April 4, 2022

SOLICITATION ADDENDUM #3
OPEN SOLICITATION #1048537
Page 1 of 1 FOR THE PROCUREMENT: for
Clinical Laboratory Services for Cervical Cancer and Breast Cancer Screening and Diagnosis

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THE FOLLOWING CHANGES ARE APPLICABLE TO THE OPEN SOLICITATION:

Change #1
The NOTICE TO VENDORS section is updated to replace the contact information for questions on the application process. Any prospective vendor questions regarding the Open Solicitation process or services to be provided should be emailed to:
HHS.Open.Solicitations@montgomerycountymd.gov

THERE ARE NO OTHER CHANGES
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THE SOLICITATION PROVISION ENTITLED “SOLICITATION ADDENDUM” IS APPLICABLE TO THIS ADDENDUM. THE CHANGES SET FORTH BELOW ARE HEREBY INCORPORATED INTO THE ABOVE-CITED OPEN SOLICITATION

ISSUED BY: ____________________________
Raymond L. Crowel, Psy.D., Director, Department of Health and Human Services
OFFICE OF PROCUREMENT
MONTGOMERY COUNTY GOVERNMENT
SOLICITATION AMENDMENT #2
OPEN SOLICITATION
#1048537
Clinical Laboratory Services for Cervical Cancer and
Breast Cancer Screening and Diagnosis
May 6, 2019

PAGE 1 OF FOR THE PROCUREMENT OF: CLINICAL LABORATORY SERVICES FOR CERVICAL CANCER AND BREAST CANCER SCREENING AND DIAGNOSIS

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CHANGES

Change 1:
Replace Open Solicitation Plan with revised Open Solicitation Plan.

Change 2:
Replace Form Contract with revised Form Contract.

Change 3:
Replace Attachment A, General Conditions of Contract Between County and Contractor with revised Attachment A, General Conditions of Contract Between County and Contractor.

Change 4:
Add Attachment B, Business Associates Agreement.

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THE SOLICITATION PROVISION ENTITLED SOLICITATION AMENDMENTS IS APPLICABLE TO THIS AMENDMENT. THE CHANGES SET FORTH ABOVE ARE HEREBY INCORPORATED INTO THE ABOVE-CITED SOLICITATION.

************************************************************************************************

ISSUED BY:

Avinash G. Sheety
Director

Office of Procurement
255 Rockville Pike, Suite 180 • Rockville, Maryland 20850 • 240-777-9900 • 240-777-9956 TTY • 240-777-9952 FAX
www.montgomerycountymd.gov

montgomerycountymd.gov/311 240-773-3556 TTY
Open Solicitation Plan
Open Solicitation #1048537 - Clinical Laboratory Services for Cervical Cancer and Breast Cancer Screening and Diagnosis

As required by Montgomery County Procurement Regulations, Code of Montgomery County Regulations (COMCOR), Section 11B.00.01, et seq., Section 4.1.6.3 (a), the Department of Health and Human Services (DHHS) / Public Health Services is submitting this Open Solicitation Plan for approval by the Director, Department of General Services, Montgomery County, Maryland.

Section 4.1.6.3 Procedure

Public Notice – Notice for this solicitation will be posted on the Montgomery County (County), Office of Procurement website. Additionally, a copy of the notice will be sent to current service provider(s) with contract(s) under Open Solicitation #5646019016.

1. Application Process – The Department of Health and Human Services (DHHS) Contract Management Team (CMT) will mail out the solicitation packet for this Open Solicitation to all providers who express an interest. The solicitation packet includes the following: 1) the Notice to Vendors; 2) the Instructions to Vendors; 3) the pre-approved Form Contract including the General Conditions of Contract Between County and Contractor, and all other attachments. Applicants must submit all required documents as described under Instructions to Vendors document.

2. Criteria for accepting or rejecting applications – The solicitation packet contains the minimum qualifications (set forth in Article III., Minimum Qualifications of the Pre-Approved Contract) for services upon which applicants will be accepted. Applications will be reviewed by DHHS staff for acceptance or rejection, based on the minimum qualifications.

3. All applicants meeting the minimum qualifications listed in the Pre-Approved Contract will be eligible to receive contracts to provide services described in the Open Solicitation. Clients will receive a list of Contractors who are participating in the County's Women Cancer Control Program (WCCP) and the clients will make their own appointments with the Contractor of their choice. The Contractor chosen by the client will then notify one of the participating laboratories of the need for laboratory services.

4. Pre-Approved Form Contract – Applicants will be required to execute a contract with the County using the Pre-Approved Form Contract (the “Form Contract”), including the General Conditions of Contract Between County and Contractor (“General Conditions”), and other attachments without modification.

5. Cost – The cost of contracts will not exceed available appropriations. Funds will be encumbered in purchase orders issued under the contracts by the Office of Procurement.

6. Cancellation – The County reserves the option to cancel this Open Solicitation at any time. Award of a contract under this Open Solicitation is subject to fiscal appropriations.

7. Changes to Forms - The County may update the Open Solicitation Form contract with updated versions of the forms listed below without issuing an amendment to the Open:
(a) General Conditions of Contract Between County & Contractor (PMMD-45);
(b) Minority Business Program & Offeror’s Representation (PMMD-90);
OPEN SOLICITATION # 1048537
Clinical Laboratory Services for Cervical Cancer and Breast Cancer Screening and Diagnosis
(Revised by Solicitation Amendment #2)

(c) Minority-owned Business Addendum to the General Conditions of Contract between County and Contractor (PMMD-91)
(d) Minority, Female, Disabled (MFD) Person Subcontractor Performance Plan (PMMD -65)
(e) Wage Requirements for Services Contract Addendum to The General Conditions of Contract Between County and Contractor, and Wage Requirements Law Certification (PMMD-177); and
(f) Business Associate Agreement

NOTICE TO VENDORS

DHHS is seeking applications from laboratories licensed in the State of Maryland.
To apply to provide the services described in this Open Solicitation, which support the County’s Women’s Cancer Control Program (WCCP), the laboratory must have an Account Manager located in Montgomery County and must be able to provide services to uninsured or underinsured women with limited income, referred by the physicians who are under contract with the County to be a service provider for the WCCP. The County will determine each client's eligibility for service(s) and provide a voucher or eligibility letter to the client for each service needed. Clients will receive a list of Contractors who are participating in the County's WCCP and will make their own appointments with the Contractor of their choice. The Contractor of choice will then notify one of the participating laboratories of the need for their services.

Service Providers applying to provide Clinical Laboratories Services for Cervical and Breast Cancer Screening and Diagnosis under this Open Solicitation, must comply with all applicable licensing and certifications requirements listed under Article III - Minimum Qualifications, of this Open Solicitation for the services provided.

A complete description of the Scope of Services is provided in the Open Solicitation packet. You may obtain a packet by contacting the Contract Management Team at 240-777-1562 to request a copy of Open Solicitation #1048537. Please be prepared to provide your name or business name, the contact person’s name, your (or business) mailing address, e-mail address, and telephone number.

The County will reimburse the Contractor for services provided which can be found at: https://www.montgomerycountymd.gov/HHS-program/coo/contractmanagement/cmtcursolicits.html

The County will enter into a contract with all applicants who meet the minimum qualifications as described in the Form Contract (Article III., Minimum Qualifications), who is found to be a responsible organization. The County will sign the Form Contract and return a copy to the applicant. The Form Contract with all Attachments will constitute the entire Contract. Please keep a copy of all of these documents for your records. The applicant must sign the County’s Form Contract which includes the General Conditions of Contract Between County and Contractor, and other Attachments as written with no modification.

Any prospective vendor questions regarding the Open Solicitation process or services to be provided should be emailed to: HHS.Open.Solicitations@montgomerycountymd.gov
OPEN SOLICITATION # 1048537
Clinical Laboratory Services for Cervical Cancer and Breast Cancer Screening and Diagnosis
(Revised by Solicitation Amendment #2)

Questions related to the technical information required in this Open Solicitation should be directed to Cristina Ruiz-McCalla, Program Manager, Women’s Cancer Control Program at 240-777-3848 or email Cristina.Ruiz@montgomerycountymd.gov

Questions of an administrative nature (e.g., requests for additional applications, contract process, and insurance) should be directed to Amanda Abbey, Contract Management Team, at 240-777-1163 or email amanda.abbey@montgomerycountymd.gov.

INSTRUCTIONS TO VENDORS

The County will enter into contracts with all applicants who meet the Minimum Qualifications stated in Article III - Minimum Qualifications, of the Pre-Approved Form Contract, that are found to be responsible organizations. If your application is accepted and approved, and your organization is found to be responsible, the County will execute the contract and return a copy to you. Once you receive notice from the County that the contract has been executed, an executed purchase order from the County, and a request for services from the County, you may begin to provide services to clients.

The County will award multiple contracts under this Open Solicitation. The County cannot guarantee a minimum number of clients or a minimum number of laboratory tests for any applicant responding to this Open Solicitation.

Award of a contract under this Open Solicitation is subject to fiscal appropriations.

The County reserves the right to cancel this Open Solicitation at any time.

Submission Documents – The following items must be submitted:

A. Form Contract and Contract Attachments - the form contract must be filled out correctly and submitted. Please follow these steps:

1. Sign the Form Contract – If the applicant is a corporation, an officer of the corporation with authority to sign contracts for the corporation must sign the Form Contract.

2. PLEASE PUT YOUR ORGANIZATION’S NAME ONLY IN THE PARAGRAPH AT THE TOP OF THE PAGE. ENTER A DATE ONLY IN THE SIGNATURE BLOCK.

3. Submit all the pages of the Form Contract (not just the signature page), including the completed attachments listed below:
   a. General Conditions of Contract Between County & Contractor, (Attachment A);
   b. Business Associate Agreement (Attachment B)
   c. Vendor Information Form (Attachment C) and
   d. Minimal Clinical Elements (Attachment D)

B. Application Documents - The following attachments are required and must be completed or the application will be rejected:
OPEN SOLICITATION # 1048537
Clinical Laboratory Services for Cervical Cancer and Breast Cancer Screening and Diagnosis
(Revised by Solicitation Amendment #2)

a. Standard Form-LLL (Attachment E)
b. OPTIONAL - Minority Business Program & Offeror’s Representation (Attachment F)
c. Minority, Female Disabled (MFD) Person Subcontractor Performance Plan (Attachment G) – Please submit your MFD plan or request a waiver.
d. Wage Requirements for Services Contract Addendum to The General Conditions of Contract Between County and Contractor. (Attachment H).

C. Location(s) and phone numbers where services will be provided. Additionally, Contractor must provide phone number and contact information for its Account Manager located in Montgomery County.

D. Certificate(s) of Insurance - Applicants must provide evidence of meeting the insurance requirements set forth in Article VII of the Pre-Approved Form Contract. Contact your insurance broker to obtain the Certificate.

E. Licenses - All applicants must possess the appropriate and required licenses, registrations, and certifications, listed in Article III. Minimum Qualifications of the Pre-Approved Form Contract as required by the State of Maryland and federal regulations for professional laboratories services.

F. Proof of legal name - Articles of Incorporation and Articles of Amendment if applicable.

G. W-9 Tax form or copy of Social Security card if Sole Proprietorship.

H. Proof of tax-exempt status - Determination Letter from IRS, if applicable.

I. Applicants must sign and submit the Vendor Application Form (Attachment C).

J. Applicants must provide a list of all professional staff that will provide services under the contract resulting from this Open Solicitation and their qualifications.

K. Briefly state in writing your experience providing clinical laboratory services. Provide this description on no more than two double-spaced typewritten pages, and attach the statement to the application.

Please return all of the above listed submissions documents to:
Department of Health and Human Services
Women’s Cancer Control Program
1401 Rockville Pike, Suite 4100
Rockville, MD 20852
Attention: Cristina Ruiz-McCalla, Program Manager
I. BACKGROUND/INTENT

The County requires clinical laboratories services for breast and cervical cancer screening and diagnostic procedures.

The Contractor must provide services to uninsured or underinsured women with limited income who are referred by the physicians who contract with the County’s Women’s Cancer Control Program (WCCP). The County will determine each client's eligibility for service(s) and provide a voucher or eligibility letter to the client for each service needed. Clients will receive a list of Contractors who are participating in the County's WCCP and will make their own appointments to the contractor of their choice. The Contractor of choice will then notify one of the participating laboratories of the need for laboratory services.

The County will award multiple contracts under this Open Solicitation. The County cannot guarantee a minimum number of clients or a minimum number of laboratory tests for any applicant who responds to this Solicitation as the selection of a service provider is client driven and the needs of each client will vary.

Services under this Open Solicitation are funded in part with federal funds from the Centers for Disease Control and Prevention. All recipients of federal funds are prohibited from using federal funds for federal lobbying. In addition, if the Contractor receives $100,000 or more in federal monies, the Contractor must disclose any federal lobbying which is done with non-federal funds using Standard Form-LLL (Attachment E).

II. SCOPE OF SERVICES

A. The Contractor must provide the following services:

1. **Cytology**
   - Pap Test
     - Cervical or vaginal slides; and
     - Cervical or vaginal collected in preservative fluid, automated thin layer preparation

2. **Microbiology**
   - (HPV) Human Papilloma Virus; and
   - amplified probe technique (high-risk panel).

3. **Pathology**
   - Cervical Biopsy;
   - Breast Biopsy;
   - Other specimens related to diagnosis of breast; and
   - Cervical cancers or pre-operative tests for surgical procedures.
B. The Contractor must pick up the pap tests, HPV tests, cervical and breast biopsies and/or other appropriately labeled specimens related to the diagnosis of cervical and/or breast cancer when requested by the medical providers contracting with Montgomery County DHHS WCCP at the providers’ office sites located throughout Montgomery County.

C. The Contractor must receive, interpret, and notify the Montgomery County DHHS WCCP of the results of all requested tests.

D. The Contractor must send the completed laboratory report (results) of the Pap test, HPV cervical biopsy, breast biopsy, or other requested diagnostic tests or specimens for each patient, to the Montgomery County DHHS WCCP in the format specified and by the time frame specified in paragraph H and I below, in order to receive payment for services provided under this Contract.

E. The Contractor must provide to the County, initially at the time of contract execution and annually on request, documentation that Pathologists are certified by the American College of Pathology.

F. The Contractor must provide to the County, initially at the time of contract execution and annually on request, documentation of each cytotechnologist/cytopathologist having passed the Cytology Proficiency Testing Program of the State of Maryland.

G. The Contractor must provide to the County, upon request, annual documentation of being in compliance with the rules for cytology services in the Clinical Laboratory Improvement Amendments of 1988 by submitting its CLIA I.D. number.

H. The Contractor must report the results of all lab tests to medical providers under contract with the Montgomery County DHHS WCCP and to the Montgomery County DHHS WCCP Contract Monitor using the standardized terminology known as the Bethesda System and indicate the presence or absence of endocervical cells on the lab report for cervical cancer screening tests.

I. The Contractor must send patients’ lab results as follows:

1. for Pap tests or cervical biopsies that are “within Normal Limits,” or which show “Benign Cellular Changes,” or “Atypical Squamous Cells of Undetermined Significance,” and for HPV results that are “negative for high-risk type,” the Contractor must send a written report by mail, within ten (10) business days from the receipt of the specimen, to the patient’s medical case manager or identified provider and the Montgomery County DHHS WCCP;

2. for Pap tests or cervical biopsies that show “Low-Grade SIL,” “High-Grade SIL,” “Squamous Cell Carcinoma,” “Adenocarcinoma” or other malignant neoplasms, and for HPV results that are “positive for high-risk type,” the Contractor must notify the patient’s medical case manager or identified
provider and the Montgomery County DHHS WCCP of the results by phone or fax within five (5) business days of receiving the specimen and must send the written report by mail at the same time;

3. for breast biopsies, surgical, and other diagnostic breast specimens, the Contractor must report all findings from the pathology lab or other lab results to the medical case manager or identified provider and Montgomery County DHHS WCCP by mail, telephone, or fax within ten (10) business days of receiving the specimen for normal or negative results and within five (5) business days of receiving the specimen for abnormal results, or for malignant neoplasms.

J. The Contractor must not charge WCCP clients for any services provided under this Contract.

K. The Contractor must provide or arrange for lab work to be picked up at the offices of physicians contracting with the WCCP at no additional charge.

L. The Contractor must abide by the applicable ethical and legal standards for protection of patient health information under the Health Insurance Portability and Accountability Act (HIPAA), and other laws and regulations governing the privacy of medical records and substance abuse treatment records. The Contractor must sign and comply with the County’s Business Associate Agreement which is incorporated by reference into and made part of this Contract as Attachment B.

III. MINIMUM QUALIFICATIONS

All applicants meeting the minimum requirements listed below will be eligible to receive a contract. The Contractor must comply with these “Minimum Qualifications” for the duration of the contract term.

A. All applicants must possess the appropriate and required licenses, registrations, and certifications, listed below as required by the State of Maryland and Federal Regulations for professional laboratory services.

1. Evidence that the applicant has passed the Cytology Proficiency Testing Program of the State of Maryland.

2. Certification evidencing compliance with the rules for cytology services in the Clinical Laboratory Improvement Amendments of 1988 with CLIA ID number.

3. Pathologist’s certification by the American College of Pathology.

4. Copy of the laboratory’s current license to operate in the State of Maryland.

B. The Contractor must follow the Minimal Clinical Elements
IV. COMPENSATION

A. The County will reimburse the Contractor at rates which can be found at: https://www.montgomerycountymd.gov/HHS-program/coo/contractmgmt/ctcurrsolicits.html

B. The County will pay the rates established in A. above for each bundled or unbundled lab test or service provided consistent with the Minimum Clinical Elements (Attachment D), and as indicated below in Paragraphs E, F and G. These rates, as determined by the test code number, include any needed specimen pick-up, lab supplies, packing, shipping supplies, and printed requisitions required for each test. The rate that the County will pay to the Contractor will be that published on the County website provided in Paragraph A above. URL for Medicare and Medicaid Clinical Lab Services fee schedule will prevail. It is the responsibility of the Contractor to obtain a copy of the most current rates from the CMS website.

C. The Contractor will be reimbursed upon submission of a monthly invoice to the County in a format approved by the County. The submitted invoice must show CPT codes of services provided and service charges.

D. The Contractor must bill the County monthly by sending invoices to the Montgomery County DHHS designated contract monitor.

E. The County will only reimburse Contractors for cytopathology, cervical or vaginal (the Bethesda System) for the Pap test using one of the following procedures: (1) slides, manual screening, or (2) collected in preservative fluid, automated thin layer
preparation, manual screening. No other Pap test methods can be reimbursed through this Contract.

F. The County will only reimburse for microbiology, human papilloma virus, amplified probe technique (high-risk panel).

G. The County will reimburse for pathology, biopsy of the cervix, biopsy of the breast and examination of other surgical pathology specimens related to diagnosis of breast or cervical cancers.

V. INVOICES

A. The Contractor must submit monthly invoices to the County in a format approved by the County. All invoices must include the following information: Invoice Number, Contractor’s name, address, contract number, patient’s name, the service provided, the CPT code, the date the service was provided, the cost for each service, amount due and a purchase order number. This fee is all inclusive and includes both the cytotechnologist’s and cytopathologist’s fees, the costs for picking up, interpreting, and reporting the result of the Pap test to the Montgomery County DHHS WCCP.

B. The Contractor must submit all claims for reimbursement under this Contract to all insurance providers that provide insurance coverage for the client before such claims are submitted to the Montgomery County DHHS WCCP for payment. The Contractor must append to all claims submitted to the Montgomery County DHHS WCCP for payment under this Contract proof (explanation of benefits) that such claims have been denied in whole or in part by all of the insurance providers of the client.

C. The Contractor must submit a monthly invoice for the reimbursable service within thirty (30) days following the service month. Services are not reimbursable unless WCCP has received all test results.

VI. TERM

This Contract shall become effective upon signature by the County’s Director, Office of Procurement and shall be for a two-year term. Before the contract term ends, and subject to fiscal appropriations, the Director may (but is not required to) renew this Contract, if the Director determines that renewal is in the best interests of the County. Contractor’s satisfactory performance does not guarantee renewal of this Contract. The Director may exercise this option to renew two (2) times for two (2) year terms each.

VII. GENERAL CONDITIONS AND INSURANCE
The attached General Conditions of Contract Between County and Contractor (Attachment A) are incorporated by reference and made part of this Contract. The following insurance requirements supersede those outlined in Provision 21 of the General Conditions.

Prior to the execution of the contract by the County, the Contractor must obtain, at their own cost and expense, the minimum following insurance coverage with an insurance company/companies licensed to conduct business in the State of Maryland and acceptable to the Division of Risk Management. This insurance must be kept in full force and effect during the term of this contract, including all extensions. The insurance must be evidenced by a certificate of insurance, and if requested by the County, the Contractor must provide a copy of the insurance policies and additional insured endorsements. The minimum limits of coverage listed below shall not be construed as a limitation of any potential liability on the part of the Contractor to the County nor shall failure to request evidence of this insurance in any way be construed as a waiver of Contractor’s obligation to provide the insurance coverage specified. The Contractor’s insurance shall be primary. Subject to applicable law, the insurance companies providing insurance coverage, as referenced in this agreement, may not limit coverage to their insured, or the County as an additional insured, to stated minimum amount(s) of insurance referenced in this contract/agreement.

**Commercial General Liability**
A minimum limit of liability of one million dollars ($1,000,000), combined single limit, for bodily injury and property damage coverage per occurrence including the following coverages:
- Contractual Liability
- Premises and Operations
- Independent Contractors
- Products and Completed Operations

**Professional Liability – MEDICAL MALPRACTICE**
Professional liability insurance covering errors and omissions and negligent acts committed during the period of contractual relationship with the County with a limit of liability of at least one million dollars ($1,000,000) per claim and aggregate and a maximum deductible of $50,000. Contractor/proposer agrees to provide a one-year discovery period under this policy.

**Workers’ Compensation/Employer’s Liability**
Meeting all statutory requirements of the State of Maryland Law and with the following minimum Employers’ Liability limits:
- Bodily Injury by Accident - $100,000 each accident
- Bodily Injury by Disease - $500,000 policy limits
- Bodily Injury by Disease - $100,000 each employee

**Additional Insured**
Montgomery County, Maryland, its elected and appointed officials, officers, consultants, agents and employees must be included as an additional insured on Contractor’s Commercial and Excess/Umbrella Insurance for liability arising out of contractor’s products, goods and services provided under this contract. Evidence of the contractor’s additional insured endorsements must
be provided upon request by the County. Additional insured endorsements CG 20 33, CG 20 37 with edition dates 4/2013, CG 20 38; or their equivalents attempting to restrict coverage will not be accepted.

Policy Cancellation
Should any of the above policies be cancelled before the expiration date thereof, written notice must be delivered to the County in accordance with the policy provisions.

Certificate Holder
Montgomery County, Maryland
DHHS/CMT401 Hungerford Drive, 6th fl
Rockville, Maryland 20850

VIII. PRIORITY OF DOCUMENTS

The following documents are incorporated by reference into and made part of this contract and are listed in order of legal precedence below in the event of a conflict in their Terms:

A. This Contract document;
B. The General Conditions of Contract Between County And Contractor (Attachment A)
C. Business Associate Agreement (Attachment B)
D. Vendor Information Form (Attachment C)
E. Minimal Clinical Elements (Attachment D)
F. Standard Form-LLL (Attachment E)
G. Minority Business program & Offeror’s Representation (Attachment F) and Minority-owned Business Addendum to the General Conditions of Contract Between County and Contractor and the Minority, Female Disabled (MFD) Person Subcontractor Performance Plan. (Attachment G)
H. Wage Requirements for Services Contract Addendum to The General Conditions of Contract Between County and Contractor. (Attachment H)
Pre-Approved Form Contract #

Clinical Laboratory Services for Cervical Cancer and Breast Cancer Screening and Diagnosis

Signature Page - Open Solicitation # 1048537

This Contract, which incorporates by reference: the, Notice to Vendors, the Instructions to Vendors, the Approved Form Contract with the attached General Conditions of Contract Between County and Contractor, Attachment A and Attachments B, C, D, E, F, G and, H copies of which have been provided to the Contractor, is entered into this __________ day of ______________, 20___ by and between________________________, hereinafter referred to as the "Contractor" and Montgomery County, Maryland. This Contract will become effective on the date of signature by the Director, Department of General Services. This Contract and any renewals or extensions of this Contract are subject to the appropriation of funds.

Part A: Contractor's Offer to Provide Services:

(Prospective Contractor Must Complete)

Contracting Corporation, Partnership Limited
Liability Company OR Proprietorship

Agency Name

Signature

Typed /Printed Name

Title

Date

Part B: County Acceptance:

MONTGOMERY COUNTY, MARYLAND

Avinash G. Shetty, Director
Office of Procurement

Date

RECOMMENDATION

Victoria Buckland, Acting Director
Department of Health and Human Services

Date

This form has been approved as to form and legality by the Office of the County Attorney.

*Must be signed by corporate officer or person legally authorized to bind organization to a contract
ATTACHMENT A

(Revised with Solicitation Amendment #2)

GENERAL CONDITIONS OF CONTRACT BETWEEN COUNTY & CONTRACTOR

1. ACCOUNTING SYSTEM AND AUDIT. ACCURATE INFORMATION
The contractor certifies that all information the contractor has provided or will provide to the County is true and correct and can be relied upon by the County in awarding, modifying, making payments, or taking any other action with respect to this contract including resolving claims and disputes. Any false or misleading information is a ground for the County to terminate this contract for cause and to pursue any other appropriate remedy. The contractor certifies that the contractor’s accounting system conforms with generally accepted accounting principles, is sufficient to comply with the contract’s budgetary and financial obligations, and is sufficient to produce reliable financial information.

The County may examine the contractor’s and any first tier subcontractor’s records to determine and verify compliance with the contract and to resolve or decide any claim or dispute arising under this contract. The contractor and any first tier subcontractor must grant the County access to these records at all reasonable times during the contract term and for 3 years after final payment. If the contract is supported to any extent with federal or state funds, the appropriate federal or state authorities may also examine these records. The contractor must include the preceding language of this paragraph in all first tier subcontracts.

2. AMERICANS WITH DISABILITIES ACT

3. APPLICABLE LAWS
This contract must be construed in accordance with the laws and regulations of Maryland and Montgomery County. The Montgomery County Procurement Regulations are incorporated by reference into, and made a part of, this contract. In the case of any inconsistency between this contract and the Procurement Regulations, the Procurement Regulations govern. The contractor must, without additional cost to the County, pay any necessary fees and charges, obtain any necessary licenses and permits, and comply with applicable federal, state and local laws, codes and regulations. For purposes of litigation involving this contract, except for contract Disputes discussed in paragraph 8 below, exclusive venue and jurisdiction must be in the Circuit Court for Montgomery County, Maryland or in the District Court of Maryland for Montgomery County.

The County’s prevailing wage law, as found at §11B-33C of the County Code, applies to certain construction contracts. To the extent applicable, the County’s prevailing wage requirements are enumerated within this solicitation/contract in the “Prevailing Wage Requirements for Construction Contract Addendum to the General Conditions of Contract between County and Contractor.” If applicable to this contract, the Addendum will be attached to the contract, and will be incorporated herein by reference, and made a part thereof.

Furthermore, certain non-profit and governmental entities may purchase supplies and services, similar in scope of work and compensation amounts provided for in a County contract, using their own contract and procurement laws and regulations, pursuant to the Md. State Finance and Procurement Article, Section 13-101, et. seq.

Contractor and all of its subcontractors must comply with the provisions of County Code §11B-35A and must not retaliate against a covered employee who discloses an illegal or improper action described in §11B-35A. Furthermore, an aggrieved covered employee under §11B-35A is a third-party beneficiary under this Contract, who may by civil action recover compensatory damages including interest and reasonable attorney’s fees, against the contractor or one of its subcontractors for retaliation in violation of that Section.

The contractor agrees to comply with the requirements of the Displaced Service Workers Protection Act, which appears in County Code, Chapter 27, Human Rights and Civil Liberties, Article X, Displaced Service Workers Protection Act, §§ 27-64 through 27-66.

Montgomery County’s Earned Sick and Safe Leave Law, found at Sections 27-76 through 27-82 of the County Code, became effective October 1, 2016. An employer doing business in the County, as defined under the statute, must comply with this law. This includes an employer vendor awarded a County contract. A vendor may obtain information regarding this law at http://www.montgomerycountymd.gov/humanrights/

4. ASSIGNMENTS AND SUBCONTRACTS
The contractor must not assign or transfer this contract, any interest herein or any claim hereunder, except as expressly authorized in writing by the Director, Office of Procurement. Unless performance is separately and expressly waived in writing by the Director, Office of Procurement, an assignment does not release the contractor from responsibility for performance of this contract. Unless otherwise provided in the contract, the contractor may not contract with any other party for furnishing any of the materials or services herein contracted for without the written approval of the Director, Office of Procurement. Any subcontract for any work hereunder must comport with the terms of this Contract and County law, and must include any other terms and conditions that the County deems necessary to protect its interests. The contractor must not employ any subcontractor that is a debarred or suspended person under County Code §11B-37. The contractor is fully responsible to the County for the acts and omissions of itself, its subcontractors and any persons either directly or indirectly employed by them. Nothing contained in the contract documents shall create any contractual relation between any subcontractor and the County, and nothing in the contract documents is intended to make any subcontractor a beneficiary of the contract between the County and the contractor.

5. CHANGES
The Director, Office of Procurement, may unilaterally change the work, materials and services to be performed. The change must be in writing and within the general scope of the contract. The contract will be modified to reflect any time or money adjustment the contractor is entitled to receive. Contractor must bring to the Contract Administrator, in writing, any claim about an adjustment in time or money resulting from a change, within 30 days from the date the Director, Office of Procurement, issued the change in work, or the claim is waived. Any failure to agree upon a time or money adjustment must be resolved under the “Disputes” clause of this contract. The contractor must proceed with the prosecution of the work as changed, even if there is an unresolved claim. No charge for any extra work, time or material will be allowed, except as provided in this section.

6. CONTRACT ADMINISTRATION
A. The contract administrator, subject to paragraph B below, is the Department representative designated by the Director, Office of Procurement, in writing and is authorized to:

(1) serve as liaison between the County and the contractor;

PMMD-45. REVISED 3/1/2018 Page 1 of 7
ATTACHMENT A

(Revised with Solicitation Amendment #2)

(2) give direction to the contractor to ensure satisfactory and complete performance;
(3) monitor and inspect the contractor's performance to ensure acceptable timeliness and quality;
(4) serve as records custodian for this contract, including wage and prevailing wage requirements;
(5) accept or reject the contractor's performance;
(6) furnish timely written notice of the contractor's performance failures to the Director, Office of Procurement, and to the County Attorney, as appropriate;
(7) prepare required reports;
(8) approve or reject invoices for payment;
(9) recommend contract modifications or terminations to the Director, Office of Procurement;
(10) issue notices to proceed; and
(11) monitor and verify compliance with any MFD Performance Plan.

B. The contract administrator is NOT authorized to make determinations (as opposed to recommendations) that alter, modify, terminate or cancel the contract, interpret ambiguities in contract language, or waive the County's contractual rights.

7. COST & PRICING DATA
Chapter 11B of the County Code and the Montgomery County Procurement Regulations require that cost & pricing data be obtained from proposed awardees/contractors in certain situations. The contractor guarantees that any cost & pricing data provided to the County will be accurate and complete. The contractor grants the Director, Office of Procurement, access to all books, records, documents, and other supporting data in order to permit adequate evaluation of the contractor's proposed price(s). The contractor also agrees that the price to the County, including profit or fee, may, at the option of the County, be reduced to the extent that the price was based on inaccurate, incomplete, or noncurrent data supplied by the contractor.

8. DISPUTES
Any dispute arising under this contract that is not disposed of by agreement must be decided under the Montgomery County Code and the Montgomery County Procurement Regulations. Pending final resolution of a dispute, the Contractor must proceed diligently with contract performance. Subject to subsequent revocation or alteration by the Director, Office of Procurement, the head of the County department, office or agency ("Department Head") of the contract administrator is the designee of the Director, Office of Procurement, for the purpose of dispute resolution. The Department Head, or his/her designee, must forward to the Director, Office of Procurement, a copy of any written resolution of a dispute. The Department Head may delegate this responsibility to another person (other than the contract administrator). A contractor must notify the contract administrator of a claim in writing, and must attempt to resolve a claim with the contract administrator prior to filing a dispute with the Director, Office of Procurement or designee. The contractor waives any dispute or claim not made in writing and received by the Director, Office of Procurement, within 30 days of the event giving rise to the dispute or claim, whether or not the contract administrator has responded to a written notice of claim or resolved the claim. The Director, Office of Procurement, must dismiss a dispute that is not timely filed. A dispute must be in writing, for specific relief, and any requested relief must be fully supported by affidavit of all relevant calculations, including cost and pricing information, records, and other information. At the County's option, the contractor agrees to mediate any related dispute involving another contractor.

9. DOCUMENTS, MATERIALS, AND DATA
All documents materials or data developed as a result of this contract are the County's property. The County has the right to use and reproduce any documents, materials, and data, including confidential information, used in the performance of, or developed as a result of, this contract. The County may use this information for its own purposes, including reporting to state and federal agencies. The contractor warrants that it has title to or right of use of all documents, materials or data used or developed in connection with this contract. The contractor must keep confidential all documents, materials, and data prepared or developed by the contractor or supplied by the County.

10. DURATION OF OBLIGATION
The contractor agrees that all of contractor's obligations and warranties, including all requirements imposed by the Minority Owned Business Addendum to those General Conditions, if any, which directly or indirectly are intended by their nature or by implication to survive contractor performance, do survive the completion of performance, termination for default, termination for convenience, or termination by mutual consent of the contract.

11. ENTIRE AGREEMENT
There are no promises, terms, conditions, or obligations other than those contained in this contract. This contract supersedes all communications, representations, or agreements, either verbal or written, between the parties hereto, with the exception of express warranties given to induce the County to enter into the contract.

12. ETHICS REQUIREMENTS/PolITICAL CONTRIBUTIONS
The contractor must comply with the ethics provisions contained in Chapters 11B and 19A, Montgomery County Code, which include the following:
(a) a prohibition against making or offering to make certain gifts. Section 11B-51(a).
(b) a prohibition against kickbacks. Section 11B-51(b).
(c) a prohibition against a person engaged in a procurement from employing or offering to employ a public employee. Section 11B-52 (a).
(d) a prohibition against a contractor that is providing a recommendation to the County from assisting another party or seeking to obtain an economic benefit beyond payment under the contract. Section 11B-52 (b).
(e) a restriction on the use of confidential information obtained in performing a contract. Section 11B-52 (c).
(f) a prohibition against contingent fees. Section 11B-53.
Furthermore, the contractor specifically agrees to comply with Sections 11B-51, 11B-52, 11B-53, 19A-12, and/or 19A-13 of the Montgomery County Code. In addition, the contractor must comply with the political contribution reporting requirements currently codified under the Election Law at Md. Code Ann., Title 14.

13. GUARANTEE
A. Contractor guarantees for one year from acceptance, or for a longer period that is otherwise expressly stated in the County's written solicitation, all goods, services, and construction offered, including those used in the course of providing the goods, services, and/or construction. This includes a guarantee that all products offered (or used in the installation of those products) carry a guarantee against any and all defects for a minimum period of one year from acceptance, or for a longer period stated in the County's written solicitation. The contractor must correct any and all defects in material and/or workmanship that may appear during the guarantee period, or any defects that occur within one (1) year of acceptance even if discovered more than one (1) year after acceptance, by repairing, (or replacing with new items or new materials, if necessary) any such defect at no cost to the County and to the County's satisfaction.
B. Should a manufacturer's or service provider's warranty or guarantee exceed the requirements stated above, that guarantee or warranty will be the primary one used in the case of defect. Copies of manufacturer's or service provider's warranties must be provided upon request.
ATTACHMENT A

(Revised with Solicitation Amendment #2)

C. All warranties and guarantees must be in effect from the date of acceptance by the County of the goods, services, or construction.

D. The contractor guarantees that all work shall be accomplished in a workmanlike manner, and the contractor must observe and comply with all Federal, State, County and local laws, ordinances and regulations in providing the goods, and performing the services or construction.

E. Goods and materials provided under this contract must be of first quality, latest model and of current manufacture, and must not be of such age or so deteriorated as to impair their usefulness or safety. Items that are used, rebuilt, or demonstrator models are unacceptable, unless specifically requested by the County in the Specifications.

14. HAZARDOUS AND TOXIC SUBSTANCES
Manufacturers and distributors are required by federal "Hazard Communication" provisions (29 CFR 1910.1200), and the Maryland "Access to Information About Hazardous and Toxic Substances" Law, to label each hazardous material or chemical container, and to provide Material Safety Data Sheets to the purchaser. The contractor must comply with these laws and must provide the County with copies of all relevant documents, including Material Safety Data Sheets, prior to performance of work or contemporaneous with delivery of goods.

15. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) COMPLIANCE
In addition to the provisions stated above in Section 3. "Applicable Laws," contractor must comply with all requirements in the federal Health Insurance Portability and Accountability Act (HIPAA), to the extent that HIPAA is applicable to this contract. Furthermore, contractor must enter into the County's standard Business Associate Agreement or Qualified Service Organization Agreement when contractor or the County, as part of this contract, may use or disclose to one another, to the individual whose health information is at issue, or to a third-party, any protected health information that is obtained from, provided to, made available to, or created by, or for, the contractor or the County.

16. IMMIGRATION REFORM AND CONTROL ACT
The contractor warrants that both the contractor and its subcontractors do not, and shall not, hire, recruit or refer for a fee, for employment under this contract or any subcontract, an alien while knowing the alien is an unauthorized alien, or any individual without complying with the requirements of the federal Immigration and Nationality laws, including any verification and record keeping requirements. The contractor further assures the County that, in accordance with those laws, it does not, and will not, discriminate against an individual with respect to hiring, recruitment, or referral for a fee, of an individual for employment or the discharge of an individual from employment, because of the individual's national origin or, in the case of a citizen or prospective citizen, because of the individual's citizenship status.

17. INCONSISTENT PROVISIONS
Notwithstanding any provisions to the contrary in any contract terms or conditions supplied by the contractor, this General Conditions of Contract document supersedes the contractor's terms and conditions, in the event of any inconsistency.

18. INDEMNIFICATION
The contractor is responsible for any loss, personal injury, death and any other damage (including incidental and consequential) that may be done or suffered by reason of the contractor's negligence or failure to perform any contractual obligations. The contractor must indemnify and save the County harmless from any loss, cost, damage and other expenses, including attorney's fees and litigation expenses, suffered or incurred due to the contractor's negligence or failure to perform any of its contractual obligations. If requested by the County, the contractor must defend the County in any action or suit brought against the County arising out of the contractor's negligence, errors, acts or omissions under this contract. The negligence of any agent, subcontractor or employee of the contractor is deemed to be the negligence of the contractor. For the purposes of this paragraph, County includes its boards, agencies, agents, officials and employees.

19. INDEPENDENT CONTRACTOR
The contractor is an independent contractor. The contractor and the contractor's employees or agents are not agents of the County.

20. INSPECTIONS
The County has the right to monitor, inspect and evaluate or test all supplies, goods, services, or construction called for by the contract at all reasonable places (including the contractor's place of business) and times (including the period of preparation or manufacture).

21. INSURANCE
Prior to contract execution by the County, the proposed awardee/contractor must obtain at its own cost and expense the minimum insurance specified in the applicable table (See Tables A and B) or attachment to these General Conditions, with one or more insurance company(s) licensed or qualified to do business in the State of Maryland and acceptable to the County's Division of Risk Management. The minimum limits of coverage listed shall not be construed as the maximum as required by contract or as a limitation of any potential liability on the part of the proposed awardee/contractor to the County, nor shall failure by the County to request evidence of this insurance in any way be construed as a waiver of proposed awardee/contractor's obligation to provide the insurance coverage specified. Contractor must keep this insurance in full force and effect during the term of this contract, including all extensions. Unless expressly provided otherwise, Table A is applicable to this contract. The insurance must be evidenced by one or more Certificate(s) of Insurance and, if requested by the County, the proposed awardee/contractor must provide a copy of any and all insurance policies to the County. At a minimum, the proposed awardee/contractor must submit to the Director, Office of Procurement, one or more Certificate(s) of Insurance prior to award of this contract, and prior to any contract modification extending the term of the contract, as evidence of compliance with this provision. The contractor's insurance must be primary. Montgomery County, MD, including its officials, employees, agents, boards, and agencies, must be named as an additional insured on all liability policies. Contractor must provide to the County at least 30 days written notice of a cancellation of, or a material change to, an insurance policy. In no event may the insurance coverage be less than that shown on the applicable table, attachment, or contract provision for required insurance. After consultation with the Department of Finance, Division of Risk Management, the Director, Office of Procurement, may waive the requirements of this section, in whole or in part.

Please disregard TABLE A. and TABLE B., if they are replaced by the insurance requirements as stated in an attachment to these General Conditions of Contract between County and Contractor.

TABLE A. INSURANCE REQUIREMENTS
(See Paragraph #21 under the General Conditions of Contract between County and Contractor)

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ATTACHMENT A

(Revised with Solicitation Amendment #2)

CONTACT DOLLAR VALUES (IN $1,000's)

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<td>each occurrence</td>
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<td>Rockville, Maryland 20850 4166</td>
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*Professional services contracts only

(Remainder of Page Intentionally Left Blank)
ATTACHMENT A

(Revised with Solicitation Amendment #2)

TABLE B. INSURANCE REQUIREMENTS
(See Paragraph #21 under the General Conditions of Contract between County and Contractor)

<table>
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<tbody>
<tr>
<td>Commercial General Liability minimum combined single limit for bodily injury and property damage per occurrence, including contractual liability, premises and operations, independent contractors, and product liability</td>
<td>300</td>
<td>500</td>
<td>1,000</td>
<td>See Attachment</td>
</tr>
</tbody>
</table>

Certificate Holder
Montgomery County Maryland (Contract #)
Office of Procurement
255 Rockville Pike, Suite 180
Rockville, Maryland 20850 4166

(Remainder of Page Intentionally Left Blank)
ATTACHMENT A

22. INTELLECTUAL PROPERTY APPROVAL AND INDEMNIFICATION - INFRINGEMENT

If contractor will be preparing, displaying, publicly performing, reproducing, or otherwise using, in any manner or form, any information, document, or material that is subject to a copyright, trademark, patent, or other property or privacy right, then contractor must: obtain all necessary licenses, authorizations, and approvals related to its use; include the County in any approval, authorization, or license related to its use; and indemnify and hold harmless the County related to contractor’s alleged infringing or otherwise improper or unauthorized use. Accordingly, the contractor must protect, indemnify, and hold harmless the County from and against all liabilities, actions, damages, claims, demands, judgments, losses, costs, expenses, suits, or actions, and attorneys’ fees and the costs of the defense of the County, in any suit, including appeals, based upon or arising out of any allegation of infringement, violation, unauthorized use, or conversion of any patent, copyright, trademark or trade name, license, proprietary right, or other related property or privacy interest in connection with, or as a result of, this contract or the performance by the contractor of any of its activities or obligations under this contract.

23. INFORMATION SECURITY

A. Protection of Personal Information by Government Agencies:
In any contract under which Contractor is to perform services and the County may disclose to Contractor personal information about an individual, as defined by State law, Contractor must implement and maintain reasonable security procedures and practices that: (a) are appropriate to the nature of the personal information disclosed to the Contractor; and (b) are reasonably designed to help protect the personal information from unauthorized access, use, modification, disclosure, or destruction. Contractor’s requirement to implement and maintain reasonable security practices and procedures must include requiring any third-party to whom it discloses personal information that was originally disclosed to Contractor by the County to also implement and maintain reasonable security practices and procedures related to protecting the personal information. Contractor must notify the County of a breach of the security of a system if the unauthorized acquisition of an individual’s personal information has occurred or is reasonably likely to occur, and also must share with the County all information related to the breach. Contractor must provide the above notification to the County as soon as reasonably practicable after Contractor discovers or is notified of the breach of the security of a system. Md. Code Ann., State Gov’t § 10-1301 through 10-1308 (2013).

B. Payment Card Industry Compliance:
In any contract where the Contractor provides a system or service that involves processing credit card payments (a “Payment Solution”), the Payment Solution must be Payment Card Industry Data Security Standard Compliant (“PCI-DSS Compliant”), as determined and verified by the Department of Finance, and must (1) process credit card payments through the use of a Merchant ID (“MID”) obtained by the County’s Department of Finance by and in the name of the County as merchant of record, or (2) use a MID obtained by and in the name of the Contractor as merchant of record.

24. NON-CONVICTION OF BRIBERY

The contractor hereby declares and affirms that, to its best knowledge, none of its officers, directors, or partners or employees directly involved in obtaining contracts has been convicted of bribery, attempted bribery, or conspiracy to bribe under any federal, state, or local law.

25. NON-DISCRIMINATION IN EMPLOYMENT

The contractor agrees to comply with the non-discrimination in employment policies and/or provisions prohibiting unlawful employment practices in County contracts as required by Section 11B 33 and Section 27 19 of the Montgomery County Code, as well as all other applicable state and federal laws and regulations regarding employment discrimination.

The contractor assures the County that, in accordance with applicable law, it does not, and agrees that it will not, discriminate in any manner on the basis of race, color, religious creed, ancestry, national origin, age, sex, marital status, disability, or sexual orientation.

The contractor must bind its subcontractors to the provisions of this section.

26. PAYMENT AUTHORITY

No payment by the County may be made, or is due, under this contract, unless funds for the payment have been appropriated and encumbered by the County. Under no circumstances will the County pay the contractor for legal fees. The contractor must not proceed to perform any work (provide goods, services, or construction) prior to receiving written confirmation that the County has appropriated and encumbered funds for that work. If the contractor fails to obtain this verification from the Office of Procurement prior to performing work, the County has no obligation to pay the contractor for the work.

If this contract provides for an additional contract term for contractor performance beyond its initial term, continuation of contractor’s performance under this contract beyond the initial term is contingent upon, and subject to, the appropriation of funds and encumbrance of those appropriated funds for payments under this contract. If funds are not appropriated and encumbered to support continued contractor performance in a subsequent fiscal period, contractor’s performance must end without further notice from, or cost to, the County. The contractor acknowledges that the County Executive has no obligation to recommend, and the County Council has no obligation to appropriate, funds for this contract in subsequent fiscal years. Furthermore, the County has no obligation to encumber funds to this contract in subsequent fiscal years, even if appropriated funds may be available. Accordingly, for each subsequent contract term, the contractor must not undertake any performance under this contract until the contractor receives a purchase order or contract amendment from the County that authorizes the contractor to perform work for the next contract term.

27. P-CARD OR SUA PAYMENT METHODS

The County is expressly permitted to pay the vendor for any or all goods, services, or construction under the contract through either a procurement card ("p-card") or a Single Use Account("SUA") method of payment, if the contractor accepts the noted payment method from any other person. In that event, the County reserves the right to pay any or all amounts due under the contract by using either a p-card (except when a purchase order is required) or a SUA method of payment, and the contractor must accept the County’s p-card or a SUA method of payment, as applicable. Under this paragraph, contractor is prohibited from charging or requiring the County to pay any fee, charge, price, or other obligation for any reason related to or associated with the County’s use of either a p-card or a SUA method of payment.

28. PERSONAL PROPERTY

All furniture, office equipment, equipment, vehicles, and other similar types of personal property specified in the contract, and purchased with funds provided under the contract, become the property of the County upon the end of the contract term, or upon termination or expiration of this contract, unless expressly stated otherwise.

29. TERMINATION FOR DEFAULT

The Director, Office of Procurement, may terminate the contract in whole or in part, and from time to time, whenever the Director, Office of Procurement, determines that the contractor is:
(a) defaulting in performance or is not complying with any provision of this contract;
(b) failing to make satisfactory progress in the prosecution of the contract; or
(c) endangering the performance of this contract.
The Director, Office of Procurement, will provide the contractor with a written notice to cure the default. The termination for default is effective on the date specified in the County’s written notice. However, if the County determines that default contributes to the curtailment of an essential service or poses an immediate threat to life, health, or property, the County may terminate the contract immediately upon issuing oral or written notice to the contractor without any prior notice or opportunity to cure. In addition to any other remedies provided by law or the contract, the contractor must compensate the County for additional costs that foreseeably would be incurred by the County, whether the costs are actually incurred or not, to obtain substitute performance. A termination for default is a termination for convenience if the termination for default is later found to be without justification.

30. TERMINATION FOR CONVENIENCE
This contract may be terminated by the County, in whole or in part, upon written notice to the contractor, when the County determines this to be in its best interest. The termination for convenience is effective on the date specified in the County’s written notice. Termination for convenience may entitle the contractor to payment for reasonable costs allocable to the contract for work or costs incurred by the contractor up to the date of termination. The contractor must not be paid compensation as a result of a termination for convenience that exceeds the amount encumbered to pay for work to be performed under the contract.

31. TIME
Time is of the essence.

32. WORK UNDER THE CONTRACT
Contractor must not commence work under this contract until all conditions for commencement are met, including execution of the contract by both parties, compliance with insurance requirements, encumbrance of funds, and issuance of any required notice to proceed.

33. WORKPLACE SAFETY
The contractor must ensure adequate health and safety training and/or certification, and must comply with applicable federal, state and local Occupational Safety and Health laws and regulations.

THIS FORM MUST NOT BE MODIFIED WITHOUT THE PRIOR APPROVAL OF THE OFFICE OF THE COUNTY ATTORNEY.
BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the "Agreement") is made by and between Montgomery County, Maryland (hereinafter referred to as “Covered Entity”), and (hereinafter referred to as “Business Associate”). Covered Entity and Business Associate shall collectively be known herein as the “Parties.”

I. GENERAL

A. Covered Entity has a business relationship with Business Associate that is memorialized in Montgomery County Contract # _____ (the “Underlying Agreement”), pursuant to which Business Associate may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996, including all pertinent regulations (45 CFR Parts 160 and 164), issued by the U.S. Department of Health and Human Services, including Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), as codified in Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), and including any and all applicable Privacy, Security, Enforcement, or Notice (Breach Notification) Rules or requirements (collectively, “HIPAA”), as all are amended from time to time; and

B. The performance of the Underlying Agreement may involve the creation, exchange, or maintenance of Protected Health Information (“PHI”) as that term is defined under HIPAA; and

C. For good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this Agreement for the purpose of ensuring compliance with the requirements of HIPAA; and

D. This Agreement articulates the obligations of the Parties as to use and disclosure of PHI. It does not affect Business Associate’s obligations to comply with the the Maryland Confidentiality of Medical Records Act (Md. Code Ann., Health-General 1 §§4-301 et seq.) (“MCMRA”) or other applicable law with respect to any information the County may disclose to Business Associate as part of Business Associate’s performance of the Underlying Agreement; and

E. This Agreement supersedes and replaces any and all Business Associate Agreements the Covered Entity and Business Associate may have entered into prior to the date hereof; and

F. The above premises having been considered and incorporated by reference into the sections below, the Parties, intending to be legally bound, agree as follows:

II. DEFINITIONS.

A. The terms used in this Agreement have the same meaning as the definitions of those terms in HIPAA. In the absence of a definition in HIPAA, the terms have their commonly understood meaning.
B. Consistent with HIPAA, and for ease of reference, the Parties expressly note the definitions of the following terms:

1. “Breach” is defined at 45 CFR § 164.402.

2. “Business Associate” is defined at 45 CFR § 160.103, and in reference to the party to this Agreement, shall mean ____________________________.

3. “Covered Entity” is defined at 45 CFR § 160.103, and in reference to the party to this Agreement, shall mean the County.

4. “Designated Record Set” is defined at 45 CFR §164.501.

5. “Individual” is defined at 45 CFR §§ 160.103, 164.501 and 164.502(g), and includes a person who qualifies as a personal representative.

6. “Protected Health Information” or “PHI” is defined at 45 CFR § 160.103.

7. “Required By Law” is defined at 45 CFR § 164.103.

8. “Secretary” means the Secretary of the U.S. Department of Health and Human Services or designee.

9. “Security Incident” is defined at 45 CFR § 164.304.

10. “Unsecured Protected Health Information” or “Unsecured PHI” means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology, as specified by the Secretary in the guidance as noted under the HITECH Act, section 13402(h)(1) and (2) of Public Law 111-5, codified at 42 U.S.C. § 17932(h)(1) and (2), and as specified by the Secretary in 45 CFR 164.402.

III. PERMISSIBLE USE AND DISCLOSURE OF PHI

A. Except as otherwise limited in this Agreement, or by privilege, protection, or confidentiality under HIPAA, MCMRA, or other applicable law, Business Associate may use or disclose (including permitting acquisition or access to) PHI to perform applicable functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement. Moreover, the provisions of HIPAA are expressly incorporated by reference into, and made a part of, this Agreement.

B. Business Associate may use or disclose (including permitting acquisition or access to) PHI only as permitted or required by this Agreement or as Required By Law.

C. Business Associate is directly responsible for full compliance with the relevant requirements of HIPAA.
D. Business Associate must not use or disclose (including permitting acquisition or access to) PHI other than as permitted or required by this Agreement or HIPAA, and must use or disclose PHI only in a manner consistent with HIPAA. As part of this, Business Associate must use appropriate safeguards to prevent use or disclosure of PHI that is not permitted by this Agreement or HIPAA. Furthermore, Business Associate must take reasonable precautions to protect PHI from loss, misuse, and unauthorized access, disclosure, alteration, and destruction.

E. Business Associate must implement and comply with administrative, physical, and technical safeguards governing the PHI, in a manner consistent with HIPAA, that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity.

F. Business Associate must immediately notify Covered Entity, in a manner consistent with HIPAA, of: (i) any use or disclosure of PHI not provided for by this Agreement, including a Breach of PHI of which it knows or by exercise of reasonable diligence would have known, as required at 45 CFR §164.410; and, (ii) any Security Incident of which it becomes aware as required at 45 CFR §164.314(a)(2)(i)(C). Business Associate’s notification to Covered Entity required by HIPAA and this Section III.F must:

1. Be made to Covered Entity without unreasonable delay and in no case later than 14 calendar days after Business Associate: a) knows, or by exercising reasonable diligence would have known, of a Breach, b) becomes aware of a Security Incident, or c) becomes aware of any use or disclosure of PHI not provided for by this Agreement;

2. Include the names and addresses of the Individual(s) whose PHI is the subject of a Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement. In addition, Business Associate must provide any additional information reasonably requested by Covered Entity for purposes of investigating the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement;

3. Be in substantially the same form as Exhibit A hereto;

4. Include a brief description of what happened, including the date of the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement, if known, and the date of the discovery of the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement;

5. Include a description of the type(s) of Unsecured PHI that was involved in the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement (such as full name, Social Security number, date of birth, home address, account number, disability code, or other types of information that were involved);

6. Identify the nature and extent of the PHI involved, including the type(s) of identifiers and the likelihood of reidentification;
7. If known, identify the unauthorized person who used or accessed the PHI or to whom the disclosure was made;

8. Articulate any steps the affected Individual(s) should take to protect him or herself from potential harm resulting from the Breach, Security Incident, or use or disclosure of PHI not permitted by this Agreement;

9. State whether the PHI was actually acquired or viewed;

10. Provide a brief description of what the Covered Entity and the Business Associate are doing to investigate the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement, to mitigate losses, and to protect against any further Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement;

11. Note contact information and procedures for an Individual(s) to ask questions or learn additional information, which must include a toll-free telephone number of Business Associate, along with an e-mail address, Web site, or postal address; and

12. Include a draft letter for the Covered Entity to utilize, in the event Covered Entity elects, in its sole discretion, to notify the Individual(s) that his or her PHI is the subject of a Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement that includes the information noted in Section III.F.4 – III.F.11 above.

G. Business Associate must, and is expected to, directly and independently fulfill all notification requirements under HIPAA.

H. In the event of a Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement, Business Associate must mitigate, to the extent practicable, any harmful effects of said disclosure that are known to it.

I. In accordance with 45 CFR §§ 164.502(e)(1)(ii) and 164.308(b)(2), Business Associate agrees to ensure that any agent, subcontractor, or employee to whom it provides PHI (received from, or created or received by, Business Associate on behalf of Covered Entity) agrees to the same restrictions, conditions, and requirements that apply through this Agreement to Business Associate with respect to such information.

J. Business Associate must ensure that any contract or other arrangement with a subcontractor meets the requirements of paragraphs 45 CFR §164.314(a)(2)(i) and (a)(2)(ii) required by 45 CFR § 164.308(b)(3) between a Business Associate and a subcontractor, in the same manner as such requirements apply to contracts or other arrangements between a Covered Entity and Business Associate.

K. Pursuant to 45 CFR § 164.502(a)(4)(ii), Business Associate must disclose PHI to the Covered Entity, Individual, or Individual's designee, as necessary to satisfy a Covered
Entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of PHI.

L. To the extent applicable, Business Associate must provide access to PHI in a Designated Record Set at reasonable times, at the request of Covered Entity or as directed by Covered Entity, to an Individual specified by Covered Entity in order to meet the requirements under 45 CFR § 164.524.

M. A Business Associate that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of health plan, must not use or disclose PHI that is genetic information for underwriting purposes, in accordance with the provisions of 45 CFR 164.502.

N. To the extent applicable, Business Associate must make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to, pursuant to 45 CFR § 164.526, at the request of Covered Entity or an Individual.

O. Business Associate must, upon request with reasonable notice, provide Covered Entity access to its premises for a review and demonstration of its internal practices and procedures for safeguarding PHI.

P. Business Associate must, upon request and with reasonable notice, furnish to Covered Entity security and privacy audit results, risk analyses, security and privacy policies and procedures, details of previous Breaches and Security Incidents, and documentation of controls.

Q. Business Associate must also maintain records indicating who has accessed PHI about an Individual in an electronic designated record set and information related to such access, in accordance with 45 C.F.R. § 164.528. Business Associate must document such disclosures of PHI and information related to such disclosures as would be required for a Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. Should an Individual make a request to Covered Entity for an accounting of disclosures of his or her PHI pursuant to 45 C.F.R. § 164.528, Business Associate must promptly provide Covered Entity with information in a format and manner sufficient to respond to the Individual's request.

R. Business Associate must, upon request and with reasonable notice, provide Covered Entity with an accounting of uses and disclosures of PHI that was provided to it by Covered Entity.

S. Business Associate must make its internal practices, books, records, and any other material requested by the Secretary relating to the use, disclosure, and safeguarding of PHI received from Covered Entity available to the Secretary for the purpose of determining compliance with HIPAA. Business Associate must make the aforementioned information available to the Secretary in the manner and place as designated by the Secretary or the Secretary's duly appointed delegate. Under this Agreement, Business Associate must comply and cooperate with any request for documents or other information from the Secretary directed to

June 3, 2015
Covered Entity that seeks documents or other information held or controlled by Business Associate.

T. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 42 C.F.R. § 164.502(j)(1).

U. Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of Business Associate or the Underlying Agreement, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and be used or further disclosed only as Required By Law or for the limited purpose for which it was disclosed to the person, and the person must agree to notify Business Associate of any instance of any Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement of which it is aware in which the confidentiality of the information has been breached.

V. Business Associate understands that, pursuant to 45 CFR § 160.402, the Business Associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation of the HIPAA rules based on the act or omission of any agent of the Business Associate, including a workforce member or subcontractor, acting within the scope of the agency.

IV. TERM AND TERMINATION.

A. Term. The Term of this Agreement shall be effective as of the effective date of the Underlying Agreement, and shall terminate: (1) when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity; or, (2) if it is infeasible to return or destroy PHI, in accordance with the termination provisions in this Article IV.

B. Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall:

1. Provide an opportunity for Business Associate to cure the breach or end the violation and, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, have the right to terminate this Agreement and to terminate the Underlying Agreement, and shall report the violation to the Secretary;

2. Have the right to immediately terminate this Agreement and the Underlying Agreement if Business Associate has breached a material term of this Agreement and cure is not possible, and shall report the violation to the Secretary; or

3. If neither termination nor cure is feasible, report the violation to the Secretary.

June 3, 2015
4. This Article IV, Term and Termination, Paragraph B, is in addition to the provisions set forth in Paragraph 27, Termination for Default of the General Conditions of Contract Between County and Contractor, attached to the Underlying Agreement, in which “Business Associate” is “Contractor” and “Covered Entity” is “County” for purposes of this Agreement.

C. Effect of Termination.

1. Except as provided in Section IV.C.2, upon termination or cancellation of this Agreement, for any reason, Business Associate must return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision applies to PHI that is in the possession of a subcontractor(s), employee(s), or agent(s) of Business Associate. Business Associate must not retain any copies of the PHI.

2. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate must provide to Covered Entity written notification of the nature of the PHI and the conditions that make return or destruction infeasible. After written notification that return or destruction of PHI is infeasible, Business Associate must extend the protections of this Agreement to such PHI and limit further use(s) and disclosure(s) of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI. Notwithstanding the foregoing, to the extent that it is not feasible to return or destroy such PHI, the terms and provisions of this Agreement survive termination of this Agreement with regard to such PHI.

3. Should Business Associate violate this Agreement, HIPAA, the Underlying Agreement, the MCMRA, or other applicable law, Covered Entity has the right to immediately terminate any contract then in force between the Parties, including the Underlying Agreement.

V. CONSIDERATION. Business Associate recognizes that the promises it has made in this Agreement shall, henceforth, be reasonably, justifiably, and detrimentally relied upon by Covered Entity in choosing to continue or commence a business relationship with Business Associate.

VI. CAUSES OF ACTION IN THE EVENT OF BREACH. As used in this paragraph, the term “breach” has the meaning normally ascribed to that term under the Maryland law related to contracts, as opposed to the specific definition under HIPAA related to PHI. Business Associate hereby recognizes that irreparable harm will result to Covered Entity in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of breach of any of the covenants and assurances contained in this Agreement, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of this Agreement. Furthermore, in the event of breach of this Agreement by Business Associate, Covered Entity is entitled to reimbursement and indemnification from Business Associate for Covered Entity’s reasonable attorneys’ fees and expenses and costs that were reasonably incurred as a proximate result of Business Associate's breach. The causes of action
contained in this Article VI are in addition to (and do not supersede) any action for damages and/or any other cause of action Covered Entity may have for breach of any part of this Agreement. Furthermore, these provisions are in addition to the provisions set forth in Paragraph 18, "Indemnification", of the General Conditions of Contract Between County and Contractor, attached to the Underlying Agreement in which "Business Associate" is "Contractor" and "Covered Entity" is "County", for purposes of this Agreement.

VII. MODIFICATION; AMENDMENT. This Agreement may be modified or amended only through a writing signed by the Parties and, thus, no oral modification or amendment hereof shall be permitted. The Parties agree to take such action as is necessary to amend this Agreement, from time to time, as is necessary for Covered Entity to comply with the requirements of HIPAA, including its Privacy, Security, and Notice Rules.

VIII. INTERPRETATION OF THIS AGREEMENT IN RELATION TO OTHER AGREEMENTS BETWEEN THE PARTIES. Should there be any conflict between the language of this Agreement and any other contract entered into between the Parties (either previous or subsequent to the date of this Agreement), the language and provisions of this Agreement, along with the Underlying Agreement, shall control and prevail unless the Parties specifically refer in a subsequent written agreement to this Agreement, by its title, date, and substance and specifically state that the provisions of the later written agreement shall control over this Agreement and Underlying Agreement. In any event, any agreement between the Parties, including this Agreement and Underlying Agreement, must be in full compliance with HIPAA, and any provision in an agreement that fails to comply with HIPAA will be deemed separable from the document, unenforceable, and of no effect.

IX. COMPLIANCE WITH STATE LAW. The Business Associate acknowledges that by accepting the PHI from Covered Entity, it becomes a holder of medical records information under the MCMRA and is subject to the provisions of that law. If HIPAA conflicts with another applicable law regarding the degree of protection provided for Protected Health Information, Business Associate must comply with the more restrictive protection requirement.

X. MISCELLANEOUS.

A. Ambiguity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with HIPAA.

B. Regulatory References. A reference in this Agreement to a section in HIPAA means the section in effect, or as amended.

C. Notice to Covered Entity. Any notice required under this Agreement to be given to Covered Entity shall be made in writing to:

Joy Page, Esq.
Deputy Privacy Official
Montgomery County, Maryland
401 Hungerford Drive, 7th Floor
Rockville, Maryland 20850

June 3, 2015
(240) 777-3247 (Voice)
(240) 777- 3099 (Fax)

Notice to Business Associate. Any notice required under this Agreement to be given Business Associate shall be made in writing to:

Address: __________________________

_______________________________

Attention: ________________________

Phone: ____________________________

D. Maryland Law. This Agreement is governed by, and shall be construed in accordance with, applicable federal law and the laws of the State of Maryland, without regard to choice of law principles.

E. Incorporation of Future Amendments. Other requirements applicable to Business Associates under HIPAA are incorporated by reference into this Agreement.

F. Penalties for HIPAA Violation. In addition to that stated in this Agreement, Business Associate may be subject to civil and criminal penalties noted under HIPAA, including the same HIPAA civil and criminal penalties applicable to a Covered Entity.

SIGNATURE PAGE FOLLOWS
IN WITNESS WHEREOF and acknowledging acceptance and agreement of the foregoing, the Parties affix their signatures hereto.

CONTRACTOR NAME

By: ____________________________
Name: __________________________
Title: ___________________________
Date: ___________________________

MONTGOMERY COUNTY, MARYLAND

By: ____________________________
Name: Victoria Buckland
Title: Acting Director, Department of Health and Human Services
Date: ___________________________
EXHIBIT A

FORM OF NOTIFICATION

This notification is made pursuant to Section III.F of the Business Associate Agreement between:

- Montgomery County, Maryland, (the “County”) and
- ________________________________ (Business Associate).

Business Associate hereby notifies the County that there has been a Breach, Security Incident, or use or disclosure of PHI not provided for by the Business Associate Agreement (an “Incident”) that Business Associate has used or has had access to under the terms of the Business Associate Agreement.

Description of the Incident:

________________________________________________________________________

________________________________________________________________________

________________________________________
Date of the Incident:

________________________________________
Date of discovery of the Incident:

Does the Incident involve 500 or more individuals? Yes/No

If yes, do the people live in multiple states? Yes/No

Number of individuals affected by the Incident:

________________________________________________________________________

Names and addresses of individuals affected by the Incident:

(Attach additional pages as necessary)

________________________________________________________________________
The types of unsecured PHI that were involved in the Incident (such as full name, Social Security number, date of birth, home address, account number, or disability code):

________________________________________________________________________

Description of what Business Associate is doing to investigate the Incident, to mitigate losses, and to protect against any further Incidents:

________________________________________________________________________

________________________________________________________________________

June 3, 2015
Contact information to ask questions or learn additional information:

Name: 

Title: 

Address: 

Email Address: 

Phone Number: 
ATTACHMENT C

VENDOR INFORMATION FORM

Please fill in the attached Application Form completely,

Legal Name of Firm:

Primary Contact Name:

Address:

City & State: Zip Code:

Telephone #: Fax #:

Email:

Billing Contact Name:

Address:

City & State: Zip Code:

Telephone #: Fax #:

Email:

Taxpayer Identification # (TIN):

Please check off one of the following: For-Profit Non-Profit Organization, e.g., 501c (3) or 501c (5) and write in which type of Non-Profit

________________________________________

Signature of Person Completing this Form

__________________________

Date

Title

Please provide the date that you will be available to start providing services.

________________________________________

I have received a copy of Open Solicitation # 1048537, reviewed and agree to accept the County's rates as indicated in this Open Solicitation and its requirements including insurance, and agree to the WCCP requirements. I have received a copy of the County's General Conditions and accept the County's terms and conditions. If my insurance underwriter will not agree to provide 45 days written notice of cancellation or change for the liability coverage, I (each insured party) will provide the County with 45 days written notice of cancellation or change of the liability insurance.

________________________________________

Applicant's Signature

Date
February 25, 2014

Dear Maryland Breast and Cervical Cancer Program Provider:

Thank you for providing breast cancer screening for uninsured or underinsured women aged 40-64 enrolled in the Maryland Breast and Cervical Cancer Program (BCCP). The Maryland BCCP is a grantee of the National Breast and Cervical Cancer Early Detection Program, funded by the Centers for Disease Control and Prevention (CDC). The policies of the national program are based on evidence in scientific literature and recommendations from national organizations such as the American Cancer Society, the United States Preventive Task Force, the National Comprehensive Cancer Network and the American College of Radiology.

We are pleased to enclose the revised “Minimal Clinical Elements for Breast Cancer Detection and Diagnosis” developed by the Medical Advisory Committee for the BCCP to serve as guidelines for the screening and management of women receiving breast cancer screening through the BCCP and diagnostic services through the BCCP Expanded.

The changes include:

- Clarification of mammogram type for women with a history of breast cancer.
- Guidelines for reimbursement for immunohistochemistry (IHC) for benign breast biopsy and reimbursement rate.
- Revisions to follow-up options after any CBE result with a mammogram result = BI-RADS 4 and negative biopsy.
- Clarification of reimbursement for surgical consult or follow-up visits.
We appreciate your cooperation in using these new guidelines. If you have any questions regarding the new “Minimal Clinical Elements for Breast Cancer Detection and Diagnosis” for the Maryland Breast and Cervical Cancer Program, please contact Courtney Lewis, Director of the Center for Cancer Prevention and Control (CCPC) at (410) 767-0824 or Courtney.lewis@maryland.gov.

Sincerely,

Stanley Watkins, M.D.
Chairman, Medical Advisory Committee
Maryland Breast and Cervical Cancer Program

Enclosure

Cc  Courtney Lewis, M.P.H., Director, CCPC
    Dawn Henninger, R.N., M.S., Program Manager, BCCP
    Holly Harshbarger, R.N., B.S., Program Nurse Consultant, BCCP
    Local BCCP Coordinators
Minimal Clinical Elements for Breast Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
January 2014

Goal:
The goal of the Minimal Clinical Elements for Breast Cancer Detection and Diagnosis is to provide clients of the Maryland Breast and Cervical Cancer Program (BCCP) with optimal, up-to-date screening for breast cancer and management of findings.

Objective:
- To provide clinical guidelines for breast cancer screening and diagnostic testing including interpretation and management of results of clinical breast examination, mammography, and diagnostic testing.
- To outline appropriate management and approved indications for procedure payment.

Detection and Management of Breast Abnormalities in the Breast and Cervical Cancer Program—Breast Cancer Minimal Clinical Elements

Section | Page
---|---
I. Maryland Breast and Cervical Cancer Program (BCCP)—Eligibility for Screening, Procedures for Screening or Initial Testing, and Eligibility for Expanded Diagnostic Testing
   A. BCCP Eligibility and Procedures for Screening or Initial Testing | 3
   B. Eligibility for Diagnostic Testing in the BCCP Expanded Services | 4

II. Findings, Management of Results, Additional Procedures and Program Coverage
   A. Results and Reports | 5
   B. Management of Findings of CBE, Initial Mammogram, and Testing | 6
   C. Additional Procedures and Program Coverage | 6

Attachment A
Flow Charts of the Maryland Breast and Cervical Cancer Program: Management of Clinical Breast Examination and Mammogram Results

I. Management when the Clinical Breast Exam is Normal/Benign | 9
II. Management when the Clinical Breast Exam is Abnormal | 10
Members of the Breast Cancer Subcommittee of the BCCP Medical Advisory Committee:

Stanley Watkins, M.D., Chairman
Hematologist/Oncologist
Annapolis Medical Specialists
Assistant Professor of Oncology, The Johns Hopkins School of Medicine (part time)

Cecilia Brennecke, M.D.
Medical Director, Johns Hopkins Imaging
Diagnostic Radiology

Robert Brookland, M.D.
Radiation Oncology/Radiation Therapy
Greater Baltimore Medical Center

Regina Hampton, M.D. FACS
Medical Director, Center for Women’s Wellness
Doctor’s Community Hospital

Kathy J. Helzlsouer, M.D., M.H.S.
Director, The Prevention and Research Center
The Weinberg Center for Women’s Health and Medicine
Mercy Medical Center

Nagi Khouri, M.D.
Associate Professor of Radiology and Radiological Science
Associate Professor of Oncology
Johns Hopkins Medical Institutions

Lorraine Tafta, M.D.
Breast Surgery
Anne Arundel Medical Center

Staff for the Breast Cancer Subcommittee
Center for Cancer Prevention and Control, Maryland Dept. of Health and Mental Hygiene
Courtney Lewis, M.P.H., Director, CCPC
Diane Dwyer, M.D., Medical Director, CCPC
Dawn Henninger, R.N., M.S., Program Manager, BCCP
Holly Harshbarger, R.N., B.S. Program Nurse Consultant, BCCP
Detection and Management of Breast Abnormalities in the Breast and Cervical Cancer Program

Breast Cancer Minimal Clinical Elements (MCE)

I. Maryland Breast and Cervical Cancer Program (BCCP)—Eligibility for Screening, Procedures for Screening or Initial Testing, and Eligibility for Expanded Diagnostic Testing

A. BCCP Eligibility and Procedures for Screening or Initial Testing

1. A woman is eligible for breast cancer screening with clinical breast examination (CBE) and mammogram in the BCCP regardless of symptoms, risk factors, or prior breast cancer/findings if she:
   a. Is 40 – 64 years old or 65+ without Medicare Part B;
   b. Meets income eligibility of household income <250% of the Federal Poverty Guideline;
   c. Has no health insurance, has health insurance that does not cover breast cancer screening, or has coverage but has not met deductible for the year; and
   d. Has not had bilateral mastectomies.

2. A woman should have a diagnostic mammogram if a woman has:
   a. A CBE with results that include:
      i. Nipple discharge that is:
         (a) Bloody;
         (b) Crystal clear (like water); or
         (c) Any other color or clarity (for example, yellow, white, milky, gray, green) if the discharge is unilateral, single duct, and spontaneous.
      ii. Discrete palpable mass—suspicious for cancer;
      iii. Nipple/areolar scaliness; or
      iv. Skin dimpling/retraction;
   b. A recommendation for a diagnostic mammogram from the Medical Case Manager.

3. A woman should have a screening mammogram as the annual exam if the woman has:
   a. A CBE with Normal findings or a CBE with Benign findings, including:
      i. Nipple discharge that does not meet the requirement for diagnostic mammogram (2., a., i., above);
      ii. Breast implant(s);
      iii. Fibrocystic changes;
      iv. Mastitis;
      v. “Lumpy” breasts;
      vi. Family history of breast cancer (premenopausal breast cancer in sister/mother); or
vii. Prior benign biopsy (within past year) when surgeon or radiologist recommends screening mammogram.

b. A history of negative screening mammogram(s) (American College of Radiology, Breast Imaging and Database Reporting System [BI-RADS] category 1, negative, or BI-RADS 2, benign finding).

4. A woman with a prior history of breast cancer (in situ or invasive, in patient who has not had bilateral mastectomies) should have a:
   a. Diagnostic mammogram for 5 years post diagnosis then;
   b. May resume screening mammogram after 5 years at the discretion of the medical case manager, radiologist and client.

5. CBE should be performed 90 days prior to the screening mammogram.

   a. Each breast should be examined including the retroareolar and peripheral areas and the upper lateral quadrant into the axilla.

   b. The preferred method of CBE is the strip technique using three levels of pressure in small circular motions with pad of three middle fingers without lubrication (MammaCare® method).

B. Eligibility for Diagnostic Testing in the BCCP Expanded Services

A woman is eligible for breast cancer diagnostic testing in the BCCP Expanded Services if she:

1. Is 40 – 64 years old, or 65+ without Medicare Part B;

2. Meets income eligibility of <250% of the Federal Poverty Guideline;

3. Has no health insurance, has health insurance that does not cover breast cancer diagnostic testing/visits, or has coverage but has not met deductible for the year;

4. Has not had bilateral mastectomies; and

5. Provides the BCCP with a recommendation from a clinician for diagnostic workup and test results of:
   a. CBE requiring further diagnosis (see I. A. 2. a.);
   b. Mammogram requiring further diagnosis;
   c. Ultrasound abnormal finding other than simple cyst(s); or
   d. Persistent, unexplained, localized pain in the breast with a negative mammogram.
II. Findings, Management of Results, Additional Procedures, and Program Coverage

A. Results and Reports
   1. CBE findings:
      a. Should be reported as:
         i. Normal exam
         ii. Benign findings
         iii. Abnormal findings:
            1. Nipple discharge that is bloody, crystal clear (like water) or any other color or clarity (for example, yellow, white, milky, gray, green) if the discharge is unilateral, single duct, and spontaneous.
            2. Discrete palpable mass—suspicious for cancer
            3. Nipple/areolar scaliness
            4. Skin dimpling/retraction
      b. CBE should report whether there are breast implants; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.
      c. CBE should report whether the patient has had a lumpectomy or a mastectomy and which breast was affected; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.

   2. Mammogram findings should be reported using American College of Radiology BI-RADS® (Breast Imaging-Reporting and Database System) Assessment Categories:
      a. Assessment is Incomplete
         0 Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison
      b. Assessment is Complete – Final Categories
         1 Negative
         2 Benign Finding(s)
         3 Probably Benign Finding – Initial Short-Interval Follow-Up Suggested
         4 Suspicious Abnormality – Biopsy Should Be Considered
         5 Highly Suggestive of Malignancy – Appropriate Action Should Be Taken
         6 Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken
            (Category reserved for lesions identified on imaging study with biopsy proof of malignancy prior to definitive therapy)

      Ref. The American College of Radiology BI-RADS® ATLAS and MQSA: Frequently Asked Questions (Updated: 7/1/09)

   c. Breast composition on mammogram should be described for all patients using the following patterns:
      i. The breast is almost entirely fat (<25% glandular)
      ii. There are scattered fibroglandular densities (approximately 25-50% glandular)
      iii. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular)
iv. The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular).

Ref. 2003 ACR® BI-RADS Atlas

3. **Ultrasound definitions**: The terms “simple cyst,” “complicated cyst,” and “complex cyst” are defined by the radiologist and stated in the report of an ultrasound examination.

4. The radiologist’s diagnostic workup/evaluation report should include the results of the diagnostic mammogram, ultrasound (when performed), CBE, and the correlation of each test with each other.

**B. Management ofFindings of CBE, Initial Mammogram, and Testing**

1. **See Attachment A.** Flow Charts of the Maryland Breast and Cervical Cancer Program: Management of Clinical Breast Examination and Mammogram Results.

2. A woman with persistent, unexplained, localized pain in the breast should be evaluated by a breast specialist or surgeon.

3. If a radiologist recommends obtaining results or copies of prior mammograms following a BI-RADS category 0 result, local programs should assist in obtaining the results or copies.

4. Image-guided percutaneous needle biopsy is the diagnostic procedure of choice for image-detected abnormalities, with few exceptions.

5. When a non-palpable or questionably palpable mass that was found on imaging is excised, the specimen should be verified by using the appropriate imaging modality while the patient is still in the operating room.

6. At least one breast tissue specimen positive for cancer should be tested for tumor markers (e.g. estrogen/progesterone receptors, her2/neu etc.) to guide clinical management.

**C. Additional Procedures and Program Coverage**

1. Providers should consult with the local BCCP for questions about coverage for payment of procedures.

2. Magnetic Resonance Imaging (MRI)
   a. The DHMH BCCP will not reimburse for MRI for breast cancer screening.
   
   b. If recommended by the managing physician, the BCCP will reimburse for a MRI of the breast for:
      i. Extent of disease in the ipsilateral breast in patients with a recent diagnosis of breast cancer;
ii. Screening of the contralateral breast in women with a current, newly diagnosed, unilateral breast cancer;
iii. Evaluation of patients undergoing current neoadjuvant chemotherapy for breast cancer;
iv. Positive margins after surgery for breast malignancy; or
v. Chest wall invasion suspected.

c. The BCCP will not reimburse for MRI of the breast for:
i. Surveillance of breast findings (for example, the program will not reimburse for MRI follow-up every 3-6 months for a surgical consult of "benign findings");
ii. Problem solving for inconclusive clinical or mammographic findings; or
iii. Evaluation of silicone breast implant integrity.

3. The BCCP will reimburse for a surgical or breast specialist consultation for a woman who has a negative mammogram but who has persistent, unexplained, localized pain in the breast.

4. BCCP funds surgical consults or follow-up visits intended to confirm or rule out breast cancer when screening tests yield abnormal results. BCCP will:
   a. Reimburse a maximum of two consults or visits to the same breast surgeon for the same breast problem (initial consultation plus a follow-up consultation).
   b. Reimburse follow-up of post-operative/post-biopsy complications of infection, hematoma, etc., following a BCCP-funded biopsy.
   c. Consider reimbursement on a case-by-case basis for follow-up surgical visits where the surgical pathology may be associated with recurrence or the presence of a more severe abnormality in the breast (e.g. certain types of atypia, phyllodes tumors) and the surgeon recommends short-term follow-up (every 3-6 months) for a maximum of 12 months.
   d. Not reimburse for ongoing surveillance for those cases in which the medical case manager or surgeon recommends frequent follow-up visits for surveillance based on a benign breast condition that is considered chronic and or based on a woman’s risk factors.

5. The BCCP will reimburse for immunohistochemical (IHC) stains as indicated below:
   a. When cancer is diagnosed on the biopsy: the BCCP will reimburse for IHC stains ordered by the clinician or pathologist.
   b. When cancer is suspected or needs to be ruled out: IHC should not be used reflexively to evaluate every breast biopsy. IHC is best used when ordered by the pathologist where IHC will clarify an ambiguous pathologic diagnosis. The most frequent use of this is where the pathologist wants to know whether an adenoma or papilloma harbors invasive disease, or whether the tumor is ductal or lobular. The BCCP will reimburse in these cases but may request more information to justify the use of IHC.
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Attachment A

Flow Charts
of the Maryland Breast and Cervical Cancer Program:

Management of Clinical Breast Examination and
Mammogram Results

I. Management when Clinical Breast Examination is
Normal/Benign Findings

II. Management when Clinical Breast Examination is
Abnormal
Management of Clinical Breast Exam and Mammogram Results:

Clinical Breast Examination: Normal or Benign Findings

Women who:
- are asymptomatic; and
- have implant(s), fibrocystic changes, mastitis, "lumpy" breasts, family history of breast cancer (premenopausal breast cancer in sister/mother), prior benign biopsy (within past year) when surgeon or radiologist recommends screening mammogram.

- Women who have:
  - a prior history of breast cancer should have a diagnostic mammogram for 5 years post diagnosis then at the discretion of the medical case manager, radiologist and client;
  - Medical Case Manager recommendation for Diagnostic Mammogram

Screening mammogram

Diagnostic mammogram

Mammogram Results:

BI-RADS 0: Needs additional imaging evaluation
  - Follow up per radiologist:
    - Diagnostic work-up (spot compression, magnification, special views, ultrasound, aspiration...)

BI-RADS 1: Negative
  - Annual follow-up: CBE with screening mammogram (if asymptomatic)

BI-RADS 2: Benign Finding
  - Follow up per radiologist (usually 6 month repeat imaging)

BI-RADS 3: Probably benign—short interval follow-up suggested
  - Radiologist communicates findings to the patient, the referring physician

BI-RADS 4: Suspicious Abnormality — Biopsy Should Be Considered
  - BI-RADS 5: Highly Suggestive of Malignancy — Appropriate Action Should Be Taken

Follow-up based on revised BI-RADS category

See BI-RADS 1, 2 or See BI-RADS 3 or See BI-RADS 4 or 5 above.

No cancer on Image-guided biopsy; and Surgeon does NOT perform biopsy

Cancer (invasive or DCIS) on prior Image-guided biopsy; surgeon performs no additional biopsy

Surgeon performs biopsy

Positive biopsy (invasive cancer or DCIS+)

BI-RADS 4 or 5 with: Negative biopsy OR biopsy that is LCIS or atypical ductal hyperplasia

BI-RADS 4 or 5 with biopsy that is LCIS or atypical ductal hyperplasia

CBE, pathology and imaging results are discordant:
- Refer to surgeon or breast specialist.

Further follow-up per surgeon*

BI-RADS 5: and Negative biopsy OR BI-RADS 4 or 5 with biopsy that is LCIS or atypical ductal hyperplasia

BI-RADS 4: AND Negative biopsy (that is, biopsy is not cancer, LCIS or atypical ductal hyperplasia)

Image-guided biopsy

Refer to surgeon or breast specialist

Management and Treatment of Cancer

Surgeon stages and initially manages breast cancer:
- Stage 0 must be offered oncologist consult.
- Stage 1-4 must see oncologist.

*Please refer to The Minimal Clinical Elements for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.

CBE: Ductal carcinoma in situ
LCIS: Lobular carcinoma in situ
Management of Clinical Breast Exam and Mammogram Results:

Clinical Breast Examination: Abnormal (other than Normal or Benign Finding)

Diagnostic mammogram (always); with Ultrasound, if recommended

CBE, Mammogram, and Ultrasound Results

BI-RADS 0
- Needs additional imaging evaluation
  - Follow up per radiologist
    - Diagnostic work-up (spot compression, magnification, special views, ultrasound, aspiration...)
  - Follow-up based on revised BI-RADS category

See BI-RADS 1, 2 or 3 or See BI-RADS 4 or 5 above

BI-RADS 1: Negative BI-RADS 2: Benign Finding
- No aspiration of cyst
- Aspirate cyst
  - Clear fluid
  - Bloody fluid

Annual follow-up: CBE with screening mammogram (if asymptomatic)

Follow up per radiologist (usually 6 month repeat imaging)

Positive biopsy (invasive cancer or DCIS+): Refer to surgeon or breast specialist

BI-RADS 3: Probably benign—short interval follow-up suggested

BI-RADS 4 AND BI-RADS 5: Highly suggestive of Malignency—Appropriate Action Should Be Taken

CBE, pathology and imaging results are discordant:
- Refer to surgeon or breast specialist.

CBE, pathology and imaging results are concordant:
- Radiologist and primary care provider recommend next steps;
  And
- Offer referral to surgeon or breast specialist.

Any clinical finding and:
- Complex cyst(s);
- BI-RADS 4: Suspicious Abnormality—Biopsy Should Be Considered; or
- BI-RADS 5: Highly Suggestive of Malignancy—Appropriate Action Should Be Taken

Image-guided biopsy

Management and Treatment of Cancer

Surgeon stages and initially manages breast cancer:
- Stage 0 must be offered oncologist consultation;
- Stage 1-4 must see oncologist

Further follow-up per surgeon*

Please refer to The National Clinical Guidelines for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.

DCIS: Ductal carcinoma in situ
CIS: Lobular

**"Abnormal Clinical Breast Exam" includes:
- Nipple discharge that is bloody, crystal clear, or of any color if unilateral, single duct, and spontaneous;
- Discrete palpable mass—suspicion for cancer
- Nipple/areolar scaliness
Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
July 2012

Goal:
The goal of the Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
is to provide clients of the Maryland Breast and Cervical Cancer Program (BCCP) with optimal,
up-to-date screening for cervical cancer and management of findings.

Objectives:
- To assist local BCCPs in evaluating cervical cytology screening interval, results and
  recommended management.
- To incorporate into the Minimal Clinical Elements the 2012 USPSTF
  Recommendations for Screening for Cervical Cancer.
- To assure the Minimal Clinical Elements remain in line with the 2001 Bethesda
  System Terminology for Reporting Results of Cervical Cytology.
- To inform clinicians of these guidelines.
- To incorporate into the Minimal Clinical Elements the 2006 American Society for
  Colposcopy and Cervical Pathology (ASCCP) Consensus Guidelines for the
  Management of Women with Cervical Intraepithelial Neoplasia and Cervical
  Cytological Abnormalities.

Attachment A: Detection of Cervical Cytologic Abnormalities in the BCCP
- Attachment A1: Screening Interval
- Attachment A2: Program Guidelines
- Attachment A3: Cervical Specimen Collection and Cytology Findings Reported (2001
  Bethesda System)

Attachment B: Management of Cervical Cytologic Abnormalities in the BCCP
- Selected ASCCP Flow Charts relevant to the Maryland Breast and Cervical Cancer
  Program: Cytology and Histology, ©2006, 2007 (The entire set of ASCCP Flow Charts is
  available at http://www.asccp.org/consensus.shtml

References:
   Bethesda 2001 Workshop. The 2001 Bethesda System: Terminology for Reporting Results of
2. Robert A. Smith, Vilma Cokkinides and Otis W. Brawley. Cancer screening the United
   States, 2009: A review of current American Cancer Society guidelines and issues in cancer
3. Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark
   Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society
   for Colposcopy and Cervical Pathology-sponsored Consensus Conference. 2006 consensus
   guidelines for the management of women with cervical intraepithelial neoplasia or
4. Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark
   Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society
   for Colposcopy and Cervical Pathology-sponsored Consensus Conference. 2006 consensus

Cervical Minimal Elements, July 2012


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Cervical Minimal Elements, July 2012
## Maryland Breast and Cervical Cancer Program
### Maryland DHMH, Center for Cancer Prevention and Control
#### Attachment A—Detection of Cervical Cytologic Abnormalities in the BCCP

### Attachment A1
#### Screening Interval

<table>
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<th>Population</th>
<th>Recommendation</th>
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<tr>
<td>Women ages 40-64</td>
<td>Screen with cytology alone every 3 years or Co-testing with cytology and HPV every 5 years</td>
</tr>
<tr>
<td>Women older than ages who have had adequate prior screening and are not high risk</td>
<td>Do not screen if adequate prior screening. (See Attachment A2 Program Guidelines #5)</td>
</tr>
<tr>
<td>Women after hysterectomy with removal of the cervix and without history of any high-grade precancerous lesion (CIN 2 or 3) or cervical cancer</td>
<td>Do not screen women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.</td>
</tr>
<tr>
<td>Women after hysterectomy with removal of the cervix and with history of high-grade precancerous lesion (CIN 2 or 3) or cervical cancer</td>
<td>Women who have had a hysterectomy for CIN disease should undergo cervical cancer screening with cytology alone every three years or co-testing with cytology and HPV every 5 years for 20 years even if it goes past the age of 65. Women who have had cervical cancer should continue annual screening indefinitely as long as they are in reasonable health.</td>
</tr>
</tbody>
</table>

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*Cervical Minimal Elements, July 2012*
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
Attachment A2
Program Guidelines

1. Program eligibility for the Maryland Breast and Cervical Cancer Program
   a. Women 40 – 64 years old or 65+ without Medicare Part B;
   b. Meets income eligibility of ≤ 250% of the Federal Poverty Guideline;
   c. Has no health insurance, has no health insurance that covers cervical cancer screening, or has coverage but has not met the deductible for the year; and
   d. Either:
      i. Has an intact cervix (no hysterectomy or supracervical hysterectomy); or
      ii. Has had a hysterectomy for cervical cancer, for CIN 2/3, or for an indication unknown to the woman.

2. Vaginal Pap tests may be performed only on women who required a hysterectomy due to cervical cancer or CIN 2/3.
   a. For other indications (symptoms or vaginal lesion), refer the woman to another program for Pap testing or evaluation.
   b. Women who have had a hysterectomy for CIN 2/3 disease should undergo cervical cancer screening every 3 years with cytology alone or co-testing with cytology and HPV every 5 years for 20 years even if screening extends beyond the age of 65.
   c. Women who have had a hysterectomy due to cervical cancer should continue annual screening indefinitely as long as they are in reasonable health.
   d. If the reason for the hysterectomy cannot be documented, she should continue routine screening with Pap testing every 3 years or co-testing every 5 years.

3. The screening interval for average risk women—
   a. Cytology alone every 3 years OR
   b. Co-testing with cytology and HPV every 5 years.

4. Women who are considered high-risk may need more intensive (i.e. annual) screening. This pertains to women who:
   a. Were exposed in utero to diethylstilbestrol (DES);
   b. Are immunocompromised; or
   c. Are HIV-infected.

5. Women age 65+ who have had adequate prior cervical cancer screening and are not otherwise at high risk for cervical cancer should not be tested. (Adequate prior screening is defined as 3 consecutive negative cytology results or 2

Cervical Minimal Elements, July 2012
consecutive negative HPV results within 10 years before cessation of screening, with the most recent test occurring within 5 years.)

6. HPV DNA Testing
   a. HPV DNA testing is reimbursable as a screening test in the BCCP if used in co-testing with cytology every 5 years.
   b. Only HPV DNA testing for high-risk genotypes is reimbursable.
   c. Reimbursement for HPV genotyping is not allowed.
   d. HPV DNA testing is reimbursable if performed as guided by ASCCP Flow Sheets in the management of abnormal cytology/histology, for example:
      i. As a follow-up test to an ASC-US result (See attachment B, ASCCP Flow, Page 7 of 16); or
      ii. For surveillance at 12 months following LSIL without evidence of CIN on colposcopy-directed biopsy (See attachment B, ASCCP Flow, page 9 of 16).

7. If the Pap test is read as “unsatisfactory for evaluation,”
   a. If the woman had prior Negative Pap test results, repeat Pap test in 4 months.
   b. If the woman had (one or more) prior Abnormal Pap test results, repeat the Pap test in 4 months.

8. If the Pap test on a premenopausal woman is read as “Normal. Satisfactory for evaluation; no endocervical cells present,”
   a. If the woman had prior Negative Pap tests for the prior 2-3 tests, then return for repeat Pap test in 12 months.
   b. If the woman did not have a history of several prior Negative Pap tests, then return for repeat Pap in 4 months.

9. If a patient has a history of cervical cancer without hysterectomy (e.g., radiation, implant, conization)
   a. If the woman is being released from gynecologic oncologist to routine screening (e.g., after 5 years of follow-up post diagnosis), obtain and review medical history of Pap test results to know what will be expected on the Pap tests in the BCCP (e.g., endocervical cells or not).
   b. If the woman has no medical records, refer first (before testing in the BCCP) to a gynecologic oncologist for consultation on appropriate Pap testing and test result interpretation.

10. Follow ASCCP Flow Sheets (Attachment B) based on Cytologic and Histologic findings.

11. Only procedures recommended in the ASCCP Flow Sheets based on the Cytologic or Histologic findings will be paid. Additional or alternative procedures are usually not paid for by the BCCP. Consultation with the local BCCP public
health program is advised before proceeding with further procedures.

Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
Attachment A3
Cervical Specimen Collection and
Cytology Findings Reported (2001 Bethesda System)

1. Specimen Collection
   a. Collection of conventional Pap smear
      i. A sample of the ectocervix is collected with a spatula rotating 360
         degrees at least once around the cervix.
      ii. A sample of the endocervix is collected preferably with a
          cytobrush rotating at least 90 degrees.
      iii. If no cervix present, a sample of the vaginal cuff only is collected
           (see BCCP Program Guidelines #1 d and #2 a, b, & c above).
   b. Collection of liquid-based cervical cytology
      i. A gynecologic sample is collected using a broom-type or
         cytobrush/spatula cervical sampling device and then rinsed into the
         collection medium following directions of the manufacturer.

2. Specimen Adequacy
   a. Satisfactory for evaluation (note presence or absence of
      - endocervical/transformation zone component).
   b. Unsatisfactory for evaluation because of... (specify reason).
      i. Specimen rejected/not processed (specify reason).
      ii. Specimen processed and examined, but unsatisfactory for
          evaluation of epithelial abnormality because of (specify reason).

3. Results
   a. Negative for Intraepithelial Lesion or Malignancy (reporting non-
      neoplastic findings is optional)
      i. Organisms (e.g., Trichomonas; fungal org. consistent with
         Candida; bacterial vaginosis; Actinomyces species; cellular
         changes consistent with Herpes simplex virus).
      ii. Other non-neoplastic findings (e.g., Reactive changes/Glandular
          status post hysterectomy/Aatrophy).
   b. Epithelial Cell Abnormalities
      i. Squamous Cell
         • ASC-US (atypical squamous cells of undetermined
           significance).
         • ASC-H (atypical squamous cells-cannot exclude high grade
           squamous intraepithelial lesion [HSIL]).
         • LSIL (low grade squamous intraepithelial lesion—includes
           Human Papilloma Virus [HPV]/ mild dysplasia/CIN 1).
- HSIL (high grade squamous intraepithelial lesion—
  includes mod. and severe dysplasia, CIS; CIN-2 & CIN-3).
- Squamous cell carcinoma

ii. Glandular Cell
- Atypical glandular cells (AGC) specify endocervical,
  endometrial, or not otherwise specified (NOS).
- Atypical glandular cells, favor neoplastic (specify
  endocervical, or NOS).
- Endocervical adenocarcinoma in situ (AIS).
- Adenocarcinoma (all types).

c. Other
- Endometrial cells (in women > 40 years of age).
- Other Malignant Neoplasms (specify).

Educational Notes and Suggestions—Women who are pregnant or who still desire
pregnancy should have additional consultation beyond these guidelines.
Attachment B—Management of Cervical Cytologic Abnormalities in the BCCP

Selected ASCCP Flow Charts
Relevant to the Maryland Breast and Cervical Cancer Program:
Cytology and Histology

Footnotes in the charts may refer to text or special situations further clarified in these references:


The entire set of ASCCP Flow Charts including the charts not included here are available at http://www.asccp.org/consensus.shtml

Charts not included here are:
- Management of Adolescent Women with Either ASC-US or LSIL
- Management of Pregnant Women with LSIL
- Management of Adolescent Women (20 years and younger) with HSIL
- Management of Adolescent Women (20 years and younger) with CIN-1
- Management of Adolescent and Younger Women with a Histological Diagnosis of CIN 2,3
Use of HPV DNA Testing as an Adjunct to Cytology for Cervical Cancer Screening in Women 30 Years and Older

- **Cytology Negative**
  - HPV (-)
    - Routine Screening
      - Not before 3 years
  - HPV (+)
    - Repeat BOTH Tests
      - @ 12 mos

- **Cytology ASCUS or Greater**
  - HPV (-)
    - Routine Screening
      - @ 2 years
  - HPV (+)
    - Cytology Negative
  - Cytology Abnormal
    - Any HPV Result

*Test only for high-risk (oncogenic) types of HPV*
Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US)

Repeat Cytology @ 6 to 12 mos

- Both Tests Negative
  - Routine Screening
- ASC (either result)
  - Colposcopy
    - Biopsy or more invasive procedure for women with no lesions, and those with unsatisfactory colposcopy

HPV Unknown
- Repeat Cytology @ 12 mos
HPV Positive
- Repeat Cytology @ 12 mos

CIN
- Repeat Cytology @ 12 mos

HPV Positive
- Repeat Colposcopy
  - 2 ASC or HPV (+)
  - Repeat Colposcopy
  - Negative
    - Routine Screening

HPV Negative
- Repeat Cytology @ 12 mos

*Test only for high-risk (oncogenic) types of HPV*
Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC - H)

Colposcopic Examination

- NO CIN 2,3
- CIN 2,3

≥ ASC or HPV (+) → Negative

Routine Screening

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Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL) *

Colposcopic Examination*

NO CIN ≥3

CIN ≥3

Cytology + ASC-HSIL

HPV DNA Testing ≥1

≥ ASC or HPV (+)

Negative

Routine Screening

*Management options may vary if the woman is pregnant, postmenopausal or an adolescent - (see text, below)

Note: The management of LSIL in Postmenopausal women is essentially the same as the management of ASC-US:


"Postmenopausal women: Acceptable options for the management of postmenopausal women with LSIL include "reflex" HPV DNA testing, repeat cytological testing at 6 and 12 months, and colposcopy.

If the HPV DNA test is negative or CIN is not identified at colposcopy, repeat cytology in 12 months is recommended.

If either the HPV DNA test is positive or the repeat cytology is ASC-US or greater, colposcopy is recommended.

If 2 consecutive repeat cytologic tests are negative for intraepithelial lesion or malignancy, return to routine cytologic screening is recommended."
Management of Women with High-grade Squamous Intraepithelial Lesion (HSIL) *

Immediate Loop Electrosurgical Excision OR Colposcopic Examination (with endocervical assessment)

Unsatisfactory Colposcopy

NO CIN 2,3 Satisfactory Colposcopy All three approaches are acceptable

CIN 2,3

Review Material*

Change in Diagnosis

HSIL at other visit

Negative Cytology or both tests Routine Screening

Other Results

* If patient is pregnant or an adolescent
* Include referral cytology, colposcopic findings, and all biopsies
* Management options may vary if the woman is pregnant, postmenopausal, or an adolescent

Copyright 2004, 2007, American Society for Colposcopy and Cervical Pathology. All rights reserved.
Initial Workup of Women with Atypical Glandular Cells (AGC)

- A subcategory of ASC-US
  - Normal-appearing endocervical cells

Then:

- Colposcopy (even endocervical sampling) and HPV DNA Testing
  - OR Endometrial Sampling
    - If > 35 yrs or at risk for endometrial neoplasia

If Endometrial and Endocervical Sampling:

- NO Endometrial Pathology
  - Colposcopy

*Not already classified. Test only for high-risk genotypes.
*Includes unexplained vaginal bleeding or conditions suggesting chronic inflammation.
Subsequent Management of Women with Atypical Glandular Cells (AGC)

- **NO CIN and NO Glandular Neoplasia**
  - HPV Status Unknown
    - Repeat Cytology
      - @ 6-mo intervals
        - Repeat Cytology and HPV DNA Testing
          - @ unless HPV (+)
          - @ 6 mo if HPV (+)
            - 2. ASC or HPV (+)
  - HPV (+)
    - Repeat Cytology
      - @ unless HPV (+)
      - @ 6 mo if HPV (+)
        - BOTH Tests Negative
          - Routine Screening

- **CIN but NO Glandular Neoplasia**
  - OR
    - **Glandular Neoplasia Irrespective of CIN**
      - Initial Biopsy
        - NO Invasive Disease

- **Initial Biopsy of NOC (glandular neoplasia) = AB**
  - Initial Biopsy of NOC (glandular neoplasia) = AB

*Should provide an intact specimen with interpretable morphology. Concurrent endocervical sampling is preferred.
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia
Grade 1 (CIN 1) Preceded by ASC-US, ASC-H or LSIL Cytology

Follow-up Without Treatment

- Cytology every 6-12 mos
- HPV Testing* every 12 mos

2x Cytology Negative or HPV (−) Once

Routine Cytological Screening

2. ASC or HPV (+)

If Persistent for AT LEAST 2 yrs

* Test only for high-risk (oncogenic) types of HPV

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Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia - Grade 1 (CIN 1) Preceded by HSIL or AGC-NOS Cytology

There are 3 Acceptable Options:

- Diagnostic Excisional Procedure
- Review of All Findings
- Observation with Colposcopy & Cytology

2X Negative Results

HSIL at either 6 or 12 mos.

Routine Cytological Screening

Change in Diagnosis

No Change

EITHER Observation or Diagnostic Excisional Procedure

*Except in special populations
†Includes referred cytology, colposcopy, findings, and all biopsies
‡Provisional colposcopy, biopsies, diary, and environmental sampling is negative.
If not, diagnostic excisional procedure.

Copyright 2004, ACOG, American Society for Colposcopy and Cervical Pathology All rights reserved.
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia - (CIN 2,3) *

Satisfactory Colposcopy

Either Excision or Ablation of Fossa *

Unsatisfactory Colposcopy or Recurrent CIN 2,3

Acceptable Follow-Up Approaches Post-treatment

Cytology at 6 mos. Intervals

Cytology & Colposcopy at 6 mos. Intervals

≥2X Negative Results

≥2 ASC (any repeat cytology)

Routine Screening at least 10 years

HPV DNA Testing performed at 6 mos. after treatment

HPV Positive (for high-risk types)

HPV Negative (for high-risk types)

Routine Screening at least 10 years

* Management options vary in special circumstances

Copyright 2004, 2001, American Society for Colposcopy and Cervical Pathology. All rights reserved.
Management of Women with Adenocarcinoma in-situ (AIS) Diagnosed from a Diagnostic Excisional Procedure

Hysterectomy - Preferred

Conservative Management
Acceptable if female

Margins Involved or ECC Positive
Re-evaluation
@ 6 mos - Acceptable
Long-term Follow-up

Margins Negative

* Using a combination of cytology, HPV testing, and salpingo-oophorectomy with adjuvant sampling

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# DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

(See reverse for public burden disclosure.)

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For Material Change Only:

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<td>Tier ______, if known:</td>
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| Congressional District, if known: 4c   |

| 5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime: |

| Congressional District, if known: |

| 6. Federal Department/Agency:      |

| 7. Federal Program Name/Description: |

| CFDA Number, if applicable:        |

| 8. Federal Action Number, if known: |

| 9. Award Amount, if known: $        |

| 10. a. Name and Address of Lobbying Registrant (if individual, last name, first name, MI): |

| b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI): |

| 11. Information requested through this form is authorized by 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure. |

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Standard Form LLL (Rev. 7-97)
INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subawardee recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in Item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (Item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in Item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in Item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in Item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, DC 20503.
MINORITY BUSINESS PROGRAM & OFFEROR'S REPRESENTATION

It is the policy of the County to recruit actively, minority-owned businesses to provide goods and services to perform governmental functions pursuant to Section 11B-57 of the County Code. Minority-owned businesses are described in County law as Minority/Female/Disabled Person owned businesses (MFD). MFD businesses include certain non-profit entities organized to promote the interests of persons with a disability demonstrating (on a contract by contract basis) that at least 51% of the persons used by the non-profit entity to perform the services or manufacture the goods contracted for by the County, are persons with a disability. MFD firms also include those firms that are 51% owned, controlled and managed by one or more members of a socially or economically disadvantaged minority group, which include African Americans who are not of Hispanic origin, Hispanic Americans, Native Americans, Asian Americans, Women and Mentally or Physically Disabled Persons.

Section 7 - “Minority Contracting”, Montgomery County Procurement Regulations specifies the procedure to be followed and will govern the evaluation of offers received pursuant to this solicitation. A copy of Section 7 of the Procurement Regulations is available upon request.

Prior to awarding contracts with a value of $50,000 or more, a prospective Contractor (who is not a certified MFD firm) must demonstrate that a minimum percentage of the overall contract value as set by the County, will be subcontracted to certified MFD businesses. A decision as to whether the prospective Contractor has demonstrated a good faith effort to meet this subcontracting requirement will be made by the Director, Office of Procurement, or his/her designee, who may waive this requirement.

A sample of the MFD Report of payment Received is attached. This form is mailed to the MFD Subcontractor to complete for documentation of payment by the Prime Contractor. It is not to be completed by the Prime Contractor nor submitted with the MFD Subcontractor Performance Plan.

The Director, Office of Procurement, or his /her designee determines whether a waiver of MFD subcontracting would be appropriate, under Section 7.3.3.5 of the Procurement Regulations.

For further information regarding the MFD Business Program, please contact the MFD Program, Office of Business Relations and Compliance at (240) 777-9912.

Offerors are encouraged (but not required) to complete the following:

I hereby represent that this is a Minority Business firm as indicated below (CIRCLE ONE):

<table>
<thead>
<tr>
<th>AFRICAN AMERICAN</th>
<th>ASIAN AMERICAN</th>
<th>DISABLED PERSON</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMALE</td>
<td>HISPANIC AMERICAN</td>
<td>NATIVE AMERICAN</td>
</tr>
</tbody>
</table>

Attach one of the following certification documents from: Maryland Department of Transportation (MDOT); Virginia Small, Women & Minority-Owned Business: Federal SBA 8(a); MD/DC Minority Supplier Development Council, Women's Business Enterprise National Council; or City of Baltimore.

PMMD-90 03/15
Minority-Owned Business Addendum to General Conditions of Contract Between County and Contractor

A. This contract is subject to the Montgomery County Code and the Montgomery County Procurement Regulations regarding participation in the Minority-Female-Disabled Person (MFD) procurement program.

B. Contractor must subcontract a percentage goals listed below of the total dollar value of the contract, including all modifications and renewals, to certified minority owned businesses. The MFD subcontracting goal may be waived under appropriate circumstances by submission of a letter to the Minority Business Program Manager. The letter must explain why a waiver is appropriate. The Director of the Office of Procurement or designee may waive, in whole or in part, the MFD subcontracting goal if the Director determines that a waiver is appropriate under Section 7.3.3.5 of the Montgomery County Procurement Regulations. In determining if a waiver should be granted, the Director may require the Contractor to submit additional information; the Director may require the Contractor to submit some or all of this information on forms approved by the Director.

For Goals by each purchasing category, please refer to www.montgomerycountymd.gov/mfd

C. The attached MFD Subcontractor Performance Plan, which must be approved by the Director, is an integral part of the contract between County and Contractor. In a multi-term contract, Contractor must submit a MFD Subcontract Performance Plan to be in effect for the life of the contract, including any renewal or modification.

D. Contractor must include in each subcontract with a minority owned business a provision that requires the use of binding arbitration with a neutral arbitrator to resolve disputes between the Contractor and the minority owned business subcontractor. This arbitration provision must describe how the cost of dispute resolution will be apportioned; the apportionment must not, in the judgment of the Director, attempt to penalize a minority owned business subcontractor for filing an arbitration claim.

E. County approval of the MFD Subcontractor Performance Plan does not create a contractual relationship between the County and the minority owned business subcontractor.

F. Contractor must notify and obtain prior written approval from the Director regarding any change in the MFD Subcontractor Performance Plan.

G. Before receiving final payment under this contract, Contractor must submit documentation showing compliance with the MFD Subcontracting Performance Plan. Documentation may include, at the direction of the Director, invoices, copies of subcontracts with minority owned businesses, cancelled checks, affidavits executed by minority owned business subcontractors, waivers, and arbitration decisions. The Director may require Contractor to submit periodic reports on a form approved by the Director. The Director may conduct an on-site inspection for the purpose of determining compliance with the MFD Subcontractor Performance Plan. If this is a multi-term contract, final payment means the final payment due for performance rendered for each term of the contract.

If the Contractor fails to submit documentation demonstrating compliance with the MFD Subcontractor Performance Plan, to the satisfaction of the Director, after considering relevant waivers and arbitration decisions, the Contractor is in breach of this contract. In the event of a breach of contract under this addendum, the Contractor must pay to the County liquidated damages equal to the difference between all amounts the Contractor has agreed under its Plan to pay minority owned business subcontractors and all amounts actually paid minority owned business subcontractors with appropriate credit given for any relevant waiver or arbitration decision. Contractor and County acknowledge that damages which would result to the County as a result of a breach under this addendum are difficult to ascertain, and that the liquidated damages provided for in this addendum are fair and reasonable in estimating the damage to the County of a breach of this addendum by Contractor. In addition, the County may terminate the contract. As the result of a breach under this addendum, The Director of the Office of Procurement must find the Contractor non-responsible for purposes of future procurement with the County for the ensuing three years.

PMMD-91 Rev. 09/15
Attachment G

MONTGOMERY COUNTY, MARYLAND
MINORITY, FEMALE, DISABLED PERSON SUBCONTRACTOR
PERFORMANCE PLAN

Contractor's
Name: ____________________________
Address: _________________________
City: _____________________________ State: ______ Zip: ______
Phone Number: ________________ Fax Number: ________________ Email: _______

CONTRACT NUMBER/PROJECT DESCRIPTION: ________________________________

A. Individual assigned by Contractor to ensure Contractor's compliance with MFD Subcontractor Performance Plan:

Name: ____________________________
Title: ______________________________
Address: __________________________
City: ______________________________ State: ______ Zip: ______
Phone Number: ________________ Fax Number: ________________ Email: _______

B. This Plan covers the life of the contract from contract execution through the final contract expiration date.

C. The percentage of total contract dollars, including modifications and renewals, to be paid to all certified minority owned business subcontractors, is ______ % of the total dollars awarded to Contractor.

D. Each of the following certified minority owned businesses will be paid the percentage of total contract dollars indicated below as a subcontractor under the contract.

I hereby certify that the business(s) listed below are certified by one of the following: Maryland Department of Transportation (MDOT); Virginia Small, Woman and Minority Owned Business (SWAM); Federal SBA (8A); MD/DC Minority Supplier Development Council (MSDC); Women's Business Enterprise National Council (WBENC); or City of Baltimore.
A Certification Letter must be attached.
For assistance, call 240-777-9912.

1. Certified by:

Subcontractor Name: ________________________________________________
Title: ____________________________________________________________
Address: __________________________________________________________
City: __________________________ State: ______ Zip: ______
Phone Number: ________________ Fax Number: ________________ Email: _______

CONTACT PERSON: ________________________________________________

Circle MFD Type:
AFRICAN AMERICAN ASIAN AMERICAN DISABLED PERSON
FEMALE HISPANIC AMERICAN NATIVE AMERICAN

The percentage of total contract dollars to be paid to this subcontractor:

This subcontractor will provide the following goods and/or services:

______________________________________________________________

PMM-65 Rev. 06/15
2. Certified by: 

Subcontractor Name: ____________________________
Title: ____________________________
Address: ____________________________
City: ____________________________ State: ____________________________ Zip: ____________________________
Phone Number: ____________________________ Fax Number: ____________________________ Email: ____________________________

CONTACT PERSON: ____________________________

Circle MFD Type:

AFRICAN AMERICAN  ASIAN AMERICAN  DISABLED PERSON
FEMALE  HISPANIC AMERICAN  NATIVE AMERICAN

The percentage of total contract dollars to be paid to this subcontractor: ____________________________
This subcontractor will provide the following goods and/or services: ____________________________

3. Certified by: ____________________________

Subcontractor Name: ____________________________
Title: ____________________________
Address: ____________________________
City: ____________________________ State: ____________________________ Zip: ____________________________
Phone Number: ____________________________ Fax Number: ____________________________ Email: ____________________________

CONTACT PERSON: ____________________________

Circle MFD Type:

AFRICAN AMERICAN  ASIAN AMERICAN  DISABLED PERSON
FEMALE  HISPANIC AMERICAN  NATIVE AMERICAN

The percentage of total contract dollars to be paid to this subcontractor: ____________________________
This subcontractor will provide the following goods and/or services: ____________________________

4. Certified By: ____________________________

Subcontractor Name: ____________________________
Title: ____________________________
Address: ____________________________
City: ____________________________ State: ____________________________ Zip: ____________________________
Phone Number: ____________________________ Fax Number: ____________________________ Email: ____________________________

CONTACT PERSON: ____________________________

Circle MFD Type:

PMMDD-65 Rev. 06/15
E. The following language will be inserted in each subcontract with a certified minority owned business listed in D above, regarding the use of binding arbitration with a neutral arbitrator to resolve disputes with the minority owned business subcontractor; the language must describe how the costs of dispute resolution will be apportioned:

F. Provide a statement below, or on a separate sheet, that summarizes maximum good faith efforts achieved, and/or the intent to increase minority participation throughout the life of the contract or the basis for a full waiver request.

G. A full waiver request must be justified and attached.

Full Waiver Approved: ___________________________ Date: ____________
MFD Program Officer

Partial Waiver Approved: ___________________________ Date: ____________
MFD Program Officer

Full Waiver Approved: ___________________________ Date: ____________
Director
Cherri Branson
Office of Procurement

Partial Waiver Approved: ___________________________ Date: ____________
Director
Cherri Branson
Office of Procurement

The Contractor submits this MFD Subcontractor Performance Plan (Plan Modification No. ____________) in accordance with the Minority Owned Business Addendum to General Conditions of Contract between County and Contractor.

CONTRACTOR SIGNATURE

USE ONE:

1. TYPE CONTRACTOR'S NAME:

Signature

Typed Name

Date

PMMD-65 Rev. 06/15
2. TYPE CORPORATE CONTRACTOR'S NAME: _____________________________________________

Signature

Typed Name

Date

I hereby affirm that the above named person is a corporate officer or a designee empowered to sign contractual agreements for the corporation.

Signature

Typed Name

Title

Date

APPROVED:

Cherri Branson, Director, Office of Procurement  Date

Section 7.3.3.4(a) of the Procurement Regulations requires:
The Contractor must notify the Director, Office of Procurement of any proposed change to the Subcontractor Performance Plan.
Attachment H

Wage Requirements for Services Contract
Addendum to The General Conditions of Contract Between County and Contractor

A. This contract is subject to the Wage Requirements Law, found at Section 11B-33A of the Montgomery County Code ("WRL" or "11B-33A"). A County contract for the procurement of services must require the contractor and any of its subcontractors to comply with the WRL, subject to the exceptions for particular contractors noted in 11B-33A (b) and for particular employees noted in 11B-33A (f).

B. Conflicting requirements (11B-33A (g)): If any federal, state, or County law or regulation requires payment of a higher wage, that law or regulation controls. If any applicable collective bargaining agreement requires payment of a higher wage, that agreement controls.

C. A nonprofit organization that is exempt from the WRL under 11B-33A (b)(3) must specify the wage the organization intends to pay to those employees who will perform direct, measurable work under the contract, and any health insurance the organization intends to provide to those employees. Section 11B-33A (c)(2).

D. A contractor must not split or subdivide a contract, pay an employee through a third party, or treat an employee as a subcontractor or independent contractor, to avoid the imposition of any requirement in 11B-33A.

E. Each contractor and subcontractor covered under the WRL must: certify that it is aware of and will comply with the applicable wage requirements; keep and submit any verifiable records necessary to show compliance; and conspicuously post notices approved and/or supplied by the County, informing employees of the wage requirements. Section 11B-33A (h).

F. An employer must comply with the WRL during the initial term of the contract and all subsequent renewal periods, and must pay the adjusted wage rate increase required under 11B-33A (e)(2), if any, which is effective July 1 of each year. The County will adjust the wage rate by the annual average increase in the Consumer Price Index for all urban consumers for the Washington-Baltimore metropolitan area, or successor index, for the previous calendar year and must calculate the adjustment to the nearest multiple of 5 cents.

G. An employer must not discharge or otherwise retaliate against an employee for asserting any right, or filing a complaint of a violation, under the WRL.

H. The sanctions under Section 11B-33 (b), which apply to noncompliance with nondiscrimination requirements, apply with equal force and scope to noncompliance with the wage requirements of the WRL.

I. The County may assess liquidated damages for any noncompliance by contractor or its subcontractor with the WRL based on the rate of 1% per day of the total contract amount, or the estimated annual contract value of a requirements contract, for each day of the violation. This liquidated damages amount includes the amount of any unpaid wages, with interest. In the event of a breach of contract under this paragraph, the Contractor must pay to the County liquidated damages noted above, in addition to any other remedies available to the County. Contractor and County acknowledge that damages that would result to the County as a result of a breach under this paragraph are difficult to ascertain, and that the liquidated damages provided for in this paragraph are fair and reasonable in estimating the damage to the County resulting from a breach of this paragraph by Contractor. If the County determines, as a result of a WRL audit that the Contractor has violated requirements of the WRL, including but not limited to the wage requirements, the County will assess the Contractor for the cost incurred by the County in conducting the audit. In addition, the contractor is jointly and severally liable for any noncompliance by a subcontractor. Furthermore, Contractor agrees that an aggrieved employee, as a third-party beneficiary, may by civil action against the violating contractor or subcontractor enforce the payment of wages due under the WRL and recover from the Contractor or subcontractor any unpaid wages with interest, a reasonable attorney's fee, and damages for any retaliation by the Contractor or subcontractor arising from the employee asserting any right, or filing a complaint of violation, under the WRL.

J. The County has established a program of random audits to assure compliance with the WRL. The Director may conduct an on-site inspection(s) for the purpose of determining compliance. Some of the documents that may be required during an audit are listed on the Wage Requirements Law FAQ web page: http://www.montgomerycountymd.gov/PRO/DBRC/WRL.html

K. The Contractor is in breach of this contract if the Contractor fails to submit timely documentation demonstrating compliance with the WRL to the satisfaction of the Director, including: the Wage Requirements Law Payroll Report Form (PMMD-183), which is required to be submitted by the end of the month (January, April, July, October) following each quarter; documents requested in conjunction with a random or compliance audit being conducted by the County; or documents otherwise requested by the Director. In the event of a breach of contract under this paragraph, or for any other violation of the WRL, the County may assess against, or withhold from payment to, Contractor, the liquidated damages noted in paragraph I. above, in addition to any other remedies available to the County. Contractor and County acknowledge that damages that would result to the County as a...
result of a breach under this paragraph are difficult to ascertain, and that the liquidated damages provided for in this paragraph are fair and reasonable in estimating the damage to the County resulting from a breach of this paragraph by Contractor.

L. For any questions, please contact the Wage Requirements Law Program Manager at 240-777-9918 or WRL@montgomerycountymd.gov.

[Remainder of Page Intentionally Left Blank]
### Contract #

**Wage Requirements Law Certification**
(Montgomery County Code, Section 11B-33A)

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<thead>
<tr>
<th>Business Name</th>
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<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>State</td>
</tr>
<tr>
<td>Phone Number</td>
<td>Fax Number</td>
</tr>
<tr>
<td>E-Mail Address</td>
<td></td>
</tr>
</tbody>
</table>

Provide, in the spaces below, the contact name and information of the individual designated by your firm to monitor your compliance with the County’s Wage Requirements Law, unless exempt under Section 11B-33A (b) (see Section B. below):

<table>
<thead>
<tr>
<th>Contact Name</th>
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</thead>
<tbody>
<tr>
<td>Phone Number</td>
<td>Fax Number</td>
</tr>
<tr>
<td>E-mail Address</td>
<td></td>
</tr>
</tbody>
</table>

In the event that you, the “Offeror,” are awarded the contract and become a Contractor, YOU MUST MARK ☐ or ☐ in all boxes below that apply.

- **A. Wage Requirements Compliance**
  This Contractor, as a “covered employer”, will comply with the requirements under County Code Section 11B-33A, “Wage Requirements” (“Wage Requirements Law” or WRL”). Contractor and its subcontractors will pay all employees not exempt under the WRL, and who perform direct measurable work for the County, the required wage rate effective at the time the work is performed. The offer price(s) submitted under this solicitation include(s) sufficient funds to meet the requirements of the WRL. A “covered employer” must submit (preferably via email) quarterly (by the end of January, April, July, and October for the quarter ending the preceding month) certified payroll records for each payroll period and for all employees of the contractor or a subcontractor performing services under the County contract governed by the Wage Requirements Law, to the Division of Business Relations and Compliance, Attn: Wage Requirements Law Program Manager. These payroll records must include the following: name; position/title; gender/race (for contracts awarded after October 1, 2015); daily straight-time hours worked; daily overtime hours worked; straight-time hourly pay rate; overtime hourly pay rate; both employer and employee share of health insurance premium; and total gross wages paid for each period. A sample of the Payroll Report Form can be found at the link below. ([http://www.montgomerycountymd.gov/PRO/DBRC/WRL.html](http://www.montgomerycountymd.gov/PRO/DBRC/WRL.html)). In lieu of the quarterly Payroll Report Form, payroll registers generally satisfy the requirement. Late submission or non-submission of this information, or any other violation of the WRL, may result in the County withholding contract payments and additional actions by the County, including but not limited to: assessing liquidated damages, terminating the contract, or otherwise taking action to enforce the contract or the Wage Requirements Law. The Contractor must ensure that NO Social Security number of any person, other than the last four digits, is included on the quarterly report.

- **B. Exemption Status (if applicable)**
  This Contractor is exempt from Section 11B-33A, “Wage Requirements,” because it is:
  1. Reserved – [Intentionally left blank].
  2. a contractor who, at the time a contract is signed, has received less than $50,000 from the County in the most recent 12-month period, and will be entitled to receive less than $50,000 from the County under that contract in the next 12-month period. Section 11B-33A (b)(1);
  3. a public entity. Section 11B-33A (b)(2).
  4. a non-profit organization that has qualified for an exemption from federal income taxes under Section 501(c)(3) of the Internal Revenue Code. Section 11B-33A (b)(3) (must complete item C below).
Contract #_____________

☐ 5. an employer expressly precluded from complying with the WRL by the terms of any federal or state law, contract, or grant. Section 11B-33A (b)(7) (must specify the law, or furnish a copy of the contract or grant).

☐ C. Nonprofit Wage & Health Information
This Contractor is a non-profit organization that is exempt from coverage under Section 11B-33A (b)(3). Accordingly, the contractor has completed the 501 (c)(3) Nonprofit Organization’s Employee’s Wage and Health Insurance Form, which is attached. See Section11B-33A (c)(2).

☐ D. Nonprofit’s Comparison Price(s) (if desired)
This Contractor is a non-profit organization that is opting to pay its covered employees the hourly rate specified in the wage requirements. Accordingly, Contractor is duplicating the blanket-cost quotation sheet on which it is submitting its price(s) in the RFP, and is submitting on this duplicate form its price(s) to the County had it not opted to pay its employees the hourly rate specified in the WRL. For proposal evaluation purposes, this price(s) will be compared to price(s) of another nonprofit organization(s) that is paying its employees an amount consistent with its exemption from paying the hourly rate under the WRL. This revised information on the duplicate cost sheet must be clearly marked as your nonprofit organization comparison price(s). In order for the County to compare your price(s), the revised information on the duplicate cost sheet must be submitted with your offer on or before the offer opening date, must show how the difference between your nonprofit organization price(s) and other organization comparison price(s) was calculated. Section 11B-33A (c)(2).

☐ E. Sole Proprietorship
Sole Proprietorships are subject to the WRL. In order to be excused from the posting and reporting requirements of the WRL, the individual who is the sole proprietor must sign the certifications below in order to attest to the fact that the Sole Proprietorship:
(1) is aware of, and will comply with, the WRL, as applicable;
(2) has no employees other than the sole proprietor; and
(3) will inform the Montgomery County Office of Business Relations and Compliance if the sole proprietor employs any workers other than the sole proprietor.

Contractor Certification

CONTRACTOR SIGNATURE: Contractor submits this certification form in accordance with Section 11B-33A of the Montgomery County Code. Contractor certifies that it, and any and all of its subcontractors that perform services under the resultant contract with the County, adheres to Section 11B-33A of the Montgomery County Code.

<table>
<thead>
<tr>
<th>Authorized Signature</th>
<th>Title of Authorized Person</th>
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<td>Typed or printed name</td>
<td>Date</td>
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PMMD-177 Rev 09/15
501(c)(3) Nonprofit Organization's Employee's Wage and Health Insurance Form

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Please provide below the employee labor category of all employee(s) who will perform direct measurable work under this contract, the hourly wage the organization pays for that employee labor category, and any health insurance the organization intends to provide for that employee labor category:

<table>
<thead>
<tr>
<th>Employee Labor Category</th>
<th>Wage per Hour</th>
<th>Name of Health Insurance Provider(s) and Plan Name* (e.g. ABC Insurer, Inc., HMO Medical and Dental)</th>
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* IF NO HEALTH INSURANCE PLAN IS PROVIDED PLEASE STATE "NONE".