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Approved By: Mohamad Khraizat	Title: Health Operations Manager
Signature: 	Date: 12-24-19

### I. POLICY

It is the policy of the Arab Community Center for Economic and Social Services- Community Health and Research Center (ACCESS-CHRC) to ensure that all medical personnel who are certified or licensed must be credentialed before assuming their duties at ACCESS.

### II. PURPOSE

The purpose of this policy is to define and detail the credentialing process maintained by the ACCESS CHRC.

### III. PROCEDURES

**A. HANDLING OF DONATED PHARMACEUTICALS:** It is the policy of ACCESS to provide for the safety of its patients through appropriate policies and careful handling of pharmaceutical products. In accordance with the Prescription Drug Marketing Act (PDMA) Sec. 203.39

- a. Donation of Drug Samples to Charitable Institutions, the following requirements will be followed by all ACCESS employees handling donated pharmaceuticals.
- b. All pharmaceuticals donated by a pharmaceutical company shall be received at ACCESS and dispensed to patients in original, unopened packaging with labeling intact. If the packing is not intact, they will not be accepted or dispensed.
- c. Delivery of donated pharmaceuticals will be by mail, common carrier, or an authorized agent of the donating pharmaceutical company.
- d. A donated drug sample shall not be dispensed to a patient until it has been examined by an ACCESS employee designated by the Medical Director to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following;
  - i. The drug sample is out of date;
  - ii. The labeling has become mutilated, obscured, or detached from the drug sample packaging;
  - iii. The packaging has been opened in such a way that the seal has been broken.
  - iv. The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;
  - v. The drug sample is for a prescription drug product that has been recalled or is no longer marketed; or

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- vi. The drug sample is otherwise possibly contaminated, deteriorated, or adulterated.
  - e. ACCESS shall dispose of any drug sample found to be unsuitable by destroying it or by returning it to the manufacturer.
  - f. ACCESS will store pharmaceuticals unopened under conditions that will maintain the sample's stability, integrity, and effectiveness, and will ensure that the pharmaceuticals will be free of contamination, deterioration, and adulteration.
  - g. ACCESS shall notify the FDA within 5 working days of becoming aware of a significant loss or known theft of prescription pharmaceuticals.
- B.** In addition, ACCESS has instituted the following guidelines for distribution of pharmaceuticals to patients.
- a. Providers will counsel patients concerning usage and side effects of pharmaceuticals which will be provided. Counseling will be documented in the medical record.
  - b. Each sample will be dispensed to the patient in its original packaging. If the seal is broken, the sample will be destroyed appropriately.
  - c. Each sample dispensed to a patient will be labeled with the patient's name, provider's name, date dispensed, and instructions for use.
  - d. Each sample dispensed will be documented in the patient record

#### **IV. COMPLIANCE WITH ALL APPLICABLE LAWS**

ACCESS Employees, interns and volunteers are bound by all applicable local, state, and federal laws, rules, regulations, and policies, all federal waiver requirements, state, and county contractual requirements, policies, and administrative directives in effect and as amended.

#### **V. LEGAL AUTHORITY AND REFERENCES**

Michigan Department of Community Health, Medicaid Provider Manual, Version October 1, 2014, Section 5.

Detroit Wayne Mental Health Authority, Peer Delivered and Operated Supports FY 13

#### **VI. EXHIBITS**

None