

**DISTRICT 2 PUBLIC HEALTH
POLICY # 223
POLICY FOR USE OF 340B DRUGS IN DISTRICT 2 PUBLIC HEALTH CLINICS**

1.0. PURPOSE

The purpose of this policy is to maintain compliance with the Federal 340B Program in order to properly utilize these drugs in District 2 Public Health Clinics.

1.1 AUTHORITY – 340B mandates and guidelines are established under Public Law 102-585, Section 602, 340B Guidelines, and 340B Policy Releases.

2.0 SCOPE

This policy applies to all employees of District 2 Public Health in TB, STD and RW programs and are reviewed yearly. TB, STD and RW qualify due to GIA status.

3.0 POLICY

It is the policy of District 2 Public Health to comply with all components of the Federal 340B Program in order to serve eligible patients who participate in STD, TB and RW Clinics. In order to comply with this policy, the following statements apply to all County Health Department clinics and Programs:

- 3.1 The District Office Drug Coordinator and Communicable Disease Coordinator will work with the State Office of Pharmacy and appropriate State Programs in order to obtain pharmaceuticals at best prices in the 340B Program.
- 3.2 The District 2 Drug Coordinator and Communicable Disease Coordinator will work with the State Office of Pharmacy to assure all County Health Departments meet 340B Program eligibility requirements.
- 3.3 The District Office Drug Coordinator and Communicable Disease Coordinator will assure that the Health Department Clinics OPA Database covered entity listing is complete, accurate, and correct, as designated in the annexes for each Program.
- 3.4 District 2 clinics will comply with all requirements and restrictions of 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the covered entity.
- 3.5 District 2 clinics will maintain auditable records demonstrating compliance with 340B requirement as described in the preceding bullet. Clinics utilize the

Mitchell and McCormick (M & M) visual health net (VHN) system to document patient visits.

3.6 Clinic nurses will work under protocol signed by the District Health Director.

3.7 District 2 clinics bill Medicaid FFS and CMO's programmatically as follows:

- STD program - When billing Medicaid FFS or CMO 340B medications will be billed at acquisition cost. Self pay patients are billed according to income.
- TB Program—Do not bill for medication
- RW Program- Do not bill for medication

Please see the Georgia Public Health Billing Manual found at http://dch.georgia.gov/sites/dch.georgia.gov/files/GA_Department_of_Public_Health_Billing_Resource_Manual.pdf The revenue generated is returned to the programmatic budget as per federal guidelines outlined in 45 (Code of Federal Regulations) CFR 92.25 (g) (1-3)- Program Income.

3.8 A yearly inventory, as mandated by the State Office of Pharmacy will be conducted on the last day of each fiscal year and submitted to the State Office as proscribed. 3.9 The Communicable Disease Coordinator will work with the State Office of Pharmacy and other programs to contact personnel at the 340B Program in the event clinic eligibility changes or if there is a material breach.

3.10 Health Department clinics acknowledge that if there is a breach of the 340B requirements, they may be liable to the manufacturer of the covered outpatient drug(s) that is the subject of violation, depending on the circumstances, may be subject to the payment of interest and/or removal from the list of 340B eligible entities.

Approval:		
	District Health Director/Appointing Authority	Date

REVISION #	REVISION DATE	REVISION COMMENTS
0	1/1/15	Initial Issue
1	7/15/15	Billing Revision
2	5/1/2016	Reviewed for Protocol

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Use of 340B Drugs in Public Health Clinics

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**STANDARD OPERATING PROCEDURES FOR UTILIZATION OF 340B DRUGS IN
PUBLIC HEALTH CLINICS - DISTRICT 2
POLICY # 223**

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 340B U On Demand at <https://www.apexus.com/solutions/education/340b-u-ondemand> 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:

- District 2 Drug Coordinator

The secondary contact for the 340B Program:

- 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

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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:

<http://openet.hrsa.gov/opa/CERegister.aspx?mode=opf&isnew=true>

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 data base, the Communicable Disease Coordinator will notify the Programmatic Authorizing Official (STD, TB or RW) within 24 hours of this change. Once staff is aware that a clinic loses eligibility, purchasing will cease immediately and any remaining 340B product purchased under that Covered Entities ID will be identified and returned to the wholesaler or manufacturer for credit if allowable or returned for destruction.

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.

Procedure for Medicaid Exclusion File Information:

- TB- Does not bill Medicaid
- RW-Does not bill Medicaid
- STD- District 2 elects to "Carve In" Medicaid

For programs in which Medicaid is billed, to prevent duplicate discounts, and ensure the database listing is consistent with actual practice the Medicaid Exclusion File (MEF) is reviewed and updated as appropriate to include:

- OPA database and MEF checked
 - Quarterly
 - During annual recertification
 - When changes are made
- All entity Medicaid and NPI numbers are listed that are used to bill Medicaid for 340B drugs, including multiple state Medicaid numbers if applicable
- The Medicaid Exclusion file is downloaded the first business day of the quarter and to ensure that District 2 clinics are listed, if not listed then the clinic site for that quarter will not bill Medicaid and an investigation to determine a corrective action will occur.

Prime Vendor Program Enrollment & Updates:

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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 (http://dph.georgia.gov/sites/dph.georgia.gov/files/related_files/site_page/4.0%20Drug%20Dispensing%20Procedure_FINAL_2014.pdf) in order to procure and manage 340B drugs in all drug rooms in District 2. All registered professional nurses or physician's assistants who dispense dangerous drugs and/or devices under the authority of an order issued in conformity with a nurse protocol or job description and as an agent or employee of the Department of Public Health or any county board of health, shall meet the same standards and comply with all record-keeping, labeling, packaging, storage and all other requirements for the dispensing of drugs imposed upon pharmacists and pharmacies with regard to such drugs and/or devices, as outlined by the following dispensing procedure. This procedure applies to all drugs and devices within the district, whether purchased through state or local funds. The Pharmacy Director for the Department of Public Health, or a qualified designee, may make periodic on-site visits to health districts and/or local health departments to provide technical assistance and review drug use, storage and handling.

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

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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:

For Programs in which District 2 bills Medicaid, District 2 will adhere to the State Medicaid policy regarding billing for 340B. The Georgia Medicaid Provide Manual is located at www.mmis.georgia.gov/portal/

- STD: When billing Medicaid FFS or CMO 340B medications will be billed at acquisition cost. Self-pay patients are billed according to income.
- TB: Do not bill for medication.
- RW: Do not bill for medication

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. The tool can be found at: http://dph.georgia.gov/sites/dph.georgia.gov/files/QA_QI%20Manual%20Final_2015.pdf

Reporting and Non-Compliance:

District 2 clinics utilize the 340B Compliance Tool yearly 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.

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Procedure for 340b Pricing Changes on a Quarterly basis

Quarterly, the following staff members meet to discuss the current 340b pricing:

- Infectious Disease and Immunization Coordinator
- Program Associate and Drug Coordinator
- APRN, Women's Health Coordinator
- Operations Analyst
- APRN, District Nursing Director

District 2 staff receives an e-mail from the State Pharmacy Procurement and Financial Manager, Division of Health Protection/Office of Pharmacy, notifying the District of Apexus 340B drug price list for contraceptives. The PVP pricing sheet is used as a monitoring tool to assist in assuring the 340B price was loaded correctly onto the District's wholesaler account. District staff, as stated above, meets to determine the need to change pricing based upon the most current invoices for that quarter. Meetings occur in July, October, January, and April.

The Drug Coordinator provides listed on the current PVP spreadsheet. The prices are compared to the most recent invoices received. If prices appear to be significantly different, then the State Office of Pharmacy is notified and the wholesaler is contacted to investigate and ensure that the current 340B price is attached to the account. Prices are adjusted in the M & M to match the current 340B invoiced price. The M & M system is District 2's electronic system by which we maintain patient encounters (electronic medical record) and billing information.

The Operations Analyst in the Technology Department takes the most recent pricing and changes the M & M system to reflect the prices for the quarter.