

**DISTRICT 2 PUBLIC HEALTH
POLICY # 223
POLICY FOR USE OF 340B DRUGS IN DISTRICT 2 Ryan White 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 RW programs and is reviewed yearly. RW qualifies 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 RW Clinics. In order to comply with this policy, the following statements apply to all Ryan White Programs:

- 3.1 The District Office Drug Coordinator and Ryan White Coordinator will work together in order to obtain pharmaceuticals at best prices in the 340B Program.
- 3.2 The District Office Drug Coordinator and Ryan White Coordinator will assure that the Ryan White Clinics OPA Database covered entity listing is complete, accurate, and correct, as designated in the Part C Program Guidelines and the Part B annex.
- 3.3 District 2 RW 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.
- 3.4 District 2 RW 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.
- 3.5 Clinic nurses will work under protocol signed by the District Health Director.
- 3.6 District 2 RW clinics 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.

- 3.7 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 Ryan White 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.
- 3.8 Ryan White 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

**STANDARD OPERATING PROCEDURES FOR UTILIZATION OF 340B DRUGS IN Ryan
White 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:

Both the District 2 Communicable Disease Coordinator and the Ryan White Coordinator is responsible for oversight of Policy # 223. This position will work with the District Drug Coordinator to assure compliance with Policy # 223.

Initial training for the District Drug Coordinator and other staff working with 340B drugs will be to complete initial basic training via 340B U On Demand at <https://www.apexus.com/solutions/education/340b-u-ondemand>. Updates are provided 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 Ryan White Coordinator is responsible for verification.

The primary contact for the 340B Program:

- District 2 Drug Coordinator

The secondary contact for the 340B Program:

- Ryan White 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 Ryan White 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 Ryan White 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://opanet.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 Ryan White Coordinator will notify the Programmatic Authorizing Official 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 Ryan White Coordinator will work with the 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:

- RW-Does not bill 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:

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

1. Under the direction and approval of the 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 Ryan White Coordinator.
4. The District Drug Coordinator (primary contact) and the Ryan White 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. Based upon inventory, the Drug Coordinator places 340B orders from Cardinal Health.
2. 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.
3. The inventory is distributed to the RW clinics based upon their current inventory and needs.
4. 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.
5. 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. Ryan White Clinics maintain records of 340B transactions from the District office to the RW Clinic for the current fiscal year and two prior fiscal years for auditing purposes.

Policy # 233

Use of 340B Drugs in Public Health Clinics

District 2

Effective 1/1/15

Revised 7/15/15

Reviewed 5/16

6. 340B inventory is stored securely. Access is limited to designated clinical staff only. Refer to Drug Dispensing Procedure for specifics.
7. The District Drug Coordinator and the RW 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 Provider Manual is located at www.mmis.georgia.gov/portal/

- RW: Does not bill for medication

Monitoring and Reporting:

District 2 RW 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 RW 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 the Ryan White 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.

Procedure for 340b Pricing Changes on a Quarterly basis

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

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

November 14, 2017

Greetings County Nurse Managers,

As most of you probably already know, this year the VFC Recertification Process will be done entirely in GRITS in the local health department.

Your immunization nurse has already updated the contact information for both the primary and secondary contact. All correspondence between GRITS and the provider will be via email to your primary and secondary contact.

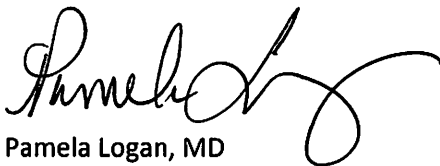
The recertify button will be activated on 11/14/17. There will be step by step instructions provided at that time.

At the end of the process, a page will come up that begins: "I certify that I am the Medical Director and I am electronically signing my name and a signature below"

In the past, this was done by paper and you sent them to the district office for the Medical Director to sign and we mailed them all into the proper location.

This year, Dr. Logan, has given proxy to the County Nurse Manager to review the process and sign Dr. Logan's name electronically.

By giving the County Nurse Manager proxy, Dr. Logan understands that your clinic is agreeing to the terms of the VFC Provider Agreement and the storage and handling of vaccines.

A handwritten signature in black ink, appearing to read "Pamela Logan". The signature is fluid and cursive, with a large loop at the end.

Pamela Logan, MD

Health Director/District 2 Public Health