Georgia Department of Public Health

POLICY APPROVAL FORM

THIS FORM IS NOT TO BE USED FOR COMMUNICATIONS, CONTRACTS, PERSONNEL OR PURCHASES.

Date Submitted:	Policy Owner:	Division:	Phone #
10/28/2021	Kimberly Hazelwood	Medical & Clinical Services/Office of Pharmacy	404-906-2835
Policy Title:	**PA-20-1601 Pharmacy Distribution Tracking Policy**		

Statement of Need:
This is a new policy for the districts regarding Pharmacy Distribution Tracking.

IMPORTANT NOTE: All changes must be made on the document and an (X) placed in the box under "Changes - Yes" on the matrix below. Any comments must be entered under "Notes" below or entered on the document being routed. If additional space is needed for comments and/or changes are made to the attachment, please document under "notes."

Date Request initiated:	Date Due to Requestor:	RETURN TO: Contact Person				Phone #
1/25/2022	1/26/2022	Mauri Smith				678-537-1098
Signature Required REQUIRED APPROVALS:	**Date Received**	**Approval of Document Signature**	**Changes** Yes	**Changes** No	**Date Approved / Completed**	**Notes:**
ELT Review Completed:	10/28/2021	Email		X	11/12/2021	
Policy Owner: Kimberly Hazelwood	11/15/2021	Email		X	11/30/2021	
DPH POLICY COMMITTEE APPROVALS						
Co-Chair: ☐ Bill Scott	11/30/2021	Email		X	11/30/2021	
Chair: ☐ Melanie Simon	1/25/2022	Email		X	1/25/2022	
COO: ☑ Rosalyn Bacon				X	2/1/2022	

INTERNAL ONLY

If applicable, Document Saved as:	Drive:	File path or location:	Date Submitted to Archives (if applicable)
Approval Form PA-20-1601 Pharmacy Distribution Tracking Policy	J:	Operations/PoliciesandForms/	

GEORGIA DEPARTMENT OF PUBLIC HEALTH
POLICY # 20-1601
PHARMACY DISTRIBUTION TRACKING POLICY

Approval:	Kathleen E. Toomey, M.D., M.P.H., Commissioner	JAN 25 2022 Date

1.0 PURPOSE

To establish supervision and oversight responsibilities of the procurement, distribution and tracking of drugs within the Georgia Department of Public Health. Responsibilities include proper storage, distribution, labeling, documentation, maintenance, and recording.

2.0 AUTHORITY

The Georgia Department of Public Health (DPH) Pharmacy Distribution Tracking Policy is published under the authority of DPH and in compliance with the Drug Quality and Security Act, Section 340B of the Public Health Service Act, Federal and State laws/rules/regulations, and pharmaceutical contractual agreements.

3.0 ACRONYMS

3.1 340B – Federal 340B Drug Pricing Program

3.2 3PL-Third Party Logistics

3.3 DEA-Drug Enforcement Agency

3.4 DPH – Georgia Department of Public Health

3.5 DQSA- The Drug Quality and Security Act (https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa)

3.6 FDA- Federal Drug Administration

3.7 TI- Transaction Information

3.8 TH- Transaction History

3.9 TI/TH/TS- Transaction Data

3.10 PVP -Prime Vendor Program Pricing

3.11 GPO -Group Purchasing Organization

3.12 AO-Authorizing Official

3.13 CE-Covered Entity

3.14 HRSA OPA- Health Resources and Services Administration, Office of Pharmacy Affairs

3.15 PHS – Public Health Service

3.16 NDC- National Drug Codes

3.17 MMCAP – Minnesota Multistate Contracting Alliance for Pharmacy

3.18 RW – Ryan White HIV/AIDS Program

4.0 SCOPE

This policy applies to all employees of the Georgia Department of Public Health.

5.0 POLICY

The policy is to provide supervision and oversight responsibilities of the procurement, distribution and tracking of drugs within the Georgia Department of Public Health.

6.0 PROCEDURES

6.1 DRUG QUALITY AND SECURITY ACT (DQSA)

The Drug Quality and Security Act (DQSA) creates a uniform, national standard for tracing pharmaceuticals through the supply chain. In compliance with the Drug Quality and Security Act, Public Health can only obtain pharmaceuticals with "authorized" trading partners for daily operations. These are manufacturers and repackagers that have a valid registration in accordance with section 510 (FDA manufacturer registration) and wholesale distributors and Third-Party Logistics (3PL's) that have a valid license under State law.

6.1.1 VALID LICENSURE/REGISTRATION

All vendors must have a valid licensure and/or registration per federal and/or state law. Wholesaler distributors and 3PL's must be licensed/registered in good standing in the state of Georgia.

The State Office of Pharmacy will verify trading partners for state purchased product. If local purchases are made the vendor must be verified by the District Pharmacist/Drug Coordinator. The verification form below (#20-1601A) must be filed and kept for 6 years.

6.1.2 TRANSACTION DATA

The terms below are important to understand as different trading partners are required to pass different combinations of the documents depending on upstream and downstream trading partners.

6.1.2.1 The transaction information (TI) includes the name of the product, strength and dosage form, National Drug Code (NDC), the container size, the number of containers, the lot number, the transaction date, the shipment date, and the name and address of the businesses from which and to which ownership is being transferred.

6.1.2.2 A transaction history (TH) is a paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.

6.1.2.3 A transaction statement (TS) is a paper or electronic attestation by the business transferring ownership of the product that it has complied with the Act.

Ownership of prescription drug products subject to the DQSA may not be accepted unless the prior owner provides transaction information, transaction history and a transaction statement (TI/TH/TS), collectively referred to as transaction data.

Key Exemptions: The following products are not subject to the tracing requirements in the bill.

- **a.** Medical convenience kits and combination products not approved as drugs or biologics.
- **b.** Sterile water and products intended for irrigation.
- **c.** Intravenous products.
- **d.** Blood and blood components intended for transfusion.
- **e.** Radioactive drugs and radioactive biologics.
- **f.** Medical gas.
- **g.** Compounded drugs.
- **h.** Dispensing drugs pursuant to a prescription.

Transaction data must be maintained for six years and be able to provide it upon request from the FDA or other appropriate federal or state official in the event of a recall or for the purpose of investigating a suspect or illegitimate product within two days.

The Department's Primary Drug Wholesaler will provide the required transaction data via a web portal. All other vendors used by the State Office of Pharmacy will be required to provide data either electronically or paper. All vendors used for local purchases must be able to provide the transactional data either electronically or paper.

Drop shipments may provide information directly to the Department either electronically or paper. This will be allowed because wholesale distributors that do not physically handle or store product are exempt. The Department will request that the primary drug wholesaler post transaction data on drop shipments after the fact for visibility purposes only.

For programs within the Department that utilize contract pharmacies and have a Bill-To and Ship-To account number, a request should be made to the vendor to provide transaction data reports to both account numbers.

6.1.3 USE #20-1601A VERIFICATION FORM

6.2 SUSPECT PRODUCT

A process must be in place to verify suspect product.

6.2.1 **Suspect product**- reason to believe that the product is potentially: – Counterfeit, diverted, stolen – Subject of fraudulent transaction – intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans.

In addition, responds to requests for information regarding suspect or illegitimate product must occur within two business days.

6.2.2 Use Form #20-1601B Suspect/Illegitimate Product Identification and Notification

7.0 PHARMACEUTICAL PROCUREMENT

7.1 CONTROLLED SUBSTANCES

The procurement of controlled substances for daily operations within DPH may be determined by the following:

7.1.1 A Medication Room or a Licensed Pharmacy without a DEA Registration:
- No controlled drugs shall be permitted.

7.1.2 A Licensed Pharmacy with a DEA Registration:
- A Public Health Georgia licensed pharmacy with an active DEA registration may possess controlled substances for the schedule(s) permitted by the DEA registration.

7.1.3 A Practitioner with Prescriptive Authority Dispensing/Administering Controlled Substances:
- If a practitioner with prescriptive authority is dispensing/administering controlled substances and has an active DEA registration, controlled substances are the responsibility of and must be in the custody of that practitioner with prescriptive authority, to whom the DEA registration belongs, in accordance with State and Federal Law and Regulations.

7.2 CONTRACTS

Multiple Pricing agreements may be accessed by Georgia Department of Public Health (DPH) for pharmacy purchases. The largest percentage is purchased under these:
- HRSA 340B Drug Purchasing Program (340B)
- MMCAP Infuse
- Prime Vendor Program Pricing (PVP)

Purchased pharmaceuticals for daily operations are for our clinics "own use" and must not be resold or given to outside partners.

7.2.1 **HRSA 340B DRUG PURCHASING PROGRAM (340B)**
The 340B program is a federally sponsored discount purchasing program that allows eligible 340B registered entities to purchase pharmaceuticals at extremely reduced prices. The program has very rigid guidelines that must be followed. Click on the link for more information on the requirements at 340B Drug Pricing Program or https://www.hrsa.gov/opa/.

For DPH, the 340B Drug Pricing Program is accessed for the following programs under the respective grants, complying with scope of service: Sexually Transmitted Disease (STD), Tuberculosis (TB), AIDs Drug Assistance Program (ADAP), RW, and Migrant Health.

7.2.1.1 The 340B guidelines stipulate:

a. Each eligible location must be registered as a 340B covered entity to receive and provide 340B-purchased pharmaceuticals. This means each DPH clinic MUST be registered separately. Each Program Authorizing Official is responsible for registering and re-certifying all sites annually. Any changes and terminations must be done immediately.
b. ALL 340B-purchased pharmaceuticals must be allowed under the scope of grant and follow 340B Regulations: e.g. these pharmaceuticals MUST be utilized specifically & ONLY for STD, TB, or Ryan White patients, etc.
c. ALL medical records MUST be auditable: All documentation of patient care MUST be recorded and must include more than dispensation/administration of the drug.
d. Public Health Districts and the County Health Departments must maintain auditable records and track 340B drugs from the time they are received from the drug wholesaler or manufacturer to the time they are dispensed/administered to a patient at the clinic.

7.2.1.2 340B Policy and Procedures:

a. The State directs each District to specify the 340B compliance staff responsible for tasks contained in the 340B Policy and Procedures template for grantees provided by Apexus located on the Apexus website @ https://www.340bpvp.com/education/340b-tools/ .
b. The 340B Policy and Procedure must include an effective date, original date of issue, date last reviewed, and date last revised.
c. Staff member(s) participating in the 340B Program complete initial basic training via webinar on the 340B and Prime Vendor Programs https://www.340bpvp.com/340b-university/webinars. Comprehensive training is conducted on the 340B Program initially upon hire and competency is also verified annually as part of staff development.
d. The State Authorizing Official will review the District's 340B Policy and Procedure which will serve for all clinics located in that District.
e. Each eligible location must be registered as a 340B covered entity to receive and provide 340B-purchased pharmaceuticals. This means each DPH clinic MUST be registered separately. Each Program Authorizing Official is responsible for registering and re-certifying all sites annually. Any changes and terminations must be done immediately. Clinics meet all 340B Program eligibility requirements. Clinic's HRSA's OPA Database covered entity listing is complete, accurate, and correct. DPH provides each district with a TB and a STD Grant in Aid which is readily available at the State Office.

f. The 340B policy and procedures include prohibition for duplicate discounts and a mitigation strategy to prevent diversion.
   1. To prevent duplicate discounts the Authorizing Official ensures that the Medicaid Exclusion File includes all NPI's and Medicaid numbers of providers in the district's clinics. DPH follows Georgia Medicaid's policy for 340B billing located at www.mmis.georgia.gov/portal/.
   2. To prevent diversion, all clinic medical records are auditable. All documentation of patient care is recorded and must include more than dispensation/administration of the drug. The medication is only dispensed/administered directly to a patient of the clinic. Providers are health department employees or contracted employees that dispense/administer directly to their own patient or the district pharmacist may dispense for a patient of one of the clinics residing in that district. Dispensing is contained to clinic patient's only. The individual receives a health care service within the scope of grant/designation such that the responsibility for care remains with the entity. A current and accurate list of providers is available at the district. Patient records are maintained at the covered entity.
   3. District and clinic staff ensure audits are conducted annually. Self-audits are part of the mitigation strategy. District and clinic staff are responsible and accountable for overseeing this process, as well as taking corrective actions based upon findings. The AO will be notified of any findings.

7.2.1.3 Auditability

In the absence of official HRSA guidance, most CE's have incorporated the proposed HRSA's guidance (although rescinded) for Administrative Dispute Resolution requiring covered entities to maintain 340B-related records for three years. However, the record retention requirement from the Drug Supply Chain Security Act is 6 years for drug manufacturers, wholesale distributors, repackagers and dispenser for Transaction Information (TI), Transaction History (TH), and Transaction Statements (TS). Therefore, all records involving 340B drugs will be retained for minimum of 6 years for auditability purposes.

7.2.1.4 Accountability

The Authorizing Official (AO) is a state employee and Principal Investigator for the covered entities (TB, STD, ADAP, etc.). The AO is fully authorized to legally bind the covered entity. Additionally, the program provides funding through Grant in Aid which provides deliverables and is a binding contract between the State of Georgia and the Georgia County Boards of Health. The Grant in Aid documents mandates compliance with 340B Law.

7.2.1.5 340B Non-Compliance

There are financial consequences for non-compliance with the 340B Drug Pricing Program. If audited and found to be diverting 340B-purchased pharmaceuticals for NON-340B use, 340B clinics can lose their 340B purchasing status which ultimately increases the pharmaceutical financial cost at approximately 50-75%.

7.2.2 MMCAP INFUSE

Georgia Department of Public Health (DPH) utilizes MMCAP Infuse when purchasing pharmaceuticals that are not allowable under the 340B Drug Pricing Program. All DPH clinics should be registered as members of MMCAP Infuse, a voluntary Group Purchasing Organization (GPO) for government facilities that provide health care services. MMCAP Infuse is a GPO contracted by the Georgia Department of Administrative Services for pharmaceutical procurement for the State of Georgia. MMCAP Infuse allows members to purchase pharmaceuticals at special negotiated contract pricing, though not as low as 340B prices. These medications can be utilized for all DPH clients.

MMCAP Infuse members will only have access to MMCAP Infuse Contract Pricing through one drug wholesaler. Therefore, if a secondary wholesaler is used, the MMCAP Infuse price will not be honored through the secondary wholesaler.

7.2.3 PRIME VENDOR PROGRAM PRICING (PVP)

A voluntary program that enables 340B covered entities to obtain pharmaceutical prices lower than 340B statutory prices and access cost-saving contracts for pharmacy items such as diabetic supplies, vaccines, diagnostic test kits, pharmacy hardware, software solutions and more. You must enroll in the PVP program at https://www.340bpvp.com/register/become-a-pvp-participant/ . For products that are not a 'covered outpatient drug' and not subject to PHS/340B pricing or eligible for Medicaid rebates, they are classified as "value-added products" within the Prime Vendor Program and may be provided to patients meeting the 'own use' guidelines under the Nonprofit Institutions Act.

7.2.4 ADDITIONAL DRUG WHOLESALER/MANUFACTURER CONTRACTS

Please contact the State Office of Pharmacy prior to entering into additional agreements as prohibitions and other factors will need to be evaluated.

7.3 DISTRICT/STATE ACCOUNTS

7.3.1 ACCOUNTS

Each district must have the following accounts set up with the primary drug wholesaler and any vendor that provides state purchased and local purchased drugs:

7.3.1.1 State Managed Accounts

Accounts are set up by the State Office of Pharmacy. Each District will have 2 accounts. One account will be for 340B purchased products and one will be for MMCAP Infuse purchased products. Each fiscal year, separate purchase order (PO) numbers will be used to track products purchased for a specific grant e.g. TB, STD, etc. Each purchase will use the appropriate PO number(s) given to the program. The district pharmacist or drug coordinator will have the ability to submit the order for approval to the State Office of Pharmacy. No orders will be accepted directly from the local requester to the vendor. The State Office of Pharmacy has administrative rights to accept, modify or change the request prior to sending to the vendor(s) for processing and to assign the correct PO number on the submission of the order. Reports can be generated to show purchases under a specific PO.

a. 340B State Account (set up by the State Office of Pharmacy)
b. MMCAP Infuse State Account (set up by the State Office of Pharmacy)

7.3.1.2 Local Managed Accounts

The district must have at a minimum, two accounts set up with the primary drug wholesaler. One account for 340B and PVP purchases and one account for MMCAP Infuse and non-340B purchases. Accounts are set up by the district pharmacist or drug coordinator and they will have the ability to submit the order to the primary drug wholesaler or other vendor(s). Local purchased product will use the districts method for submitting orders for the Clinics to the district pharmacist or drug coordinator.

a. 340B Local Account
b. MMCAP Infuse Local Account

7.4 VENDOR ORDERS FOR STATE PURCHASES

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**.

7.4.1 Point of Contact for State Purchases

The District Health Director will appoint a Pharmacist or Drug Coordinator to perform all pharmaceutical related tasks including requesting drug orders on behalf of the TB and STD programs from the Office of Pharmacy. This list of appointed Pharmacists and Drug Coordinators will be provided to the Office of Pharmacy annually.

7.4.2 Personnel Change

As positions change and new personnel are acquired please contact the Office of Pharmacy and Cardinal Health's Sales Representative for your area regarding Cardinal Order Express website access and training. For emergencies and period of personnel transition, the Office of Pharmacy will assist to ensure drug orders do not encounter disruption.

7.5 STATE PURCHASING DRUG ORDERING INSTRUCTIONS

7.5.1 Therapeutic Alternatives

Products placed on the formulary may be represented by the chemical or the brand name and will be subject to therapeutic substitution. Therefore, the brand names listed in any document are to serve only for recognition of the chemical name and strength listed.

7.5.2 Budgeting

Due to fluctuations in funding, every effort will be made to provide all products listed on the State formulary. However, if funding is inadequate, local dollars may have to support purchasing.

7.5.3 STD/TB

Place order via Cardinal Order Express, for the STD or TB programs. Alert the Business Analyst in the Office of Pharmacy for STD/TB via email that an order has been placed. Provide the district's account number in the email.

7.5.4 STD-Contraception

Place order via Cardinal Order Express, for the STD-Contraception -Women's Health program. Alert the Business Analyst in the Office of Pharmacy for STD-C via email that an order has been placed. Provide the district's account number in the email.

7.5.5 Building the Order

When building an order 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 placed on September 29, 2016 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.

7.5.6 Items Not Found in Cardinal Order Express

For all other drug or condom orders not available through Cardinal Order Express, please forward an email listing the items and quantities needed to the Business Analyst in the Office of Pharmacy for STD/TB/STD-C via email.

7.6 DISTRICT OPERATIONS RECEIVING THE ORDER

Upon receipt of pharmaceuticals and/or medical devices, invoices must be signed and dated. Any discrepancies must be clearly noted on the invoice and reported within one business day to the distributor. Resolution must be noted on the invoice. All invoices must

be maintained on file for six years.

7.6.1 Invoice Management for State Purchased

For purchases made by the State Office of Pharmacy, signed and dated invoices must be submitted to the State Office of Pharmacy within 72 hours of receiving the product. If invoices are not received with the product shipment (e.g. drop shipment), notify the State Office of Pharmacy.

7.6.2 Invoice Management for Local Purchases

For local purchases made by the district pharmacist or drug coordinator, signed and dated invoices must be submitted to the district within 72 hours of receiving the product. If invoices are not received with the product shipment (e.g. drop shipment), notify the appropriate district personnel.

7.6.3 Funding Source Product Identification

The clinics may receive drugs purchased from the state office or district. To ensure that 340B drugs purchased with local funds will not be mixed with the 340B drugs purchased by the State Office of Pharmacy, county purchased drugs are to be coded with stickers and the inventory kept physically and electronically separate.

7.6.3.1 Local Purchases

a. The district will place a GREEN sticker on all local purchased 340B product.
b. The district will place a RED sticker on all local purchased NON-340B product.

7.6.3.2 State Purchases

a. State Purchased 340B Product will not have a sticker
b. State Purchased Non-340B will have a YELLOW sticker

7.6.4 Storage and Security

All drugs shall be stored in a secured area (under lock and key when not in use). All access entries to the medication room(s) must always be locked prohibiting outside entry. Security of the medication room(s) must be maintained 24 hours a day. Authorization to the medication room(s) must be reserved to those employees performing functions requiring access such as dispensing and inventory management and control.

Whenever more than one authorized person has access to drugs from a common inventory, one person shall be designated "in charge" of said inventory. The person designated "in charge" of said inventory shall ensure that a complete and accurate record of all drugs on hand, received, dispensed, issued, removed or otherwise disposed of, has been kept in accordance with the record-keeping requirements of the Board of Pharmacy.

The district must keep a current list of those employees authorized to have access to the medication room(s). This list must be kept on file and signed annually by the District Health Director and the person "in charge" of said inventory.

The medication room(s) should be sufficiently secure to deny access to unauthorized persons. When the security of the medication room is breached, a police report should be filed, and an actual count of the inventory should be conducted and documented.

7.6.5 Unpacking the Pharmacy Order

7.6.5.1 Verify the cold chain has been preserved and report and document any breach in the cold chain appropriately. (Use **Form #20-1601C**)

7.6.5.2 Upon receipt, all items must immediately be verified against the packing slip, purchase order or invoice for:

- **a.** Number of totes are correct
- **b.** Correct product received
- **c.** Correct number of units received
- **d.** No damage or breakage has occurred in shipment
- **e.** Expiration date should have at least six (6) months dating remaining
- **f.** Correct price

7.6.5.3 Upon receipt of pharmaceuticals and/or medical devices, invoices must be dated and signed *(with full signature)*. If possible, have another staff member verify the information by dating and signing the invoice. Any discrepancies must be clearly noted on the invoice and reported within one business day to the distributor for local purchases and the State Office of Pharmacy and distributor for state purchases. Resolution must be noted on the invoice.

7.6.5.4 For purchases made by the State Office of Pharmacy, signed and dated invoices must be submitted to the State Office of Pharmacy within 72 hours of receiving the product for payment. Follow the district process for payment of local purchases.

7.6.5.5 File invoices by month in sequential order. All invoices must be maintained on file for six years.

7.6.5.6 State and Local purchases will arrive from vendor in separate totes.

7.6.5.7 Appropriately sticker each product to identify State or Local purchased and 340B or Non-340B.

7.6.5.7.1 Local Purchases:

a. The district will place a GREEN sticker on all local purchased 340B product.
b. The district will place a RED sticker on all local purchased NON-340B product.

7.6.5.7.2 State Purchases:

a. State Purchased 340B Product will not have a sticker
b. State Purchased Non-340B will have a YELLOW sticker

7.6.5.8 Separate the product(s) by NDC, lot number, and expiration date. Count each product by lot number and expiration date.

7.6.5.9 Existing inventory is counted and balanced before adding the new shipment to the inventory. Unresolved variances are reported to the District Pharmacist/ Drug Coordinator.

7.6.5.10 Enter the receipt of items into the district's electronic database or manual form using the date, lot numbers, expiration date, National Drug Codes (NDC), name of drug, strength, quantity and adding it to the inventory. Also record the PO/Invoice number if the system allows. Inventory will be identified as either state or local purchased and by lot number and price. If using a manual form, the additional identifier used to indicate funding stream will be listed above the lot number on the form.

7.6.5.11 Product(s) shall be placed on their proper storage shelves, separated by program, state or local, and 340B or non-340B. Ensure shortest dated inventory is utilized first when filling an order.

7.6.5.12 All stock of pharmaceuticals and medical supplies with expiration dates shall be inspected monthly to ensure that no item remains on the shelf that is expired or damaged. If damaged or expired, the next step is to remove the inventory from the database to expired items. The expired items will then be prepared for pick up by the contracted reverse distributor.

7.6.5.13 All drugs and medical supplies are required to be stored off the floor and adequately spaced to permit cleaning and inspection. However, it is suitable to keep supplies on a pallet.

7.6.5.14 Use Form #20-1601C Unpacking Pharmacy Orders

7.7 TRANSFER STOCK INVENTORY INTO UNIT-OF-USE OR UNIT DOSE CONTAINERS

Any drugs removed from the original manufacturer's container for transfer into Unit-of-Use or Unit Dose containers must be done so under the direct supervision of a licensed pharmacist. The Unit-of-Use or Unit Dose packaged medications must be labeled appropriately with the drug name, drug strength, quantity, lot number, and manufacturer. The label must contain the initials of the pharmacist verifying accuracy. The expiration date must be listed as one year from the date of repackaging or sooner if labeled on the original container. Unit-of-Use or Unit Dose packaging must be child resistant. Unit-of-Use or Unit Dose medications must adhere to the same Distribution, Inventory, Tracking and 340B Policies and Procedures as those listed for other medications.

7.8 DISTRICT FILLING CLINIC ORDERS

7.8.1 Clinic submits dated drug order request to the district by program or the Pharmacist/Drug Coordinator may generate an electronic order on behalf of the clinic that provides the documentation of the order.

7.8.2 The district pharmacist/drug coordinator signs out the correct purchased item(s) by program, Lot number(s), Expiration date(s), NDC(s), Name and strength, Quantity.

7.8.3 Product quantity is deducted from the District Central Distribution Pharmacy inventory and entered into local inventories based on funding source. Products can only be transferred to clinics under the same grant number associated with the same funding source. For example, products purchased under PO's assigned to the STD program cannot be shipped to a TB clinic.

7.8.4 When drugs are requested by the county clinics, the central distribution center creates a "transaction" printout/packing slip/drug requisition form, and this printout accompanies the drugs.

7.8.5 Two copies of the transaction printout/packing slip/drug requisition form are made. One copy will go with the shipment to the clinic and the other copy will be maintained at the District Central Distribution Pharmacy.

7.8.6 Clinic receiving the shipment checks in items, verifies shipment, and denotes any discrepancies on the transaction printout/packing slip/drug requisition form (discrepancies must be reported within 1 business day to the District pharmacist/drug coordinator. Sign and date the form and return a copy to District Pharmacy staff.

7.8.7 Use Form #20-1601D District Filling Clinic Orders

7.9 CLINICS RECEIVING THE ORDER FROM THE DISTRICT

7.9.1 Receive the drug order from the District

7.9.2 Verify the cold chain has been preserved and report and document any breach in the cold chain appropriately.

7.9.3 Upon receipt, all items must immediately be verified against the transaction printout/packing slip/drug requisition form for:

a. Number of totes are correct
b. Correct product received
c. Correct number of units received
d. No damage or breakage has occurred in shipment
e. Expiration date should be at least six (6) months in the future, unless the product can be used before the expiration date

7.9.4 Upon receipt of pharmaceuticals and/or medical devices, invoices must be signed *(with full signature)* and dated by the receiving clinic staff. Any discrepancies must be clearly noted on the transaction printout/packing slip/drug requisition and

reported within one business day to the District Central Distribution Pharmacy. Resolution must be noted on the transaction printout/packing slip/drug requisition. If possible, have another staff member verify the information by dating and signing the transaction printout/packing slip/drug requisition.

7.9.5 Make a copy of the signed/dated transaction printout/packing slip/drug requisition form and file the original sequentially by date and keep for 6 years and send the copy to the District.

7.9.6 Existing inventory is counted and balanced before adding the new shipment to the inventory. Unresolved variances are reported to the District.

7.9.7 After making sure the inventory is balanced, the new inventory is added to the electronic record or Log Book identified by program, 340B or Non 340B and state or local purchased including: the date, correct lot numbers, expiration date, National Drug Codes (NDC), name of drug, strength, quantity and record the PO/Invoice number if the system allows. If using a manual drug dispensing sign out sheet, the additional identifier used to indicate funding stream will be listed above the lot number on the drug dispensing page.

7.9.8 Place received product into the clinic's physical inventory. Product(s) shall be placed on their proper storage shelves, separated by:

a. program
b. state or local
c. 340B or non-340B

7.9.9 When stocking new inventory, expiration dates are checked to make sure that the oldest of the drug is going to be dispensed FIRST.

7.9.10 The entire stock of pharmaceuticals and medical supplies with expiration dates shall be inspected monthly to ensure that no item remains on the shelf that is expired or damaged. The next step is to remove the inventory from the database to expired items. The expired items will then be prepared and sent back to the District Central Distribution Pharmacy.

7.9.11 All drugs and medical supplies are required to be stored off the floor and adequately spaced to permit cleaning and inspection. However, it is suitable to keep supplies on a pallet.

7.9.12 Use Form #20-1601E Clinic Unpacking Pharmacy Orders from District

7.10 RETURNS TO VENDORS

Transaction Information, Transaction History or Transaction Statements will not need to be provided when returning products to the vendor in which they were acquired.

7.10.1 State Purchased

7.10.1.1 Contact the State Office of Pharmacy to either create a return authorization with the appropriate vendor or to provide authorization for reverse distributor returns

7.10.1.2 State Office of Pharmacy will validate the appropriate program and account for the return (340B/non 340B)

7.10.1.3 Remove product from inventory

7.10.1.4 Prepare products for return as directed

7.10.1.5 All documents are to be kept on file for 6 years and copy submitted to the Office of Pharmacy

7.10.2 Local Purchased

7.10.2.1 Pharmacist/drug coordinator will determine appropriate program and account 340B or non 340B

7.10.2.2 Utilize appropriate vendor or reverse distributor

7.10.2.3 Remove product from inventory

7.10.2.4 Prepare products for return as directed

7.10.2.5 All documents are to be kept on file for 6 years

7.10.3 Clinic Returns

7.10.3.1 Complete the District's appropriate tracking form to be accompanied by the product(s) when clinics return expired, unused, overstocked, recalled, or damaged stock back to the district office. The form must contain the following:

a. State or local purchase
b. Program
c. 340B or non-340B product
d. Date of transaction
e. Lot number(s)
f. National Drug Codes (NDC)
g. Name of drug and strength
h. Quantity
i. Expiration date Signature of the clinic staff returning product and a signature of the receiving district pharmacist/drug coordinator attesting to the delivery and accuracy of the shipment. After verification return a copy to the clinic. Each location will file by month and keep on hand for 6 years.

7.10.3.2 Inventory is to be removed from the shipping clinic and entered into the inventory of the receiving site on the same day of the transaction. Any discrepancy must be researched and documented by the pharmacist/drug coordinator.

7.10.3.3 The district central distribution pharmacy will be the pickup location for the reverse distributor. Stock is separated by state/local purchases and 340B/Non-340B. A representative from the reverse distributor

scans in returns by the appropriate state or local account and provides a printout of each. The state return list is faxed to the office of pharmacy regarding the returns of state purchased drugs and the district maintains the local return documentation. All documents state/local purchases are filed at the district central distribution pharmacy for auditability purposes and kept for 6 years.

7.10.3.4 Monthly an "Expired Drug Report" shall be generated to ensure that any outdated inventory is removed from the shelves.

7.10.3.5 Use Form #20-1601F Clinic Returns to District

8.0 REVISION HISTORY

REVISION #	REVISION DATE	REVISION COMMENTS
0	1/25/2022	Initial Issue

9.0 RELATED FORMS

PA-20-1601A – Verification Form
PA-20-1601B – Suspect/Illegitimate Identification and Verification Form
PA-20-1601C – Unpacking Pharmacy Orders
PA-20-1601D – District Filling Clinic Orders
PA-20-1601E – Clinic Unpacking Pharmacy Orders from Districts
PA-20-1601F – Clinic Returns to District

VERIFICATION FORM
Authorized Trading Partner /Transactional Data

Verify trading partners have a valid licensure and/or registration per federal and/or state law. Wholesaler distributors and 3PL's are licensed/registered in good standing in the state of Georgia.

Please use the state & federal websites below to validate:

Georgia Board of Pharmacy:

https://gadch.mylicense.com/verification/Search.aspx?facility=N

FDA:

https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm

Verify the wholesale distributor does not engage in the wholesale distribution of Prescription drugs that are purchased or received from **pharmacies or practitioners, or from wholesale distributors that obtained them from pharmacies or practitioners.**

Only accept product if the previous owner provides the "3Ts" (Transaction History, Transaction Information, and a Transaction Statement). 3Ts must be kept for 6 years and may be maintained with wholesale distributor(s) or other third-party vendor(s).

Drop shipments- wholesale distributors that do not physically handle or store product are **exempt**. 3T's may be provided directly to the purchaser. Requests can be made to the primary drug wholesaler to post transaction data on drop shipments after the fact for visibility purposes only.

ONLY APPLICABLE IF USING CONTRACT PHARMACIES: Contract Pharmacies, "Ship To Bill To" accounts-Vendor provides transaction data reports to both account numbers.

Trading Partner	Date Verified Re-verified in 6 months	Initials Re-verification Initials	Transactional Data Electronic OR Paper Maintained By DPH OR Vendor
1.			□ Electronic □ Paper □ DPH □ Vendor
2.			□ Electronic □ Paper □ DPH □ Vendor
3.			□ Electronic □ Paper □ DPH □ Vendor
4.			□ Electronic □ Paper □ DPH □ Vendor
5.			□ Electronic □ Paper □ DPH □ Vendor
6.			□ Electronic □ Paper □ DPH □ Vendor
7.			□ Electronic □ Paper □ DPH □ Vendor

SUSPECT/ILLEGITIMATE PRODUCT IDENTIFICATION AND NOTIFICATION

Date:		Time:		OF SEGREGATION OF PRODUCT	
DPH Staff Name:					
VENDOR NAME:					
DATE/TIME OF NOTIFICATION TO VENDOR:					
PHONE #:		FAX #:			
DIRECTIONS/ACTION PLAN GIVEN FROM VENDOR CONTACT:					

If there are any discrepancies or suspicious or adulterated product received, personnel will isolate said product from other stock, and immediately contact wholesaler or 3PL for resolution and follow instructions.

PRODUCT NAME/STRENGTH:				QUANTITY:	
NDC#:		LOT #(S):		EXPIRATION DATE(S):	
PRODUCT NAME/STRENGTH:				QUANTITY:	
NDC#:		LOT #(S):		EXPIRATION DATE(S):	
PRODUCT NAME/STRENGTH:				QUANTITY:	
NDC#:		LOT #(S):		EXPIRATION DATE(S):	
PRODUCT NAME/STRENGTH:				QUANTITY:	
NDC#:		LOT #(S):		EXPIRATION DATE(S):	
PRODUCT NAME/STRENGTH:				QUANTITY:	
NDC#:		LOT #(S):		EXPIRATION DATE(S):	

File all records related to the product for 6 years.

UNPACKING PHARMACY ORDERS

STATE PURCHASED: ☐	DISTRICT PURCHASED: ☐	DATE:	
		Staff Initials:	

		Yes	No	N/A
1	**UNPACK AND CHECK ITEMS REQUIRING REFRIGERATION IMMEDIATELY**			
	Cold chain has been preserved Report and document any breach in the cold chain appropriately			
2	Upon receipt, immediately verify all items against the packing slip, purchase order or invoice for: • Correct number of totes			
	• Correct product received			
	• Correct number of units received			
	• Damage or breakage identified in shipment			
	• Expiration date is at least six (6) months in the future			
	• Correct price			
3	Signed and dated invoices			
	If possible, 2nd person verifies shipment and signs and dates invoice			
	Clearly noted discrepancies on the invoice			
	Reported within one business day to the distributor for local purchases and the State Office of Pharmacy and distributor for state purchases.			
	Noted resolution of discrepancy on the invoice			
	Submitted invoices (signed & dated) for purchases to the State Office of Pharmacy within 72 hours of receiving the product for State Purchased product Followed district process for payment of local purchases			
4	Filed invoices by month in sequential order			
5	Sticker product to identify State or Local purchased and 340B or Non-340B items			
	Local Purchases: •Placed GREEN sticker on all local purchased 340B product.			
	•Placed RED sticker on all local purchased NON-340B product.			
	State Purchases:			
	•State Purchased 340B Product does not have a sticker			
	•Placed a Yellow sticker on State Purchased Non-340B product			
6	Separated product(s) by NDC, lot number, and expiration date. Counted each product by lot number and expiration date			
7	Counted existing inventory and balanced before adding the new inventory.			
	If applicable, unresolved variances reported to the District Pharmacist or Coordinator			
8	Entered the receipt of items into the district's electronic database or manual form using the following: • Date			
	• Lot number(s)			
	• Expiration date(s)			
	• National Drug Codes (NDC)			
	• Name of drug and strength			
	• Quantity			
	If system allows: Recorded the PO/Invoice number			
	Inventory identified with: • State/Local & 340B/non-340B			
	• Price			

	• Lot number			
	• If using a manual form, listed the additional identifiers used to indicate funding stream above the lot number on the form.			
9	Placed received product into district's physical inventory. Product(s) placed on their proper storage shelves, separated by: • program			
	• state or local			
	• 340B or non-340B			
	• shortest dated inventory moved to the front			
1	Removed expired or damaged product from shelves			
	Removed the inventory from the database to expired items			
	Prepared product for pick up by the contracted reverse distributor			
1	All drugs and medical supplies are stored off the floor and adequately spaced to permit cleaning and inspection. It is suitable to keep supplies on a pallet.			

DISTRICT FILLING CLINIC ORDERS

Shipping Pharmacy Items to the Clinics		Mark Completed with staff Initials Provide explanation for any items not completed	
Clinic Site:			
DATE:			
1. Clinic submits dated drug order request to the district by program			
2. Sign out the correct item(s) by • Program			
• Lot number(s),			
• Expiration date(s)			
• NDC(s), Name, and Strength			
• Quantity			
3. Deduct product from Central inventory			
4. Enter local inventories based on funding source			
5. Create a "transaction" printout/packing slip/drug requisition form			
6. Make 2 copies of the transaction printout/packing slip/drug requisition form		One copy with the shipment to the clinic	☐
		Maintain a copy at the central district distribution pharmacy	☐

CLINIC UNPACKING PHARMACY ORDERS FROM DISTRICT

CLINIC LOCATION:			
DATE:		INITIALS:	

	Yes	No	N/A
UNPACK AND CHECK ITEMS REQUIRING REFRIGERATION IMMEDIATELY			
Cold chain has been preserved Report and document any breach in the cold chain appropriately			
Upon receipt, all items must immediately be verified against the transaction printout/packing slip/drug requisition form for:			
• Correct product received			
• Correct number of units received			
• Damage or breakage in shipment			
• Expiration date is at least six (6) months in the future			
Signed and dated invoices. (full signature)			
Clearly note discrepancies on the transaction printout/packing slip/drug requisition and report within one business day to the District Central Distribution Pharmacy			
If applicable, noted resolution on the transaction printout/packing slip/drug requisition.			
Made a copy of the signed/dated transaction printout/packing slip/drug requisition form and filed the original sequentially by date and sent the copy to the District.			
Count and balance existing inventory before adding the new shipment to the inventory Report unresolved variances to the District Drug Coordinator/Pharmacist			
Entered the receipt of items into the district's electronic database or manual form using the following: • Date			
• Correct lot number(s)			
• Expiration date(s)			
• National Drug Codes (NDC)			
• Name of drug and strength			
• Quantity			
If system allows: • Recorded the PO/Invoice number			
• If using a manual drug dispensing sign out sheet, listed the additional identifier used to indicate funding stream above the lot number on the drug dispensing page.			
Placed received product into the clinic's physical inventory. Product(s) shall be placed on their proper storage shelves, separated by: • program • state or local • 340B or non-340B • shortest dated inventory moved to the front			
Removed expired or damaged product from shelves			
Removed the inventory from the database to expired items. Prepared for pick up by the contracted reverse distributor.			
All drugs and medical supplies are stored off the floor and adequately spaced to permit cleaning and inspection. It is suitable to keep supplies on a pallet.			

CLINIC RETURNS TO DISTRICT

DATE:		INITIALS:	

	REASON			PRODUCT INFORMATION		QTY	INVENTORY	
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				
	UNUSED/ OVERSTOCKED		340B PROGRAM	NDC#			Removed	
	RECALLED		Non-340B	Name of drug & strength			Balanced	
	DAMAGED		STATE	Lot #				
			LOCAL	Expiration date				