REQUEST FOR PROPOSAL

CLINICAL LABORATORY SERVICES

APPENDIX A

RFP STATEMENT OF WORK

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1.0 INTRODUCTION:

1.1 Overview

The ACCESS Community Health and Research Center (CHRC) provides medical health services to over 6,000 active clients, many of whom receive prescription medication treatment. Drug therapy and associated care often require supporting clinical laboratory services to ensure patient safety and treatment efficacy. It is the goal of CHRC to provide both laboratory tests and monitoring in a cost effective and seamless manner by working closely with a comprehensive Laboratory Services Provider (LSP) contractor in an effort to meet the clinical laboratory service needs of CHRC's directly-operated clinics and programs .

2.0 SCOPE OF WORK:

2.1 Laboratory

"Laboratory" means facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories. In addition, Proposer shall provide a full spectrum of laboratory services including, but not limited to, the aforementioned.

2.2 Payor Status

The designated LSP maintains financial responsibility for clients who have no access to other sources of healthcare benefits. CHRC clients are always required to pursue enrollment in Medicaid, Medicare, or other available coverage sources, but a significant proportion of the CHRC client

population is either ineligible or in a state of transition between coverage periods. **Therefore, the LSP is the payor of last resort.**

2.2.2 Contractor shall maintain contracted status with Medicaid, Medicare, or other third parties at all times during the term of the Contract.

2.2.3 Contractor shall be responsible for verifying Medicaid, Medicare, and other third-party payor eligibility and for billing Medicaid, Medicare, and third parties directly when a client is eligible. In the event Contractor is unable to bill an eligible client's third party due to loss or nonexistence of a contract, CHRC reserves the right to decline reimbursement and direct client to an alternate LSP as designated by client's own health plan (Refer to Invoicing, Section 2.6).

2.3 LABORATORY ORDERS AND RESULTS:

Contractor is expected to maintain a comprehensive list of available laboratory orders. CHRC shall provide the "Authorized Order List (AOL)" to Contractor upon execution of the contract.

2.3.1 When an order is received from any CHRC Provider, and any individual Laboratory Request is not found within the AOL, Contractor shall follow procedures for prior authorization for the individual laboratory request as outlined in the Clinical Laboratory Services Agreement.

2.3.2 CHRC shall only reimburse Contractor for orders transmitted electronically or manually on approved forms; verbal orders are not permitted. Illegible or unclear orders shall be clarified with ordering facility prior to processing.

2.3.3 CHRC reserves the right to withhold payment for ambiguous or otherwise non-explicit orders which are processed without authorization or clarification.

2.3.4 Laboratory results shall be transmitted to or made available electronically to CHRC Providers within a reasonable period of time and in a manner consistent with Health Insurance Portability

and Accountability Act (HIPAA) privacy rules. Contractor shall provide approximate response times for laboratory result inquiries.

2.3.5 Each ordering facility within CHRC shall maintain a separate subaccount with Contractor for the purpose of tracking utilization and transmission of laboratory results.

2.3.6 STAT order results, for orders requested on an immediate basis, are to be returned to CHRC Provider electronically within four (4) hours of result availability. "Electronically" may occur via uploading to secure internet portal or by fax.

2.3.7 Proposers shall provide Commonly Used Laboratory Test List and provide prices for all laboratory tests listed, as well as include the additional fee for each draw/venipuncture procedure as part of the Cost Proposal Format.

2.4 OTHER LAB SERVICES:

2.4.1 Proposer is expected to accommodate multiple methods of sample acquisition, including routine or on-call pickup from designated locations, phlebotomy services at point of care, or via staffed blood draw facilities with all of CHRC's geographic areas.

2.4.2 Proposer's sample acquisition programs should be available during directly-operated clinic/program hours of operation or at alternative laboratory service sites that are geographically accessible and located within a convenient proximity of each CHRC directly operated ordering facility.

2.4.3 Proposer should have policies and procedures in place when a sample is lost or otherwise mishandled by staff or contracted courier.

2.4.4 Proposer shall be accessible via telephone, e-mail, or fax during business hours (9:00 a.m. to 5:00 p.m., Monday through Friday) to all CHRC directly-operated ordering facilities for technical support, laboratory, or other general inquiries.

2.4.5 Proposer's laboratory director and personnel shall provide consultation regarding receipt, performance results, and methodological/clinical interpretation of laboratory test results.

2.4.6 Proposer shall provide all materials and supplies required to stabilize samples and maintain samples integrity in transit to the laboratory.

2.4.7 Proposer and Proposer's staff shall conform to applicable CHRC facility rules and regulations while conducting clinical laboratory tests on ACCESS premises.

2.5 REQUISITION ORDER FORMS:

2.5.1 Contractor shall provide laboratory requisition order forms and catalogs to all CHRC directly-operated ordering facilities. CHRC's proprietary client identification number, known as the "Client IS Number (#)," and other complete patient/client identifying information (e.g., date of birth, Social Security Number, primary insurance) shall be provided on each order form by clinic/program staff authorized to verify Medicaid/Medicare eligibility. Client IS # shall be documented by Contractor's information system upon receipt and processing of each requisition order form.

2.5.2 When the Client IS # is not documented or otherwise illegible on a requisition order form, Contractor shall contact directly-operated ordering facility to verify information.

2.5.3 The Client IS # is critical for accurate tracking and analysis of laboratory results in association with departmental quality assurance initiatives.

2.5.4 Client's identifying information, including third-party benefits information, shall be explicitly documented on each requisition order form. Indigent clients shall be documented on requisition order forms as having "No Coverage" by ordering personnel. Contractor shall contact directly-operated ordering facility for clarification when third-party benefits information is missing or otherwise ambiguous.

2.6 Lab Assisted Clientele

2.6.1 Contractor must check client's primary insurance health coverage (e.g., Medicaid, Medicare, HMO). The CHRC often services a population who are refugees with no citizenship, asylum seekers, or those indigent cases who have no coverage or other financial resources. These, deemed as Lab Assisted patients, receive a reduced, if not free of charge, rate for laboratory services. Such cases are referred by on-site physicians, and all documentation must be accompanied by each client per instance. In addition, these referrals are limited to $2,000 of cases per month, and are governed by the CHRC Clinical Manager.

2.6.2 Bundled laboratory orders consisting of grouped orders must be explicitly itemized. Electronically transmitted invoices must be HIPAA compliant.

2.6.3 CHRC reserves the right to review orders for accuracy against original requisition order forms. Orders which do not reference original order form shall be held in suspense for payment pending clarification.

2.7 Information Systems Integration

CHRC anticipates implementation of an Electronic Health Record (EHR) in the near future. The goal of CHRC is to integrate multiple aspects of care, including ordering and viewing of laboratory services and results within one cohesive user interface. Standards based Application Program Interfaces (APIs) for laboratory ordering and viewing of results within external systems should be made available by Contractor when needed for such integration initiatives. The Contractor works cooperatively with CHRC towards implementation of this interface upon request.

3.0 Staffing and Specific Tasks

Contractor shall furnish all staff, services, supplies, facilities, materials, equipment, vehicles, and other items required to perform the services specified in this RFP and Appendix A, SOW. Additionally, Contractor shall ensure that the following staff and volunteer requirements are met:

3.1 STAFFING:

3.1.1 Background and Security Investigations and Requirements: Contractor shall ensure that criminal clearances and background checks have been conducted for all Contractor's staff, and volunteers. The cost of such criminal clearances and background checks is the responsibility of the Contractor whether or not the Contractor or Subcontractor's staff pass or fail the background and criminal clearance investigations.

3.1.2 Language Ability: Contractor's personnel, as well as all Subcontractor's staff who are performing services under this contract, shall be able to read, write, speak, and understand English in order to conduct business with the CHRC. In addition to having competency in English, Contractor shall attempt to ensure there is a sufficient number of bilingual staff to meet the language needs of the community served which is to include threshold languages of Arabic and Hispanic

3.1.3 Service Delivery: Contractor shall ensure all professional staff, paraprofessional staff, and volunteers providing clinical laboratory services are able to provide services in a manner that effectively responds to differences in cultural beliefs, behaviors and learning, and communication styles within the communities the Contractor provides services.

3.1.4 Experience: Contractor shall be responsible for securing and maintaining staff that possess expertise and professional licenses and certifications required to provide services required in this SOW. Contractor shall obtain written verification for staff with foreign degrees that the degrees are recognized as meeting established standards and requirements of an accrediting agency authorized by the U.S. Secretary of Education.

3.2 SPECIFIC TASKS:

3.2.1 Documentation: Contractor shall maintain documentation in the personnel files of all professional and paraprofessional staff, interns, and volunteers of: (1) all training hours and topics; (2) copies of resumes, degrees, and professional licenses; and (3) current criminal clearances. Contractor shall provide CHRC, at the beginning of each contract term and

within 30 days of any staff change(s), a roster of all staff that includes: (1) names and positions; (2) work schedules; and (3) e-mail addresses, fax and telephone numbers.

3.2.2 Changes: Contractor shall advise CHRC in writing of any change(s) in Contractor's key personnel at least 24-hours before proposed change(s), including names and qualifications of new personnel. Contractor shall ensure that no interruption of services occurs as a result of the change in personnel.

4.0 ADMINISTRATIVE TASKS:

4.1 Days/Hours of Operation: Proposer shall provide the name, e-mail address, and telephone number of the contact person for after-hours services. Proposer's service delivery sites shall be open at a minimum from Monday through Friday, from 9:00 a.m. until 5:00 p.m. In addition, Proposer's Clinical Manager or County approved alternate shall have full authority to act for Proposer on all matters relating to the daily operation of this contract and shall be available during the CHRC's regular business hours of Monday through Friday, from 9:00 a.m. until 5:00 p.m., to respond to CHRC inquiries and to discuss problem areas.

5.0 SERVICE DELIVERY SITE(S) AND GEOGRAPHIC COVERAGE:

5.1 Proposer must be in compliance with all federal, State, and local laws and regulations pertaining to certification rules as identified in the contract between the Wayne County Medical Health Plan and the State of Department of Medical Health, referred to as State or SDMH.

5.2 Services shall be delivered at the service delivery sites listed by Proposer. Proposer shall request approval from the CHRC Program Manager in writing a minimum of 30 days before terminating services at any of the location(s) listed before commencing services at any other location(s) not previously approved in writing by the CHRC Program Manager. All service delivery sites listed by Proposer must be operational within 30 days of the commencement of the contract.

5.4 Proposer shall have the capability to provide clinical laboratory services for all CHRC directly-operated medical health clinics/programs located within Wayne County's geographic boundaries. Proposer must provide clinical laboratory services, e.g., collecting samples for specific tests, performing tests, for clients in directly-operated medical health clinics/programs at a time scheduled by the clinics/programs and at laboratory service sites which are geographically accessible. The purpose of these laboratory service sites is to provide medical health clients with the alternative of going to a laboratory service site without an appointment. Clinical managers are to have a say as to when and where blood draws are to be done.

6.0 QUALITY CONTROL PLAN:

6.1 Proposer shall establish and utilize a comprehensive Quality Control Plan to assure that County procedures are in place for identifying and correcting clinical laboratory testing deficiencies; handling complaints and incident reports; and ensuring compliance with all requirements, County audits, and professional and legal standards. The Plan must be submitted to CHRC for review and approval. The Plan shall be effective on the contract start date and shall be updated and resubmitted for CHRC approval as changes occur. The Plan shall include:

6.1.1 Activities to be monitored, frequency of monitoring, samples of forms to be used in monitoring, title/level and qualifications of personnel performing monitoring functions.

6.1.2 Ensuring the services, deliverables, and requirements defined in the contract are being provided at or above the level of quality agreed upon by the County, CHRC and the Proposer.

6.1.3 Ensuring that professional staff rendering services under the contract has the necessary prerequisites.

6.1.4 Identifying and preventing deficiencies in the quality of service before the level of performance becomes unacceptable.

6.1.5 Taking any corrective action, if needed, including a commitment to provide to the County upon request a record of all inspections, the corrective action taken, the time the problem is first identified, a clear description of the problem, and the time elapsed between identification and completed corrective action.

6.1.6 Continuing to provide services to the CHRC in the event of a strike or other labor action of the Proposer's employees.

6.1.7 A record of all inspections conducted by the Proposer, any corrective action taken, the time a problem was first identified, a clear description of the problem, and the time elapsed between identification and completed corrective action, shall be provided to the CHRC upon request.

7.0 CONTRACT DISCREPANCY REPORT:

Verbal notification of a contract discrepancy will be made to the Contract Project Monitor as soon as possible whenever a contract discrepancy is identified. The problem shall be resolved within a time period mutually agreed upon by the CHRC and the Contractor. The CHRC Clinical Manager will determine whether a formal Contract Discrepancy Report (CDR) shall be issued. Upon receipt of this document, the Contractor is required to respond in writing to the CHRC Clinical Manager within five (5) business days, acknowledging the reported discrepancies or presenting contrary evidence. A plan for correction of all deficiencies identified in the CDR shall be submitted to the CHRC Clinical Manager within ten (10) business days.

8.0 CHRC/COUNTY OBSERVATIONS:

In addition to departmental contracting staff, other CHRC or County personnel may observe performance, activities, and review documents relevant to this contract at any time during normal business hours. However, these personnel may not unreasonably interfere with the Contractor's performance.

9.0 DATA COLLECTION:

Contractor shall have the ability to collect, manage, and submit data as directed by CHRC to demonstrate client outcomes inclusive of the guidelines set forth by CHRC and the State. Contractor shall perform data entry to support these activities.

10.0 PRIVACY AND ELECTRONIC SECURITY:

10.1 Proposer shall comply with federal and State laws as they apply to Protected Health Information.

10.2 Any Proposer that is deemed a "Covered Entity" under HIPAA shall comply with the HIPAA privacy and security regulations independently of any activities or support of CHRC or Wayne County.

10.3 Any Proposer that is deemed a "Business Associate" of County under HIPAA shall enter into a Business Associate Agreement with Wayne County to ensure compliance with the privacy and electronic security standards.

11.0 SUBCONTRACTOR(S):

11.1 If Proposer intends to employ a Subcontractor(s) to perform some of the services described in this SOW, the transmittal letter shall clearly indicate the other agency(s) involved, and Proposer shall clearly describe the role of the Subcontractor in the provision of clinical laboratory services in the Proposal Package. A statement from all Subcontractors indicating their willingness to work with the Proposer and the intent to sign a formal contract between the parties shall be submitted with the signature of the person authorized to bind the subcontracting organization.

11.2 If Proposer is selected for funding, Proposer shall obtain prior written approval from CHRC in order to enter into a particular subcontract and all requests must be in writing. Proposer shall remain responsible for any and all performance required of it under the contract.

11.3 All Subcontracting Agreements shall be required for CHRC review after award of the contract, if any.

12.0 GREEN INITIATIVES:

12.1 Contractor shall use reasonable efforts to implement "green" practices for environmental and energy conservation benefits.

12.2 Contractor shall notify CHRC's Clinical Manager of Contractor's new green initiatives prior to the contract commencement.

13.0 PERFORMANCE REQUIREMENTS SUMMARY:

13.1 Contractor to provide a Performance Requirements Summary (PRS)listing of services provided. PRS(s) are intended to be completely consistent with the contract and the SOW, and are not meant in any case to create, extend, revise, or expand any obligation of Contractor beyond that defined in the contract and the SOW. In any case of apparent inconsistency between services as stated in the contract and the SOW and the PRS, the meaning apparent in the contract and the SOW will prevail. If any service seems to be created in the PRS which is not clearly and forthrightly set forth in the contract and the SOW, that apparent service will be null and void and place no requirement on Contractor.

14.0 OUTCOME MEASUREMENT:

14.1 Contractor's ability to perform as required will be measured via the following methods:

14.1.1 Ongoing tracking of Contractor or client complaints pertaining to level of service provided by Contractor.

14.1.2 Ongoing monitoring and documentation of Contractor's billing inaccuracies by ACCESS/CHRC Accounts Payable Division.

14.1.3 Ongoing tracking of unauthorized laboratory orders processed by Contractor.

15.0 Terms of Occupancy (General):

15.1 Lease terms are based at an annual cost of $33,420 per year, or with monthly installments at $2,785 per month, and deemed as a Gross Lease. Lease duration to be one(1) year from inception date. Once terms are

mutually agreed upon by ACCESS and Contractor, a formal agreement shall be submitted and executed by both parties.

15.2 Vendor Selection Criteria will be based on the following:

15.2.1 Contractor providing laboratory services no less than five(5) years, and able to meet all requirements as outlined in the SOW.

15.2.2 Contractor pricing based on specific services, as well as total number of services provided.

15.2.3 Contractor maintains all licensures required by the State of Michigan and Department of Health Services.