in State or Federal court, which may be available to the Agency or the State of Iowa.
4. **Indemnification / Hold Harmless:** The Service Entity agrees to indemnify, defend, and hold harmless the State of Iowa, the Iowa Agency of Health and Human Services, and their officers, employees, and agents (collectively, “Indemnitees”) from and against any and all claims, actions, suits, liabilities, damages, losses, or expenses—including attorney fees—arising out of or resulting from (a) the negligent acts or omissions or willful misconduct of the Service Entity, its employees, contractors, or agents in connection with the performance of this Agreement; or (b) any breach of this Agreement by the Service Entity. This provision shall survive termination or expiration of the Agreement.
5. **Access to Participant Records:** The Service Entity shall retain and make available to the Agency, its auditors, or authorized representatives all records related to services provided under this agreement for six (6) years. This obligation survives expiration or termination.
6. **Key Compliance Obligations:**
   a. The Service Entity shall comply with all financial, recordkeeping, and audit-related obligations as described in the Agency’s General Terms and Conditions, incorporated herein by reference.
   b. Upon request, the Service Entity will provide de-identified service-level data elements and documentation (e.g., EOBs) necessary for Program monitoring, federal reporting, payment, or audit, consistent with privacy laws.
   c. This Agreement is funded in whole or in part with federal funds. The Service Entity shall comply with all applicable requirements set forth in the Agency’s Contingent Terms for Federally Funded Contracts, available at https://hhs.iowa.gov/media/9495/download?inline, as of the effective date of this agreement. These terms are incorporated herein by reference and made a part of this agreement as if fully set forth herein.

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This form must be completely filled out to be considered valid; handwritten submissions will not be accepted. If the Service Entity has multiple Tax ID#s, each Tax ID# will require a separate Service Entity Agreement. By signing this document, the parties agree to the terms and conditions set forth in this agreement.

For the Iowa Department of Health and Human Services Signature: Jill Lange, MPH, RD, LD Division Administrator, Health Promotion & Prevention Division of Public Health	**For the Service Entity** Legal Name of Entity: Tax ID # relevant to this agreement: Signature: Authorized Representative Name: Title: Date: Phone: Email:

Required Billing Information			
Billing Entity Name			
Billing Address			
Street			
PO Box or Other*			
City			
State			
County			
Billing Contacts			
Name		Name 2*	
Phone Number		Phone Number 2*	
Email Address		Email Address 2*	

*Optional Information