

Instructions/annotation for preparation of this contract:

Lines “ _____ ” are provided to be filled in with names, addresses, procedures, etc.

Square brackets “ [] ” denote material that needs to be deleted, modified, or added to.

Singe asterisk “*” at the start of a section, denote sections that may be omitted.

Double asterisks “**” at the start of a section, denote sections that may be omitted under certain circumstances as noted below that section.

**Laboratory Service Contract for the
Maryland Cancer Education, Prevention, Screening, Diagnosis, and Treatment Program**

Preamble

Whereas the State of Maryland has awarded funds to the State of Maryland Department of Health and Mental Hygiene (DHMH) for the purposes of prevention, early detection and treatment of colon and rectal cancer for low income Maryland residents, and

Whereas the DHMH has awarded funds to the local health departments in each jurisdiction in the state to coordinate the provision of clinical services including screening, and linkage to diagnostic, treatment and follow-up services, and

Whereas it is necessary for each local health department to contract with local laboratories to provide clinical and pathology laboratory services.

Whereas the State of Maryland DHMH has mandated certain requirements be agreed to in regard to the provision of these services.

Now, therefore, the laboratory and _____ Local Health Department, as specified below, agree as follows:

This agreement, entered into on _____ by and between the _____ Local Health Department, hereinafter called the “LHD”, and _____ (laboratory), hereinafter called the “Contractor,” shall commence on _____ and shall terminate on _____ and shall be subject to one-year renewal(s) or extension(s) with modification(s) up to four (4) times by both parties on an annual basis. This agreement shall be for the purpose of providing clinical services as specified in Part I., Section A., below, only to clients referred to the Contractor by the LHD under the conditions specified below.

Part I. The Contractor agrees to:

Laboratory Services and Reporting

- A. Provide the following laboratory services to clients referred by the LHD:
- processing and reading of colorectal biopsy specimens
 - [complete blood counts
 - immunohistochemical stains
 - other services agreed to by the LHD]
- B. *Provide services on the times specified below: [during normal business hours] or [_____].
- C. Follow the most recent version of the Colorectal Cancer Minimal Elements for Screening, Diagnosis, Treatment, Follow-up and Education (attached) developed by the Colorectal Cancer Medical Advisory Committee of the Maryland Department of Health and Mental Hygiene as the standard for care for Maryland residents screened through the Maryland Cancer Education, Prevention, Screening, Diagnosis and Treatment Program, specifically Section VII, Histologic Classification of Polyp or Tumor, page 4 (Attachment I).
- D. Report all findings from the pathology laboratory or other laboratory results to the LHD [Contract Monitor] [Case Manager] or _____ by [mail, telephone, email, or fax] within 10 working days of receiving the specimen and send the written report by mail at the same time.

Qualifications and insurance

- E. Have clinical services performed by a pathologist who has received specialized medical training to perform these procedures.
- F. Provide a copy of each physician's current Maryland medical license and a copy of his/her specialty board certification, if applicable, for each physician performing services under this contract to the LHD Contract Monitor along with this signed contract.
- G. Obtain and maintain appropriate insurance coverage for services rendered under this contract, and provide documentation of current malpractice insurance to the LHD Contract Monitor along with this signed contract.
- H. Provide documentation of being in compliance with the rules for Clinical Laboratory Improvement Amendments (CLIA) of 1988 by submitting its CLIA Identification number along with this signed contract.

Billing

- I. Send the completed medical report (results) of the pathology for the patient to the LHD by the time frame specified in Part I., Section D., in order to receive payment.
- J. Not bill a patient for any charge for the performance of laboratory services listed in Part I., Section A., above, subject to the provisions of Part III., Section B, below.
- K. Not bill the LHD for any service other than the performance of laboratory services listed in Part I, Section A. above, and LHD-approved procedures or physician office visits.
- L. If the laboratory rates are set by the HSCRC, provide one or more of the laboratory services listed in Part I., Section A., above, at a rate approved for the laboratory by the Maryland Health Services Cost Review Commission (HSCRC).
- M. If the Maryland HSCRC does *not* set the rate for service, provide one or more of the laboratory services listed in Part I., Section A., above, at a rate no more than the Medicare rate fee, as specified on the attached schedule or any schedule that may be substituted on a yearly basis by the LHD due to changes in federal Medicare reimbursement rates. (Attachment 2)
- N. Include on each bill the Contractor's name, address, and Federal Tax Identification or Social Security Number, the patient's name, the service provided, the date the service was provided, the cost for each service, and the amount that is due and owing.
- O. Obtain payment for laboratory services by billing _____ of the LHD at the following address: _____
- P. Submit a bill for the reimbursable laboratory service rendered within 9 months of the date of service(s).

Other

- Q. Comply with the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §§1320d et seq. and 45 CFR Parts 160 and 164, HIPAA) and the Maryland Confidentiality of Medical Records Act (Md. Code Ann., Health-General, §§4-301 et seq.) as they apply to Contractor's operations pursuant to this agreement.
- R. Not be in arrears with respect to the payment of any monies due and owing the State of Maryland, or any department or unit thereof, including but not limited to the payment of taxes and employee benefits, and not become in arrears during the term of this Contract.

- S. (1) Not discriminate in any manner against an employee or applicant for employment because of race, color, religion, creed, age, sex, marital status, national origin, ancestry, or physical or mental handicap unrelated in nature and extent so as to reasonably preclude the performance of such employment; (2) include a provision similar to that contained in subsection (1) above, in any subcontract except a subcontract for standard commercial supplies or raw materials; and (3) post and cause subcontractors to post in conspicuous places available to employees and applicants for employment, notices setting forth the substance of this clause.

Part II. The LHD agrees to:

- A. Pay the Contractor pursuant to the attached reimbursement schedule, or any schedule that may be substituted for the attached schedule on a yearly basis by the LHD due to changes in the Medicare or Medicaid reimbursement rates, or pursuant to a rate approved for the laboratory by the Maryland Health Services Cost Review Commission (HSCRC) only for laboratory services listed in Part I, Section A., above, and no other medical procedures or physician office visits unless pre-approved by the LHD.
- B. Communicate with the Contractor regarding clinical, laboratory, insurance, case management, and billing information.

Part III. The Contractor and the LHD agree that:

- A. This contract is funded with State funds appropriated by the Maryland General Assembly under the Cigarette Restitution Fund (State Finance and Procurement Article, § 7-317, Annotated Code of Maryland).
- B. Funds from the LHD under this contract are funds of last resort. Payment by the LHD for laboratory services to the Contractor will cease in any given fiscal year when the LHD Cancer Education, Prevention, Screening, Diagnosis and Treatment grant funds are depleted. The Contractor shall bill the patient for additional services provided by the Contractor after funds are depleted using the Contractor's usual and customary billing methods.
- C. The Contractor shall bill the patient for services provided by the Contractor that are not part of this contract and not approved by the LHD using the Contractor's usual and customary billing methods.
- D. If funds for LHD payment for laboratory services are depleted, the Contractor and the LHD [Case Manager] shall continue to communicate regarding laboratory and case management issues.
- E. Payment for services will not occur until the completed medical report of the clinical services for the patient is received by the LHD.
- F. Bills submitted after nine (9) months from the date of service will not be reimbursed.

G. The Contractor is not covered by the Maryland Tort Claims Act.

H. The LHD is not a “Business Associate” of the contractor under HIPAA.

I. Regarding HIPAA:

1. The activities covered by this agreement constitute treatment, payment, or health care operations as defined in HIPAA regulations at 45 CFR §164.501;
2. The LHD is a public health authority (defined in 164.501) and as authorized by the Cigarette Restitution Fund law (MD Ann. Code of Health General Article §§ 13-1101 to 13-1119) is seeking to collect or receive information under a previously executed grant agreement with the LHD for the purpose of preventing or controlling disease, injury or disability and for the purpose of conducting public health surveillance, investigations and interventions; and, further,
3. The LHD is engaged in health oversight activities (as defined in 164.501) required by the Cigarette Restitution Fund law to oversee this government program.
4. It is therefore agreed that the patient information (medical and billing) that the Contractor is required to provide to the LHD in Part Section I., above, **[insert correct section numbers that apply to your contract if you have changed them from this template]** may be provided pursuant to HIPAA regulations at (42 U.S.C. §§ 1320d et seq. and 45 CFR Parts 160 and 164, HIPAA) and the Maryland Confidentiality of Medical Records Act (Md. Code Ann., Health-General, §4-301 et seq.) without prior express authorization from the patient or the patient's representative.

J. The Contract Monitor for the LHD is:

Name (typed) _____

Title (typed) _____

Business Address (typed) _____

Business Telephone Number (typed) _____

The LHD Contract Monitor is the primary point of contact for the LHD for matters relating to this contract. The Contractor shall contact this person immediately if the Contractor is unable to fulfill any of the requirements of this contract or has any questions regarding the interpretation of the provisions of the contract.

K. The Contract Monitor for the Contractor is:

Name (typed) _____

Title (typed) _____

Business Address (typed) _____

Business Telephone Number (typed) _____

The Contractor Contract Monitor is the primary point of contact for matters relating to this contract. The Contractor Contract Monitor shall contact the LHD Contract Monitor immediately if the Contractor is unable to fulfill any of the requirements for the contract or if there are any questions regarding the interpretation of the provisions of the contract.

- L. This contract may be terminated by either the Contractor or the LHD by giving 14 calendar days prior written notice to the other party's Contract Monitor. In the event of a contract termination, the LHD will pay the contractor all reasonable costs associated with this contract that the Contractor has incurred to the date of termination.
- M. The following attached document(s) is (are) incorporated into and hereby made a part of this contract:
 - 1. The reimbursement schedule or any schedule that may be substituted on a yearly basis by the LHD for the attached schedule due to changes in federal Medicare or Medicaid reimbursement rates.
 - 2. Colorectal Cancer Minimal Elements for Screening, Diagnosis, Treatment, Follow-up, and Education.

In witness whereof, these authorized representatives of the Contractor and the LHD hereby set forth their signatures showing their consent for the Contractor and the LHD to abide by the terms of this contract.

For the Contractor

(Signature)

Name (printed)

Title (printed)

Date of Signing

For the LHD

(Signature)

Name (printed)

Title (printed)

Date of Signing