Purpose:
The purpose of this standard operating procedure for utilization of 340B Drugs in Public Health Clinics is to outline how the District Office and Health Department Clinics will assure compliance with the policy.

Procedure:
The District 2 Communicable Disease Coordinator is responsible for oversight of Policy # 223. This position will work with the District Drug Coordinator, applicable District Program Coordinators, and local County Nurse Managers to assure compliance with Policy # 223.

Initial training for the District Drug Coordinator and other staff working with 340B drugs will complete initial basic training via webinar on the 340B and Prime Vendor Programs at https://docs.340bpvp.com/apps/public/gps/gps.html and are provided updates by the State Office of Pharmacy Staff as the need is determined by the State. This training is conducted upon hire. Competency is verified by annual verbal assessment during protocol meeting held in May of each year. The Communicable Disease Coordinator is responsible for verification.

The primary contact for the 340B Program:

- Kristi Dabney – District 2 Drug Coordinator

The secondary contact for the 340B Program:

- Constance Martin, RN, Communicable Disease Coordinator

Enrollment, Recertification, Change Requests:

Recertification Procedure:
OPA requires entities to recertify their information as listed in the OPA database annually. Each Program’s Authorizing Official annually recertifies each clinic’s information by following the directions in the email sent from the OPA to each Program’s Authorizing Official by the requested deadline.

The District Communicable Disease Coordinator works with the State Office of Pharmacy and State Programs to provide information on each site annually for the recertification procedures.

Questions regarding recertification are submitted to: 340b.recertification@hrsa.gov
Enrollment Procedure:

District 2 Public Health works with the State Office of Pharmacy and Program Staff to evaluate a new service area or facility in the District to determine if the location is eligible for participation in the 340B Program. The criteria used include: service area must be within the scope of the grant/designation received by the covered entity that confers 340B patient definition.

If a new clinic opens in District 2 which meets this criteria, the Communicable Disease Coordinator works with the State Program Coordinator’s Authorizing Official to complete the online registration process during the registration window (January 1 – January 15 for an effective start date of 4/1; April 1 – April 15 for an effective start date of 7/1; July 1 – July 15 for an effective start date of 10/1; and October 1 – October 15 for an effective start date of 1/1). Follow the online registration below:

Enrollment Procedure: New Contract Pharmacy(ies):

District 2 does not utilize contract pharmacies for services.

Procedure to Change Programmatic Clinic Information on the OPA Database:

If there is any change in information or eligibility in a clinic database, the Communicable Disease Coordinator will notify the Programmatic Authorizing Official (STD, TB, or Family Planning) within 24 hours of this change. Once staff is aware that a clinic loses eligibility, purchasing will cease immediately.

If there is a change to a clinic’s information outside of the annual recertification time frame, the Communicable Disease Coordinator will work with the State Programmatic Authorizing Official to submit an online change request within 24 hours of being notified of the need for a change.

Prime Vendor Program Enrollment & Updates:

The District Drug Coordinator and Communicable Disease Coordinator will work with the State Programmatic Authorizing Official to assure appropriate updates and/or enrollments are completed in a timely manner.

1. Under the direction and approval of the State Program Authorizing Official, the clinic will complete an online 340B program registration with OPA.
2. The Office of Pharmacy will assist the clinic with the prime vendor program registration at https://www.340bpvp.com/register/apply-to-participate-for-340b/
3. The Prime Vendor Program staff will validate the information and send confirmation e-mail to the District 2 Communicable Disease Coordinator.
4. The District Drug Coordinator (primary contact) and the Communicable Disease Coordinator (secondary contact) will log onto the website at www.340bpvp.com to select a user name and password.
Procurement, Inventory Management, and Dispensing Procedure:

District 2 follows the State of Georgia, Public Health Drug Dispensing Procedure in order to procure and manage 340B drugs in all drug rooms in District 2.

1. Monthly, each county clinic submits their inventory of 340B drugs to the District Drug Coordinator.
2. Based upon inventory, the Drug Coordinator places 340B orders from Cardinal Health. This order is first approved by the State Office of Pharmacy.
3. Upon the arrival of the order from Cardinal Health, the Drug Coordinator checks the inventory in by examining and counting the order against the wholesaler invoice. Any discrepancy is reported to the State Office of Pharmacy immediately via phone and/or e-mail.
4. The inventory is distributed to the county clinics based upon their current inventory and needs.
5. RN’s and/or APRN’s operating under protocol signed by the District Health Director maintain a clinic drug room in order to dispense 340B drugs to patients according to Nurse Protocol and Drug Dispensing Procedure. District 2 does not refer patients to contract pharmacies.
6. The District Drug Coordinator maintains records of 340B transactions for a period of 2 years in a readily retrievable and auditable format located at the District Office. County Health Department Clinics maintain records of 340B transactions from the District office to the County Clinic for the current fiscal year and two prior fiscal years for auditing purposes.
7. 340B inventory is stored securely. Access is limited to designated clinical staff only. Refer to Drug Dispensing Procedure for specifics.
8. The District Drug Coordinator and Health Department clinic staff inventories the 340B drugs on a monthly basis and abides by all drug dispensing procedure requirements. Any discrepancies are reported to immediate supervisors.

Reimbursement Procedures:

District 2 clinics do not bill third party payors for STD drugs or TB drugs (Medicaid or private pay insurance).

District 2 clinics bill Medicaid for reimbursement for the long acting reversible contraceptives (LARC methods which include the intrauterine devices and implants) and for Depo Provera at current Medicaid pricing. Oral contraceptives for patients who have Medicaid or another third party payor are called to the patient’s pharmacy of choice.

Monitoring and Reporting:

District 2 clinic sites utilize the attached “340B Compliance Self-Assessment: Self Audit Process” on an annual basis to assure compliance with the 340B Policies and Procedures.

The District 2 Quality Assurance Team makes site visits to clinic sites on a bi-annual basis to review programs, drug rooms, protocols, and procedures.
Reporting and Non-Compliance:

District 2 clinics utilize the 340B Compliance Tool on the frequency basis recommended to assure compliance with the 340B rules and regulations. Any discrepancy will be reported immediately to the District Drug Coordinator and District Communicable Disease Coordinator. The District Director of Nursing and State Office of Pharmacy and appropriate State Program Coordinator/Authorizing Official will be notified within 24 hours of corrective action.