COUNTY BOARD OF HEALTH
POLICY # CL-223
USE OF 340B DRUGS IN RYAN WHITE CLINICS

Approval:		3.25.22
	District Health Director	Date

1.0 PURPOSE

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

2.0 AUTHORITY

The County Board of Health Use of 340B Drugs in Ryan White Clinics Policy is published under the authority of the County Board of Health (CBOH) and in compliance with the following:

2.1 Public Law 102-585, § 602

2.2 340B Guidelines

2.3 340B Policy releases

3.0 SCOPE

3.1 This policy applies to all employees of District 2 Public Health in RW Programs. RW qualifies due to GIA status.

3.2 Initial training for the District 2 RW staff working with 340B drugs will be to complete training at the 340B University on Demand found at: https://www.340bpvp.com/340b-university/online-learning and the additional Modules found at: https://education.apexus.com/#/login. The training is required upon hire and through protocol updates held by the District Nursing Director. The RW Coordinator is responsible for ensuring staff complete initial training and attend the protocol updates conducted by the District Nursing Director staff.

3.3 The primary contact for the 340B program is the District Nursing Director.

3.4 The secondary contact for the 340B program is the Assistant District Nursing Director.

3.5 Upon unavailability, the third contact for the 340B program is the District 2 Program Manager for the RW program.

4.0 POLICY

It is the policy of District 2 Public Health to comply with all components of the Federal 340B Drug Program in order to serve eligible patients who participate in RW Clinics. To comply with this policy, the following statements apply to all Ryan White Programs:

4.1 The District Office Drug Coordinator and Ryan White Coordinator will work together to obtain pharmaceuticals at best prices in the 340B Program.

4.2 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.

4.3 District 2 Ryan White Clinics will comply with all requirements and restrictions of the 340B Drug Program as part of the requirements under the Ryan White CARE 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.

4.4 District 2 Ryan White Clinics will maintain auditable records demonstrating compliance with 340B requirements as described in the preceding bullet. Clinics utilize the Mitchell and McCormick (M & M) visual health net (VHN) system to document patient visits.

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

4.6 District 2 Ryan White clinics do not bill for medication. Please see the Georgia Public Health Billing Manual found at: http://dch.georgia.gov/sites/dch.geogia.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.

4.7 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 if 340B drugs are utilized by the District 2 Ryan White program.

4.8 The Ryan White Coordinator will work with the State Office of Pharmacy and other programs to contact personnel at the 340B Drug Program in the event clinic eligibility changes or if there is a material breach.

4.9 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.

5.0 ENROLLMENT, RECERTIFICATION, OR CHANGES

Currently, the Ryan White Program within District 2 does not utilize 340B drugs.

5.1 The Office of Pharmacy Affairs 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 sent to them through an email.

5.2 The District Nursing Director works with the District Program Manager and the RW Coordinator and State Office of Pharmacy to provide information on each site annually for the recertification procedures. Questions regarding recertification are submitted to: 340b.recertification@hrsa.gov

5.3 If there is any change in information or eligibility in a clinic data base, the RW Coordinator will notify the Programmatic Authorizing Official within 24 hours of the change. Once staff is aware that a clinic has lost 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.

5.4 If there is a change to a clinic's information outside of the annual recertification time frame, the RW 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.

6.0 PROCUREMENT, INVENTORY MANAGEMENT, AND DISPENSING PROCEDURES:

6.1 District 2 follows the State of Georgia, Public Health Drug Dispensing Procedure file:///C:/Users/amstratton/Downloads/4.0%20Drug%20Dispensing%20Procedure_FINAL2014.pdf and nurse protocols https://dph.georgia.gov/clinical-services/office-nursing/nurse-protocols-and-quality-assurancequality-improvement 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 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 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 or local health departments to provide technical assistance and review drug use, storage, and handling.

6.2 The process is as follows:

6.2.1 Monthly, each county clinic submits their inventory of 340B drugs to the District Drug Coordinator.

6.2.2 Based upon the inventory and approval from the State Office of Pharmacy, the District Drug Coordinator places an order for 340B drugs.

6.2.3 Upon delivery of the drug order, the District Drug Coordinator checks the inventory by examining and counting the order against the wholesaler invoice. Any discrepancies are reported immediately to the State Office of Pharmacy by phone or email.

6.2.4 The inventory is then distributed to the RW clinic based upon their current inventory and need.

6.2.5 RN's or APRN's operating under nursing protocol signed by the District Health Director maintain a clinic drug room to dispense 340B drugs to patients according to nursing protocol and drug dispensing procedures. District 2 RW Program does not currently utilize 340B medications.

6.2.6 The District Drug Coordinator maintains records of 340B transactions for a period of two years in a readily retrievable and auditable format located at the District Office. RW 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.

6.2.7 Access to 340B inventory is limited to designated clinical staff only and 340B medications are stored in a secure area.

6.2.8 When and if applicable, the District Drug Coordinator and the RW designated clinic staff inventory the 340B drugs monthly and abide by all drug dispensing procedure requirements. Any discrepancies are reported immediately to the RW Coordinator, Program Manager and District Drug Coordinator.

7.0 REIMBURSEMENT

District 2 RW Program does not bill Medicaid

For programs in which District 2 bills Medicaid, District 2 will adhere to the State Medicaid Policy regarding billing for 340B.

8.0 MEDICAID EXCLUSION FILE INFORMATION

For programs in which District 2 bills Medicaid, District 2 reviews the Medicaid Exclusion File (MEF) to prevent duplicate discounts and to ensure the database listing is consistent with actual practice. This takes place:

a. Quarterly

b. During annual recertification

c. When changes are made

d. To verify appropriate NPI numbers are listed

e. To verify District 2 clinics are listed eligible to bill Medicaid

9.0 MONITORING AND REPORTING

9.1 District 2 RW will utilize the attached "340B Compliance Self-Assessment: Self Audit

Process" on an annual basis if 340B drugs are utilized to assure compliance with the 340B Policies and Procedures. (See Attached)

9.2 District 2 RW will utilize the 340B Compliance Tool yearly to assure compliance with the 340B rules and regulations when 340B drugs are utilized in the clinic. Any discrepancy will be reported immediately to the RW Coordinator, Program Manager, and District Pharmacy Coordinator. The District Nursing Director, Assistant Nursing Director, District Health Director, State Office of Pharmacy, and appropriate State Program Coordinator for RW will be notified within 24 hours of corrective action.

9.3 On a quarterly basis, the appropriate District 2 staff receive an email from the State Pharmacy Procurement and Financial Manager, Division of Health Protection/Office of Pharmacy, notifying the District about Apexus 340B drug pricing and list of drugs. The pricing sheet is used as a monitoring tool to assist in assuring the 340B price was loaded correctly onto the District's wholesaler account.

9.4 As a result, the appropriate District 2 staff meet to determine the need to change pricing based upon the most current invoices for that quarter.

9.4.1 Meetings are to occur quarterly in July, October, January, and April.

9.4.2 The following staff make up the District 2 340B Drug Inventory and Compliance Team:

1. District Health Director
2. District Administrator
3. District Nursing Director
4. District Assistant Nursing Director
5. District Drug Coordinator
6. District Program Manager
7. District IT Manager
8. Women's Health Program Coordinator
9. Ryan White Coordinator
10. TB Program Coordinator

9.5 The appropriate District 2 staff provides the 340B Drug Inventory and Compliance Team a list with the current prices and a list with the most up-to-date/recently released prices for comparison. If the prices appear to be significantly different, the State Office of Pharmacy is notified and the wholesaler is contacted to investigate and ensure the current 340B price

is attached to the account. The District IT Manager and District Pharmacy Coordinator work together to adjust the prices in the M&M system (the Districts electronic medical record and billing system).

10.0 REVISION HISTORY

REVISION #	REVISION DATE	REVISION COMMENTS
1	7/15/2015	Billing Revision
2	5/2016	Reviewed
3	2/10/2022	Revised

11.0 RELATED FORMS

340B Compliance Self-Assessment: Self-Audit Process A Quick Self-Assessment for the DIC Team pgs. 1-6

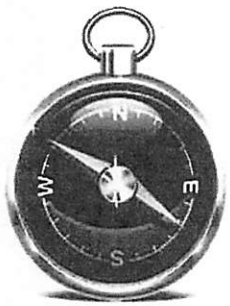
3408 Compliance Self-Assessment: Self-Audit Process

A Quick Self-Assessment for DSH Leaders

Purpose: The purpose of this tool is to provide a sample internal 340B audit process to assist disproportionate share hospital (DSH) leaders subject to the GPO Prohibition in conducting a self-audit to promote 340B program integrity.

Instructions:

1. Identify staff/other participants necessary for the self-audit and set a timeframe.
2. Gather the data listed in Table 1.
3. Select a sample using the criteria listed in Appendix 1.
4. Perform an assessment of the data by following the assessment criteria in Table 1.
5. Ask the 340B audit interview questions in Appendix 2 to entity staff participating in the self-audit.
6. Review self-audit results and correct any area not meeting the assessment criteria. If you need help, contact Apexus Answers (ApexusAnswe rs@340bpvp.com), who will provide assistance or connect you with a resource that can provide help.
7. Incorporate this practice into organizational/departmental policies and procedures.
8. Repeat at regular intervals and maintain records of all self-assessment activity.



Are you on the way to 3408 program integrity?

This tool will help you find out!

Table 1. Audit Procedures - Data Assessment

Data	Assessment Criteria
Policies, Entity Eligibility, HRSA 340B Database	
1. All policies and procedures related to 340B	☐ Policies include relevant criteria from entity's 340B pharmacy program Policy and Procedure Manual.
2. Data policies for any vendor software-e.g., wholesaler, split-billing	☐ Policies are identified, current, and signed.
3. Most recently filed Medicare cost report worksheets: • A • C • E, Part A • S • S2	☐ *Worksheet* A: All clinics participating in 340B are listed as reimbursable. ☐ Worksheet C: All clinics participating in 340B have associated outpatient charges (column 7). ☐ *Worksheet E. Part* A: Line 33 shows a number >11.75%. ☐ *Worksheet* S: The signature block showing the official time/date of submission should be consistent with the addition or removal of any clinics from the HRSA 340B Database. ☐ *Worksheet* S2: Line 21 should be consistent with the type of hospital control indicated at registration, Lines 3-19 will list sites that are on the cost report with a unique identifier (e.g., rural center/skilled nursing).
4. Copies of any contracts with state or local government to provide health care services to low-income individuals	☐ Contract is signed by an official authorized to bind the government. ☐ The original date of the agreement predates the 340B registration date on the HRSA 340B Database (or is effective at date of registration). ☐ The contract is for the care of indigent patients and is in force.
5. Copy of 340B contract(s) with pharmacies and/or other 340B service provider(s)	☐ Contract(s) align with all criteria in the Final Notice Regarding 340B Drug Pricing Program: Contract Pharmacy Services
6. Medicaid ID Number, Provider Number, or NPI for all entity sites billing Medicaid for 340B drugs, and point of contact with state Medicaid agency	☐ Medicaid billing information in the HRSA 340B Database for all entity sites is (1) accurate and complete, (2) based on current state policy requirements, and (3) reflects current actual practices by the entity.
Drug Transactions	
Transaction Samples: 7. Ensure that each 340B service area (main pharmacy, outpatient clinics, contract pharmacy, retail pharmacy, etc.) is included in the sample. 8. Identify a 6-month continuous time frame within the prior year. 9. Select two samples of approximately 25 transactions each[1]: a. Sample #1: 3-5 high-cost drugs b. Sample #2: Medicaid transactions	☐ The entity maintains records of the patient's health care. ☐ The patient received health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. ☐ The provider-entity relationship is substantiated by contract/em(2loyment/other records per clinic site.

[1] See Appendix 1 for suggested data elements.

Data	Assessment Criteria
	☐ The prescription was from a provider NPI matching the eligible provider list at the time of prescribing. ☐ If 340B drugs are used for referral prescriptions, a policy is accessible and in operation. ☐ The patient had outpatient status at the time of the 340B drug administration/dispensing. ☐ The patient received health care services from the parent entity or at an outpatient clinic that is reimbursable on the hospital's most recently filed Medicare cost report and registered on the HRSA 340B Database. ☐ A group purchasing organization (GPO) was not used to purchase covered outpatient drugs in 340B registered areas per policy release criteria here. ☐ If using 340B for Medicaid, the wholesaler invoice price for a specific NOC on a specific date matches the reported billing cost from dispensing/administration records for Medicaid. Note: ☐ May need to convert from units to quantity dispensed. ☐ May need to look at the prior quarter's pricing due to delays in quarterly price fluctuations. ☐ Costs may not match if the DSH doesn't bill payer at cost; this should be explained. ☐ The entity pays for, owns, and receives reimbursement for 340B drugs (especially in a contract pharmacy situation). ☐ If using 340B to bill for Medicaid patients, the entity has information and documentation to support the policy that Medicaid does not seek a rebate on any 340B drug (e.g., Fee for Service (FFS) or Managed Care{, MCO), and physician-administered drugs), including: ☐ Citations from state regulations, policy, or provider manual ☐ Documented discussion/engagement with Medicaid to ensure prevention of duplicate discounts ☐ If state Medicaid does not have a 340B policy to exclude 340B claims from rebate requests, the entity does not use 340B for Medicaid prescriptions.

Data	Assessment Criteria
10. Starting inventory balance at beginning of sample timeframe and end of sample timeframe, an accounting of all inventory (3408 , GPO, non-**GPO/WAC, etc.)**	☐ 3408 drugs are not resold or transferred to a non-patient. D The entity is able to provide an accounting for disposition of all inventory in the selected sample. D The DSH has separate purchasing usage/records for 340B and GPO. D Expired or unused 340B drugs are returned to the wholesaler or destroyed (not donated/diverted).

Appendix 1: Suggested Data Elements for Audit Sample

Specific Data Elements for Transactional Sample

1. An identifying number (prescription number or any other prescription tracking number)
2. Admission and discharge date and time (source might be ADT system or other hospital data source)
3. Date of service (date entity's health care professional provided services to patient, resulting in the 340B Rx)
4. Service type-hospital location associated with health care service (clinic code or other identifying element); this may be two separate data elements (clinical service received location and prescription dispensing location)
5. Date and time the drug was dispensed/administered
6. Hospital identification number (often hospital billing number, used to look up insurer of record)
7. Item number (used in identifying actual drug)
8. NOC number
9. Item description (often from pharmacy system)
10. Prescriber name (prescribing health care professional)
11. 340B price paid
12. Drug charge (hospital's charge-full price, the amount billed to any insurer, including co-pays)
13. Dispensing fee (if any)
14. Amount paid by the payer
15. Payer (private third party, cash, Medicare, Medicaid, etc.)
16. Medicaid ID (transaction number and/or other identifying number)

General Data Elements

1. Proof of provider-entity relationship (contract/employment records, referral documentation, other)
2. Eligible provider list for entity (including credentialed and per diem: name, NPI, date of eligibility/termination, assigned clinics and contracts/employment/referral/other documents)
3. Hospital wholesaler account(s) list, description of accounts (340B, inpatient GPO, Non-GPO/WAC, etc.)
4. NCPDP number (if applicable, for retail pharmacies)
5. Description of hospital definitions used for outpatient and covered outpatient drugs
6. A list of hospital centers eligible for 340B
7. Current drug price list

Appendix 2: Sample 3408 Staff Interview Questions

Financial Management

1. On forms U8-04/837I and CMS-1500/837P, what is the price billed to Medicaid? (340B/AAC/other?)
2. How did you identify areas eligible for 340B?
3. What level of confidence do you have in your entity's compliance with the 340B program?
4. What questions do you have about the 340B program?
5. Describe reports you use to ensure that your entity complies with preventing duplicate discounts.
6. Describe 340B internal audits performed.

Pharmacy Director

1. How often are your 340B policies and procedures updated?
2. What level of confidence do you have in your entity's compliance with the 340B program?
3. Describe 340B internal audits performed.
4. Who has access to update the entity's current health care professional list (for 340B)?
5. How do you define "outpatient" at your institution for 340B purposes?
6. Explain how you handle referral prescriptions.
7. What are your major compliance concerns?
8. Describe the three most critical reports you review concerning 340B.
9. How do you know that your independent agreements on pharmaceutical solutions, and contrast media do not violate the GPO Prohibition?
10. Describe your split-billing software. Walk through what you do when there is a discrepancy in data.
11. What types of wholesaler accounts do you have for outpatient drug purchases?

Purchasing Coordinator

1. How many wholesaler accounts do you purchase from?
2. What is your role in maintaining 340B compliance?
3. Describe the process for transferring items between 340B and GPO on an emergency basis.
4. For a multi-dose item, how is the product accumulation accounted for, regarding replenishment of a full package size?
5. Expired medications:
   a. What is the process for their disposition?
   b. What records do you provide to the return company to ensure that the 340B price is credited?

Hospital Administration

1. What level of confidence do you have in your entity's compliance with the 340B program?
2. What is the intent of the 340B program, and how does your entity use 340B programs savings?