COUNTY BOARD OF HEALTH
POLICY # CL- 224
STD 340B STANDARD OPERATING PROCEDURES

Approval:	District Health Director	4.14.22 Date

1.0 PURPOSE

This document contains descriptions of the policies and procedures used at District 2 Public Health (D2PH) STD Clinics to maintain compliance with the 340B Program.

2.0 DEFINITIONS

Definitions of terms may be found in [Appendix B: 340B Glossary of Terms]. STD: Covered outpatient drugs for the STD program must be within the scope of service of the grant and provided to patients of D2PH. The STD nurse protocol provides for covered outpatient drugs that can be issued by those operating under the Nurse Protocol Manual. In cases where the drug is being prescribed by the MD or APRN with prescriptive authority, the drug must be within the scope of the grant.

3.0 REFERENCES

Georgia Department of Public Health (DPH) Standard Operating Procedures for STD 340B, 340B Glossary of Terms, Office of Pharmacy Affairs (OPA) website, Georgia Department of Public Health Office of Nursing: Nurse Protocols for Registered Professional Nurses in Public Health, and District Drug Dispensing Manual.

4.0 POLICY REVIEW, UPDAES AND APPROVAL

This policy will be reviewed, updated, and approved annually by the District Health Director, District Administrator, and the Director of Nursing whenever there is a clarification, or change in the rules, regulations or guideline to the 340B Program requirements.

5.0 BACKGROUND

5.1 Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services.

5.1.1 This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

5.2 The 340B Program is administered by the Federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

(OPAIS) as a participant in the 340B Program, NGHD:

5.3.1 Agrees to abide by specific statutory requirements and prohibitions;

5.3.2 May access 340B drugs.

6.0 340B POLICY STATEMENTS:

As a participant in the 340B Drug Pricing Program, D2PH STD Clinic's policies are:

6.1 STD Clinic personnel use any savings generated from local purchases from 340B in accordance with 340B STD program intent which may include trainings and/or personnel.

6.2 STD Clinics meet all 340B program eligibility requirements as defined in this internal program policies.

6.3 D2PH STD Clinic's OPA Database covered entity listing is complete, accurate, and correct and STD Clinics receive a grant or designation consistent with that conferring 340B eligibility. The program grant is accessible electronically through PHIL (Public Health Info Links) website.

6.4 D2PH complies with all requirements and restrictions of Section 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. [REFERENCE: Public Law 102-585, Section 602, 340B Program Requirements, 340B Policy Releases]

6.5 D2PH maintains auditable records demonstrating compliance with the 340B requirements described in the preceding bullet.

6.6 Prescribers in the STD programs are employed by the covered entity, or under contractual or other arrangements with the covered entity, and the individual receives a health care service (within the scope of grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with the covered entity. In the event a patient becomes inactive in the program, 340B drugs will immediately be discontinued and a discontinue form will be sent by the county clinic to the District Infectious Disease Coordinator. [Drug Dispensing Manual and signature sheets are located online.] The current list of Prescribers, APRN's, and RN's operating under the nurse protocol statue is kept on file. D2PH clinics and District Pharmacy / Drug inventory and compliance staff use the Mitchell and McCormick electronic system for maintenance of pharmacy and clinic inventory and dispensing or issuing of STD medications. Drug inventory reports are done monthly and compared with physical count. Corrections are printed in hard copy along with explanation and kept in the pharmacy / drug room or clinic for 2 years. 340B stock meds are not combined with other inventories in the drug room. Each inventory is properly labelled.

6.7 D2PH STD Clinics may bill Medicaid for 340B drugs following state guidelines. This information is accurately reflected on the OPA website / Medicaid Exclusion File.

6.7.1 D2PH Pharmacist / Drug Coordinator / or District Health Director the DPH STD Authorizing Officials will notify OPA immediately of any changes on the OPA website / Medicaid Exclusion File.

6.7.2 Medicaid reimburses STD Clinics for 340B drugs per state policy and does not collect rebates on claims from STD Clinics. (State Medicaid Manual)

6.8 STD Clinics have systems / mechanisms and internal controls prepared to reasonably ensure ongoing compliance with all 340B requirements. A self-audit tool shall include monthly inventories, dispensing records, and are completed and reviewed annually by designated 340B committee member(s). Programmatic audits conducted annually at a minimum by STD managers and satisfy patient eligibility requirements.

6.9 STD Clinics acknowledge their responsibility to contact the District Pharmacist / Drug Coordinator and compliance staff, the State Office of Pharmacy, the DPH State STD Director to coordinate the contact to OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach (i.e., Nonqualified patient receives 340B meds, noncontract physician on records, inadequate patient record) by the STD Covered entity of any of the foregoing policies. A material breach affecting 5 percent or less of clinic patients in a volume sample of the previous thirty-day period in a specified D2PH county would, upon discovery, require that corrective action immediately take place. If more than 5 percent are affected, this would immediately be corrected and reported to HRSA.

6.10 STD Clinics acknowledge that if there is a material breach of the 340B requirements, STD Clinics may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

6.11 STD Clinics elect to receive information about the 340B program from trusted sources, including, but not limited to, the following:

- The Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA)
- The 340B Prime Vendor Program, managed by Apexus

6.12 STD Clinics use contract pharmacy services (if applicable). The contract pharmacy arrangement is performed in accordance with HRSA requirements and guidelines including, but not limited to, the following:

- The STD Clinics obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements.

- The STD Clinics has used an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism).

- The signed contract pharmacy services agreement(s) complies with 12 contract pharmacy essential compliance elements (http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf).

7.0 RESPONSIBLE STAFF, COMPETENCY

STD Clinic's staff are engaged with 340B program compliance. All clinical staff member(s) must complete initial basic training via webinar on the 340B and Prime Vendor Programs (https://www.340bpvp.com/340b-education/ondemand-curriculum) and attend 340B University, University OnDemand (https://www.apexu.com/solutions/education/340b-u-ondemand), or State Office of Pharmacy training every 2 years on the even year. This training will be confirmed by the employee's supervisor and submitted to the District. Initial comprehensive training is conducted upon hire for clinical staff through online training. Competency is verified annually by the County Nurse Manager through verbal assessment. [The following staff is not specific for all entities and not all inclusive.]

7.1 District Pharmacist and District Drug Director: Responsible for the procurement, distribution, and inventory control of District STD drugs

7.2 Infectious Disease Educator: Follow 340-B guidelines as outlined in the Public Health Master Agreement Annex

7.3 District Administrator: Ensures that cost of drug to Medicaid patients do not exceed the price paid for the drug, and this will be monitored during self-audits

7.4 District Women's Health Program Director: Follow 340B guidelines as outlined in the Public Health Master Agreement Annex

8.0 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS

8.1 Recertification Procedure

OPA requires entities to recertify their information as listed in the OPA database annually. STD's DPH Authorizing Official annually recertifies each STD Clinic's information by following the directions in the recertification email sent from the OPA to STD's Authorizing Official by the requested deadline. The Authorizing Official should receive and email with instructions to log into the 340B OPAIS Registration Application at https://340bregistration.hrsa.gov and access your *My Dashboard* to review the tasks.

8.2 Enrollment Procedure: New Clinic Sites

8.2.1 The Nurse Director and/or the Deputy Nurse Director will evaluate a new service

area or facility to determine whether 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 status, have outpatient drug use, and have patients who meet the 340B patient definition.

8.2.2 If a new clinic meets these criteria, the STD Clinic's Authorizing Official completes the online registration process during the registration window (January 1 – January 15 for an effective start date of April 1; April 1 – April 15 for an effective start date of July 1; July 1 – July 15 for an effective start date of October 1; and October 1 – October 15 for an effective start date of January 1). See: http://opanet.hrsa.gov/opa/CERegister.aspx?isnew=true.

8.2.3 D2PH follows the online registration process at: http://opanet.hrsa.gov/opa/CERegister.aspx?isnew=true.

8.3 Enrollment Procedure: New Contract Pharmacy(ies)

8.3.1 The District Pharmacist ensures that a signed contract pharmacy services agreement, containing the 12 essential compliance elements in the Contract Pharmacy Guidance (see Appendix D), is in place between the entity and the contract pharmacy prior to submission to HRSA. This staff ensures that D2PH STD Clinic's legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.

8.3.2 The District Pharmacist, Nurse Director and/or Deputy Nurse Director completes the online process at: http://opanet.hrsa.gov/opa/CPRegister.aspx during the registration window (January 1–January 15 for an effective start date of April 1; April 1–April 15 for an effective start date of July 1; July 1–July 15 for an effective start date of October 1; and October 1–October 15 for an effective start date of January 1).

8.3.3 The District Pharmacist, Nurse Director and/or Deputy Nurse Director ensures that the contract pharmacy registration request is certified online within 15 days from the date the online registration was completed. The pharmacy's responsible representative may be the owner, president, CEO, COO, or CFO.

8.3.4 The District Pharmacist, Nurse Director and/or Deputy Nurse Director begins the contract pharmacy arrangement only on or after the effective date shown on the HRSA 340B website.

8.4 Changes to D2PH Information in HRSA Database Procedure

8.4.1 It is the D2PH Clinic staff's ongoing responsibility to immediately inform the DPH STD Authorizing Officials so that OPA can be informed of any changes to its information or eligibility. As soon as the STD Clinic staff is aware that it loses eligibility, it will notify the DPH STD Authorizing Official and OPA immediately and

stop purchasing (or may be required to repay manufacturers).

8.4.2 STD Clinics have an internal self-audit plan conducted annually by the Nurse Director and/or Deputy Nurse Director and 340B committee members. An online change request will be submitted to OPA by the DPH STD Authorizing Official for changes to D2PH STD Clinic's information outside of the annual recertification timeframe. Change form will be submitted to OPA as soon as the covered entity is aware of the need to make a change to its database entry. This database will be examined periodically by the Women's Health Director as they are aware of needed changes. The database will be reviewed annually during the recertification period by the District Pharmacist. Results are submitted to appropriate District staff. [Appendix C]

9.0 PRIME VENDOR PROGRAM ENROLLMENT, UPDATES

9.1 Enrollment in PVP:

1. Covered entity completes online 340B program registration with HRSA.
2. Covered entity with the assistance of GDPH OOP completes online PVP registration (https://www.340bpvp.com/register/apply-to-participate-for-340b/).
3. PVP staff validates information and sends a confirmation e-mail to covered entity.
4. Covered entity logs on to www.340bpvp.com, selects user name / password.

9.2 Update PVP Profile:

To update your profile:

1. Access www.340bpvp.com.
2. Click **Login** in the upper right corner.
3. Input your log-in credentials.
4. In the upper right corner, arrow by your name, and click **My Profile** to access page https://members.340bpvp.com/webMemberProfileInstructions.aspx.
5. Click **Continue to My Profile** to access page https://members.340bpvp.com/webMemberProfile.aspx.
6. You will find a list of your facilities; click on the 340B ID number hyperlink to view or change profile information for that facility.
7. The **My Profile Change Request** form is divided into two categories: HRSA Information and 340B Prime Vendor Program (PVP) Participation Information.
8. To update HRSA Information, complete the 340B Change Form

(http://opanet.hrsa.gov/OPA/CRPublicSearch.aspx) and submit it via e-mail to the Office of Pharmacy Affairs at hrsastaff@opa.gov. After the HRSA 340B Database has been updated, the PVP database will be updated during the nightly synchronization.

9. To update the 340B PVP participation information, you can edit your DEA number, distributor, and/or contacts, and click "submit."

10.0 340B PROCUREMENT, INVENTORY MANAGEMENT, DISPENSING

10.1 340B inventory is procured and managed in the following settings:

1. Clinic administration/Nurse Protocol dispensing
2. In-house pharmacy
3. Contract pharmacy
4. D2PH STD has established a pricing policy applying income-based discounts and third-party billing and reconciliation wherein Medicaid will be charged the acquisition cost for approved 340B STD drugs.

10.2 Pharmacy, Physician Dispensing, Nurse Protocol Processes

10.2.1 STD Clinics use either 340B inventory only, electronically or physically separate 340B or non-340B purchased inventory. Pharmacists, Physicians, APRN's or Registered Nurses operating under Nurse Protocol dispense / issue 340B drugs only to patients meeting all the criteria in the STD grant.

10.2.2 The D2PH Pharmacist or District Pharmacy staff places 340B orders from Cardinal Health through periodic inventory review and shelf inspections of PAR [Periodic Automatic Replacement] levels by using Cardinal Order Express.

10.2.3 The D2PH Pharmacist and/or District Pharmacy Staff checks in 340B inventory by examining the Cardinal Health invoice against the order, and reports inaccuracies to Cardinal Health and/or the State Office of Pharmacy.

10.2.4 County Floor Stock orders are placed by appropriate STD staff in the county clinic utilizing the appropriate form from the Drug Dispensing Manual, filled by District Pharmacy from State or Private Pay inventory, and Shipped to County clinics by courier. These medications are transferred from District Pharmacy stock by pharmacy personnel to the ordering county through the VHN Transaction mode by lot number and NDC number.

10.2.5 District Pharmacist maintains records of 340B related transactions for a period of 2 years in a readily retrievable and auditable format located at the Public Health District.

10.2.6 340B inventory is stored securely and access is limited to designated pharmacy and/or clinical staff.

10.2.7 D2PH Pharmacist and/or District Pharmacy Staff, and/or STD Clinic Staff examine drug inventory monthly and abide by the Drug Dispensing Procedure requirements as relates to expired drug returns. The District Pharmacy staff returns expired medications through Inmar, a Reverse Distributor. District drug inventory is submitted to District Pharmacy and to State Office of Pharmacy annually.

10.3 Clinic Administered Drugs, Standard Dispensing Processes

Processes will vary based upon state law, permit type, etc. D2PH may use the Med Room, Dispensing Physicians, APRN's and Registered Nurses utilizing the Nurse Protocol Process.

10.4 Contract Pharmacy Sample Standard processes

10.4.1 D2PH has contracted with Curant to facilitate both the design and implementation of the 340B contract pharmacy program. The entity is responsible for 340B compliance. The executed contract with Curant appears in the Appendix.

10.4.2 D2PH STD Clinic uses a replenishment or physical inventory model for contract pharmacy services.

10.4.3 340B-eligible prescriptions may be presented to Curant via [e-prescribing, hard copy, fax, phone]. Curant verifies patient, prescriber, and clinic eligibility via [barcode, pharmacy benefits manager (PBM) eligibility file, other]. Updates are made to this mechanism by D2PH monthly.

10.4.4 Curant staff dispenses prescriptions to 340B-eligible patients using Curant non-340B drugs.

10.4.5 Curant/D2PH staff places 340B orders on behalf of D2PH STD Clinic, based on 340B-eligible use as determined by prescriptions from McKesson.

10.4.6 D2PH pays invoice to McKesson for all 340B drugs.

10.4.7 Curant staff receives 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to McKesson and D2PH STD Clinic staff within one month.

10.4.8 Curant notifies D2PH if Curant does not receive the 11-digit NDC replenishment order within 3 days of the original order fulfillment request. D2PH STD Clinic will reimburse Curant at a pre-negotiated rate for such drugs.

10.4.9 Any non-replacement 340B inventory is stored at Curant and is clearly marked as

belonging to the 340B entity. The inventory is protected by a security system. Only pharmacy employees have access to the pharmacy.

10.4.10 Curant will provide a monthly report to D2PH.

11.0 REIMBURSEMENT

11.1 The covered entity may obtain reimbursement for STD 340B drugs from Medicaid, private insurers, private pay, etc. according to Georgia Department of Public Health Resource Manual. STD Clinic staff requests Medicaid reimbursement from Georgia Medicaid detailed in the Georgia Medicaid Provider Manual.

Note: Reimbursement policies are different depending on the state Medicaid program, and these policies are subject to change.

11.2 Resources for 340B Medicaid information are:

11.2.1 HRSA website, Medicaid section

Georgia Medicaid Provider Manual visit https://www.mmis.georgia.gov/portal/ and highlight the "Provider Information" tab at the top. Select "Provider Manuals" and scroll through the list of manuals at the bottom of the page until you locate "Pharmacy Services".

Part II Policies and Procedures Manual for Pharmacy Services APR 2021 20210401154244.pdf (georgia.gov)".

12.0 RECOMMENDED MONITORING AND REPORTING

The covered entity uses the process outlined in: [Appendix C:340B Compliance Self-Assessment: Self-Audit Process to Ensure 340B Compliance].

Additional monitoring or reporting includes [list].

12.1 Reporting 340B Non-Compliance

Non-compliance will warrant a report to OPA / manufacturer, a review of records kept, documentation, and plan for corrective action. [Reference: existing covered entity 340B compliance policy, Self-Reporting Non-Compliance Tool].

12.2 340B Compliance Review

The 340B Compliance Review summarizes activities necessary to ensure a comprehensive review of 340B compliance at STD Clinics. D2PH staff is responsible and accountable for overseeing this review process, as well as taking corrective actions based on the findings.

Activity	Frequency (suggested)	Area of Focus		
		Entity Eligibility	No Diversion	No Duplicate Discount
Review of all HRSA 340B Database information for STD Clinic sites within the NGHD. NGHD staff responsible: District Pharmacist, District ID Director	Annually	X		
Review of 340B self-audit reports, NGHD staff responsible: District Pharmacist, District ID Director, Clinic Drug Coordinator	Monthly		X	X
Review of quarterly contract price load. NGHD staff responsible: District ID Director	Quarterly		X	
Third-party vendor external audit of Entity/contract pharmacy (optional). NGHD Staff responsible: CFO	Annually	X	X	X

13.0 REVISION HISTORY

REVISION #	REVISION DATE	REVISION COMMENTS
1	1/07/2020	Revised
2	2/02/2022	Revised

14.0 RELATED FORMS

APPENDIX A: List of Entities, Prescribers and Registered Nurses
APPENDIX B: 340B Glossary of Terms
APPENDIX C: Self-Audit Tool
APPENDIX D: Contract Pharmacy Compliance Elements
APPENDIX E: Pharmaceutical Procurement and Distribution
340B Self-Audit Worksheets

APPENDIX A -- LIST OF ENTITIES, PRESCRIBERS AND REGISTED NURSES

340B ENTITY	PRESCRIBERS & REGISTERED NURSES	
	TB CLINICS	STD CLINICS
Banks County Health Department 667 Thompson Street • Homer, GA 30547	Staff RNs	Staff RNs Staff APRNs
Dawson County Health Department 54 Hwy 53 East • Dawsonville, GA 30534	Staff RNs	Staff RNs Staff APRNs
Forsyth County Health Department 428 Canton Hwy • Cumming, GA 30040	Staff RNs	Staff RNs Staff APRNs
Franklin County Health Department 6955 GA 145 South • Carnesville, GA 30521	Staff RNs	Staff RNs Staff APRNs
Habersham County Health Department 185 Scoggins Drive • Demorest, GA 30535	Staff RNs	Staff RNs Staff APRNs
Hall County Health Department 1290 Athens Street • Gainesville, GA 30507	Staff RNs TB Nurse	Staff RNs Staff APRNs
Hart County Health Department 64 Reynolds Street • Hartwell, GA 30643	Staff RNs	Staff RNs Staff APRNs
Lumpkin County Health Department 60 Mechanicsville Road • Dahlonega, GA 30533	Staff RNs	Staff RNs Staff APRNs
Rabun County Health Department 184 Main Street, Ste 200, • Clayton, GA 30525	Staff RNs	Staff RNs Staff APRNs
Stephens County Health Department 64 Boulevard, Ste. 102 • Toccoa, GA 30577	Staff RNs	Staff RNs Staff APRNs
Towns County Health Department 1104 Jack Dayton Circle • Young Harris, GA 30582	Staff RNs	Staff RNs Staff APRNs
Union County Health Department 67 Chase Drive • Blairsville, GA 30512	Staff RNs	Staff RNs Staff APRNs
White County Health Department 1331 Helen Hwy • Cleveland, GA 30528	Staff RNs	Staff RNs Staff APRNs

APPENDIX B – 340B GLOSSARY OF TERMS

340B Glossary of Terms: HTTPS://WWW.340BPVP.COM/EDUCATION/340B-TOOLS/

Under HOT LINKS: Click **340B Tools**
Click on **ALL TOOLS**
At the bottom – click on **Glossary of Terms**:
340b-glossary-of-terms.pdf (340bpvp.com)

APPENDIX C – SELF-AUDIT TOOL

340B Compliance Self-Assessment: Self –Audit Process

Item	Criteria	Status: Compliant/ Non-Compliant	Comments/Plan to Resolve
1. All Clinic Policies & Procedures Related to 340B	Policies include relevant criteria from STD 340B Policy and Procedure Manual		
2. Data Policies for any Vendor Software, i.e., Wholesaler, Contract Pharmacy, etc..	Policies are identified, current, and signed		
3. 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 OPA database for all entity sites is accurate and complete, based upon state policy, and reflects current practices by the entity.		
4. Ensure that each 340B service area is included in the sample (in-house pharmacy, clinics, contract pharmacy, retail pharmacy, etc.)	Entity maintains records of the individual's health care. Individual 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 (referral for consultation) such that responsibility for the care provided remains with the covered entity.		
5. Identify a 6-month continuous time frame within the prior year	Provider-entity relationship is substantiated by contract/employment/other records per clinic site.		
6. Select a sample, of approximately 50 transactions – include Medicaid transactions if you bill Medicaid	Provider-entity relationship is substantiated by contract/employment/other records per clinic site. Prescription was from 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. Patient received health care services from the entity that are within the scope of grant, and registered on the OPA database (if at a different address than the parent) Wholesaler invoice price for a specific NDC on a specific date matches reported billing cost from dispensing/administration		

APPENDIX D – CONTRACT PHARMACY COMPLIANCE ELEMENTS

HRSA has provided essential covered entity compliance elements as guidance for the contractual provisions expected in all contract pharmacy arrangements.

Excerpt from:
http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf

(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State, and local laws. A ''ship to, bill to'' procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased but ships the drug directly to the contract pharmacy. In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or ''in-house.''

(c) The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice. When a patient obtains a drug from a pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records).

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines. Both parties

agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. See 42 U.S.C. 256b(a)(5)(B). The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to HRSA, by the covered entity.

(j) The covered entity and contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.

(k) Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. See 42 U.S.C. 256b(a)(5)(c). The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

(l) Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

APPENDIX E – PHARMACEUTICAL PROCUREMENT AND DISTRIBUTION

Introduction

The Office of Pharmacy provides pharmaceuticals for the detection, treatment, and prevention of disease to the state's 159 county public health (PH) system, and for detection of infectious disease in high-risk groups such as Nursing Home residents and Substance Abuse Treatment Center clients at 237 sites throughout the state. This distribution system for public health drugs includes a combination of a "Bill to Ship to" process.

The Office of Pharmacy works with all PH programs which have pharmaceutical budgets directly or indirectly to facilitate budget projections, determine inventory levels, link purchasing to the appropriate pharmaceutical contracts (Minnesota Multistate Contracting Alliance for Pharmacy, Section 340B/Public Health Service Contract, Centers for Disease Control, Prime Vendor Program), determine formulary inclusion/exclusion, and determine/review contract needs for pharmacy services for programs, districts or counties. Examples of pharmaceuticals provided by PH programs include childhood and adult vaccines, antibiotic and anti-tuberculosis drugs for infectious disease, AIDS/HIV antiretrovirals and drugs for related diseases, and drugs involved in family planning programs, maternal and child health needs, chronic disease and primary care. Overall drug/vaccine purchases for PH clinics/programs exceed $50 million.

Pharmaceutical Supply Catalog

The Division of Public Health, State Office of Pharmacy maintains a Pharmaceutical Supply Catalog for state budgeted pharmaceutical formulary items. The catalog is updated July 1st on an annual basis. Every District Pharmacy Director and/or District Drug Coordinator should obtain an updated version of the catalog during July. The Pharmaceutical Supply Catalog lists pharmaceuticals available by each Public Health Program.

Instructions for Ordering

All State Budgeted Public Health pharmaceutical supplies must be ordered through Cardinal Express. Each of the 18 Public Health Districts should have a minimum of four Cardinal accounts: one State 340B account; one District 340B account, one State MMCAP account, one District MMCAP account. State and District 340 B accounts are linked to 340B, 340B PVP, and MMCAP pricing and can only be used to purchase pharmaceuticals for STD, RW and ADAP clinics. The State and District MMCAP accounts are linked to MMCAP pricing and can be used for all other Public Health pharmaceutical purchases.

General Procurement Process for State Pharmaceutical Budgeted Items

The below is the current instructions for ordering State Supplied Pharmaceuticals.
INSTRUCTIONS FOR ORDERING STATE SUPPLIED PHARMACEUTICAL AND SUPPLY PRODUCTS
Most Public Health Pharmaceutical Supplies are ordered via Cardinal Order Express (orderexpress.cardinalhealth.com). In the situation where that is not possible, please contact the Office of Pharmacy at **404-657-9859**.
The District Health Director will appoint one or more Pharmacists or Drug Coordinators to requests drug orders from the Office of Pharmacy.

See Drug Ordering instructions below.

When orders are placed via Cardinal Express, for the STD or TB programs alert Cynthia Wynn, cynthia.wynn@dph.ga.gov that an order has been placed. Provide the district's account number in the email.

When orders are placed via Cardinal Express, for the Women's Health program alert Rashunda Finley, Rashunda.Finley@dph.ga.gov that an order has been placed. Provide the district's account number in the email.

When building a requisition on the Cardinal Order Express website the following program initials are to be used: Sexually Transmitted Diseases (STD) Sexually Transmitted Diseases Contraceptives (STD-C) and Tuberculosis (TB).

Prior to sending for approval, please separate the requests by program and annotate the requisition by using the program's initials followed by the date. For example, an order for the Tuberculosis (TB) program will be annotated in the "Purchase Order" entry box as TB092816. A Sexually Transmitted Disease (STD) program order will be STD092816.

As positions change and new personnel are acquired, please contact the Office of Pharmacy and Sheilah Wells regarding Cardinal Express website access and training.

For all other drug or condom orders not available through Cardinal Order Express, please forward an email to Cynthia Wynn, cynthia.wynn@dph.ga.gov,and list the items and quantities needed.

During times of an emergency Cardinal may allow alternative processes for ordering. Include the State Office of Pharmacy on all correspondence.

If acquiring product through an alternative vendor, an order may be placed with the vendor via phone or fax dependent upon the vendor's established process. An account number will need to be established if one does not exist. A PO must be connected to the individual order. Ensure that price/cost quoted is PHS, PVP, MMCAP price or better when applicable.

Non-routine pharmaceutical item purchases should follow individual program purchasing procedures. The State Office of Pharmacy will provide assistance as necessary.

Genetics Program

This program has been transferred to Emory University Genetics Program for assistance please call 404-778-8594. The State Office of Pharmacy provide assistance when necessary.

Vaccine Distribution

Please follow the State Immunization Guidelines for vaccine distribution.

PHARMACEUTICAL STORAGE TEMPERATURES

NOTE: Specific directions for storage temperatures are stated in the drug product monograph or on the drug product label. Please check drug product/package for required storage temperatures (i.e., Depo-Provera)

DEFINITIONS

COLD - Any temperature not exceeding 8 degrees Celsius (46 Fahrenheit). A refrigerator is a cold storage unit in which the temperature is maintained between 2 and 8 degrees Celsius (36 to 46 Fahrenheit). The "cold storage unit" is the only acceptable storage environment for refrigerated vaccines. A freezer is a cold storage unit in which the temperature is maintained between (-20 to +5) degrees Fahrenheit Celsius (-29 to -15). **FOR FROZEN VACCINES (FLUMIST, PROQUAD, and VARIVAX VACCINE), the freezer temperature must be maintained at an average temperature of -15 degrees Celsius (+5 degrees Fahrenheit) or colder.**

COOL- Any temperature between 8 and 15 degrees Celsius (46 to 59 Fahrenheit).
Any article, for which storage in a cool place is indicated, may be stored in a refrigerator, unless otherwise specified in the individual monograph.

ROOM TEMPERATURE - The temperature prevailing in a working area. Controlled room temperature is maintained between 15 and 30 degrees Celsius (59 to 86 Fahrenheit).

WARM - Any temperature between 30 and 40 degrees Celsius (86 to 104 Fahrenheit).

EXCESSIVE HEAT - Any temperature above 40 degrees Celsius (104 Fahrenheit).

PROTECTION FROM FREEZING - Whereby freezing subjects a product to loss of strength, or potency or to destructive alteration of the dosage form, the container label bears an appropriate instruction to protect the product from freezing.

REFERENCES: Remington's Pharmaceutical Sciences, Mack Publishing Co., 1990; 18th Ed.: 1505.

NOTE: Thermometers should be located in both freezer and the refrigerator units. Do not place the thermometer on the walls (bottom surface, sides) of the unit. These areas may be colder or warmer than the overall temperature of the unit. Temperatures are monitored once daily.

CARDINAL SUPPORT INFORMATION

Non-routine pharmaceutical orders can be processed by ordering needed items from Cardinal Health during evenings, weekends and holidays using the following phone numbers:

Cardinal Customer Service Support:
Phone 866-641-1199
Fax: 866-551-0530
Emergency Number 877-772-0346