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I. Policy

The Department of Health (DOH) will use the process and procedures outlined in this policy for all entities that procure, store, administer, dispense, issue, or otherwise distribute prescription or over-the-counter (OTC) drugs, including vaccines, to county health department (CHD) clients.

II. Authority

- A. Section 1.04, Florida Statutes, Construction of Statutes, Definitions
- B. Section 20.03(11), Florida Statutes, Organizational Structure, Definitions
- C. Section 20.155, Florida Statutes, Board of Governors of the State University System
- D. Chapter 154, Florida Statutes, Health Facilities, Part III
- E. Chapter 287, Florida Statutes, Procurement of Personal Property and Services
- F. Chapter 381, Florida Statutes, Public Health: General Provisions
- G. Section 383,14, Florida Statutes, Screening for Metabolic Disorders
- H. Chapter 384, Florida Statutes, Sexually Transmissible Diseases
- I. Chapter 385, Florida Statutes, Chronic Diseases
- J. Chapter 392, Florida Statutes, Tuberculosis Control
- K. Chapter 458, Florida Statutes, Medical Practice
- L. Chapter 459, Florida Statutes, Osteopathic Medicine
- M. Chapter 464, Florida Statutes, Nursing
- N. Chapter 465, Florida Statutes, Pharmacy
- O. Chapter 466, Florida Statutes, Dentistry, Dental Hygiene, and Dental Laboratories
- P. Chapter 499, Florida Statutes, Drug, Cosmetic and Household Products
- Q. Chapter 893, Florida Statutes, Comprehensive Drug Abuse Prevention and Control
- R. Florida Administrative Code Rule 64B16, Board of Pharmacy
- S. Florida Administrative Code Rule 61 N-1, Regulations for Drugs, Devices, and Cosmetics
- T. 340B PHS, Section 340B of the Public Health Service Act
- U. Public Law (PL)104-191- HIPAA Health Insurance Portability and Accountability Act of 1996
- V. 45 Code of Federal Regulations, Parts 160, 162, and 164: Health Information Privacy
- W. Pharmacy Practice Law, The Robinson-Patman Act (1936), PL 74-692, NonProfit Institutions and "Own Use," 15 U.S.C. §13

III. Signature Block with Effective Date

Signature on File

April 24, 2018

Celeste Philip, MD, MPH
Surgeon General and Secretary

Date

IV. Definitions

Definitions used throughout this document can be found on the [Bureau of Public Health Pharmacy SharePoint](#) site.

V. Protocol

- A. Outcome:** This guidance is to ensure the most efficient and safe processes for procurement, administering, dispensing, and issuing OTC and prescription drugs, including vaccines, to CHD clients.
- B. Personnel:** This policy applies to all DOH personnel, contracted staff, and volunteers.
- C. Competencies:**
1. Knowledge of day-to-day management of medication in clinic and pharmacy operations.
 2. Knowledge of federal and Florida laws, rules and DOH policies.
- D. Areas of Responsibility:**
1. **Bureau of Public Health Pharmacy (BPHP):** To practice and provide the most cost effective pharmaceutical program management and to provide the necessary support to state operated DOH pharmacies in Florida.
 2. **CHD Staff:** Adhere to protocol in this policy.

VI. Procedures**A. Section 1: Format of the Policy**

This policy is designed to familiarize CHD personnel with the policies and procedures governing the procurement, inventory management and control, and distribution of pharmaceuticals within DOH CHDs.

B. Section 2: Statewide Pharmaceutical Procurement

Specific Authority: Section 381.0203(1), Florida Statutes, grants to the DOH the authority and responsibility to contract on a statewide basis for the procurement of drugs.

C. Section 3: Funding Sources, Pharmacy Allocation, and Medicaid Billing**1. BPHP Funding Sources**

- a. **Lump Sum Appropriation for Drugs:** The Florida Legislature appropriates funding annually for the procurement of core public health drugs. The programs involved include: HIV/AIDS, Insulin, Family Planning, Epilepsy, Immunizations, Sexually Transmitted Diseases (STD), Tuberculosis (TB), Phenylketonuria (PKU),

and General Clinic.

b. Direct Funding from State and Federal Program Offices:

If state and federal central program offices receive supplemental/additional funding for drugs and/or devices that exceed lump sum appropriations identified in a. above, the program manager shall contact the BPHP Business Operations Office at 850-922-9036 to arrange for transfer of funds to BPHP prior to any procurement. The program manager must identify all of the following in writing:

- (1) Funding source
- (2) Funding amount
- (3) Grant requirements for procurement
- (4) Timeframe for procurement
- (5) Name(s) of product(s) to be procured
- (6) Total amount(s) of product(s) to be procured
- (7) Amount to be distributed to each site

2. Billing Medicaid for Prescriptions

- a. CHDs without a Pharmacy:** CHDs shall submit the necessary Medicaid client and provider information to the BPHP for Medicaid approved pharmaceutical products or devices obtained from the BPHP that are issued, dispensed, or administered to clients eligible to receive 100 percent Medicaid benefits. The required form for Medicaid submissions will be completed and submitted through the Pharmaceutical Forms System (PFS) and is available through the Internet or intranet at <https://fdohcentralpharmacy.com/login.aspx>.

The criteria for determining if reimbursement for a product should be performed by the CHD are as follows:

- 1) The client is Medicaid eligible and has a third-party provider coverage;
- 2) The products that are listed in the PFS drop-down box are non-reimbursable, or the place of service does not have access to PFS; and
- 3) The reimbursement must be requested at the place of service according to Medicaid classification (coding) of the product.

Any funds received by a CHD as remuneration or reimbursement for any pharmaceuticals or devices procured through or by the BPHP shall be returned to BPHP by means of Journal Transfer. These funds will be reinvested in the current fiscal year to the drug budget allocations. Current coding for that transfer can be obtained from the BPHP Business Office by calling 850-922-9036, extension 3014.

- b. CHDs with a Pharmacy:** CHDs with a pharmacy license(s) having a need to bill Medicaid for prescriptions filled must obtain one (1) Medicaid provider number from the Medicaid Program Office. All Medicaid providers must have obtained two (2) National Provider Identifier (NPI) numbers in order to be reimbursed for Medicaid service provision. See the Agency for Health Care Administration's website for further information. See (1) and (2) below.

- (1) 340B Public Health Service (PHS) Medicaid Provider Number. CHD pharmacies filling HIV/AIDS (ADAP or other Ryan White programs), TB, STD, Family Planning or other 340B PHS Program prescriptions for Medicaid, Medicaid HMO and PPO eligible clients and using pharmaceuticals or devices obtained from the BPHP or through a wholesale distributor PHS account, must bill Medicaid for eligible clients using their PHS NPI. See subparagraph 2. b., directly above, regarding NPI. The PHS-related NPI must be registered with HRSA OPA for the site seeking Medicaid reimbursement.
- (2) CHD pharmacies desiring to bill Medicaid for non-340B PHS eligible clients must obtain a second non-340B Medicaid number and NPI number for prescriptions other than for those listed in 2.b(1).

Any funds received by a CHD as remuneration or reimbursement for any pharmaceuticals or devices procured through or by the BPHP shall be returned to BPHP by means of a Journal Transfer. These funds will be reinvested in the current fiscal year to the drug budget allocations. Current coding for that transfer can be obtained from the BPHP Business Office by calling 850-922-9036, extension 3014.

- c. Medicaid Billing for Prescriptions Filled by BPHP:** When a CHD client's prescription is filled by BPHP and the client is Medicaid eligible, the BPHP will bill Medicaid for reimbursement of the drug. Information regarding the client's coverage must be submitted from the CHD along with the client profile when a new prescription is submitted to BPHP. Reimbursements are returned to the drug budget allocations for the current fiscal year.

- d. **Retroactive Medicaid Billing:** CHD clients who are eligible for and receiving drug assistance through one of the state program offices (i.e., HIV/AIDS Drugs Assistance Program TB, STD, Family Planning) may subsequently become Medicaid eligible after the date of service. Therefore, prescriptions filled under the eligibility requirements of the program office and filled with drugs obtained from the BPHP may be retroactively billed to Medicaid for up to 12 months prior to the establishment of Medicaid eligibility.
- (1) **Retroactive Medicaid Billing for PHS Purchased Drugs:** CHD pharmacies must retroactively bill Medicaid for prescriptions purchased at a PHS price and must use their 340B (PHS) Medicaid number and NPI numbers. Medicaid is billed the PHS drug acquisition cost and pharmacies are reimbursed at drug acquisition cost plus the customary dispensing fee.
- (2) **Retroactive Medicaid Billing for Non-PHS-Purchased Drugs:** CHD pharmacies wishing to retroactively bill Medicaid for prescriptions not purchased at a PHS price must use their regular NPI. Medicaid is billed the non-340B drug acquisition cost; pharmacies are reimbursed at acquisition or allowable cost plus the customary dispensing fee.
3. **Rabies Vaccine:** CHDs must purchase all rabies related products. Contact the Office of Budget and Revenue Management for more information on reimbursement policies.
4. **Centralized Medicaid Billing for Specific Pharmaceutical Products or Devices Obtained from the BPHP:** CHDs receiving Medicaid approved pharmaceutical products or devices from the BPHP must submit the necessary Medicaid client and provider information to the BPHP for billing. These forms are submitted through the BPHP's PFS.

D. Section 4: Pharmacy Logistics

1. **BPHP Accessibility:** The BPHP is a mail-order pharmacy that also provides assistance and advice to CHDs and their clients regarding pharmacy services or operations for prescriptions filled and dispensed by the BPHP only. During regular business hours (Monday-Friday; 8:00 am - 5:00 pm; excluding state holidays), the BPHP can be reached by calling 850-922-9036. An on-call pharmacist can be reached after regular business hours for emergencies regarding BPHP dispensed prescriptions by calling 850-445-9446.

For individual CHD clients, the BPHP provides both an Internet-based portal and an interactive voice recognition (IVR) system on its telephone network for client generated prescription refill requests at 800-554-4584.

The PFS is available through the Internet to CHDs requesting refills for multiple clients. A username and password is required for the use of this system and can be obtained by [self-registration through PFS](#).

- 2. Audit Trails:** All CHDs shall establish and maintain a system, either in electronic or manual form, to provide accurate audit trails for all pharmaceuticals ordered, received, inventoried, and distributed by the CHDs.

Part of the audit trail requirements are to receive inbound audit trail documents with the inbound pharmaceutical drugs that meet the requirements of section 499.0121(6), Florida Statutes, and Florida Administrative Code, rule 61N-1.012 (2). Accordingly, all outbound prescription drugs not dispensed to an identified client should be the subject of an audit trail document that complies with the above-mentioned provisions and must be created at the time of the transaction. A CHD must have a restricted drug distributor license in order to move outbound pharmaceutical drugs.

Manual or electronic inventory control procedures must contain sufficient documentation to enable the CHD to track a drug from its initial order through its receipt and final disposition. Issue documents or invoices, transfer documents, accurate medical record entries, and careful attention to maintaining administration logs are all essential to a complete audit trail. Maintaining good records helps rectify discrepancies between actual inventory and calculated inventory.

- 3. Individual Pharmaceutical Records:** An individual manual inventory control or electronic record forms must be established and maintained for each drug in stock. Each drug record shall provide space for the following information:
- a. The drug name, strength, and dosage form
 - b. The stock control level and reorder point
 - c. The date of drug receipt or disbursement
 - d. The source of drug receipt, the client's name to whom disbursed, the name of the receiving facility for drugs transferred, or the reason for an inventory adjustment (e.g., breakage, spillage, etc.)
 - e. A referring document number for audit purposes such as a purchase order number, invoice number, request number, or issue document number
 - f. The quantity of drug received or disbursed

- g. The new inventory balance (perpetual inventory balance)
- h. The unit-of-issue unit price of the drug (used for end of the year financial and insurance reporting)
- i. The name or initials of person receiving or disbursing the drug
- j. A stock number to act as a unique identifier, which will include the National Drug Code (NDC) number and the lot number
- k. Any other appropriate data (i.e., manufacturer's drug expiration date)

CHD pharmacies should utilize the inventory management and control system available with their pharmacy software dispensing system to maintain records of drug receipts.

4. Record Keeping Requirements

- a. **CHD Without a Licensed Pharmacy:** In a CHD without a licensed pharmacy, the medical director and/or the physician, whose license and/or DEA registration licenses drugs to be stored/administered, is accountable for producing any pharmaceutical related documentation required or requested during an inspection or audit. The task of maintaining this documentation may be delegated to another member of the CHD staff.
- b. **CHD With a Licensed Pharmacy:** In a CHD with a licensed pharmacy, the pharmacy manager of record with the Florida Board of Pharmacy is responsible and accountable for producing any pharmaceutical related documentation required or requested during an inspection or audit.

Prescription drug audit trail records and content thereof required to be kept are those described in section 499.0121 (6) (b), Florida Statutes, and Florida Administrative Code, rule 61N-1.012 (2). Audit trail and inventory records must be kept for no less than six (6) years from the date of disposition of the prescription drug.

5. Record of Drug Receipts and Disbursements

- a. **Drug Receipts:** All drug orders, regardless of source, must be checked in upon receipt and added to the pharmaceutical inventory.
- b. **Drug Disbursements:** All drug disbursements, regardless of receiving entity, must be reduced from the CHD pharmaceutical inventory.

6. Segregation of Controlled Substance Invoices: Invoices, issue

documents, or other documents related to the receipt or distribution of controlled substances must be maintained separately from documents for other pharmaceuticals or supplies. These records should be maintained in a sequential, readily retrievable manner.

7. **Storage of Pharmaceuticals in Clinics**

- a. **Climate Controlled Area:** All drugs not requiring refrigeration, freezing or special handling must be stored in a clean, well-lighted, and adequately ventilated climate-controlled area. Special attention should be focused on avoiding extreme temperature variations and moisture.
- b. **Refrigeration:** All drugs requiring refrigeration or freezing must remain refrigerated or frozen during storage. CHDs must either maintain a manual log of daily temperatures in the refrigerator and freezer or the unit must be connected to a temperature monitoring system.
- c. **Bulk Stock Storage:** Drugs must be separated and not combined with other commodities in the storage area. All bulk stock must be kept in tightly sealed containers to prevent pilferage, contamination, and loss of potency.
- d. **Storage of Pharmaceuticals at Non-Clinic Locations**
 - (1) **License Required:** Prescription drugs, stored off-site at non-clinic locations (i.e., a drug warehouse) must be stored in a licensed facility. The most appropriate license for a CHD with a drug warehouse is a restricted prescription drug distributor – health care entity or government program license, as applicable.
 - (2) **Storage Requirements:** The housing of pharmaceuticals in any off-site location (i.e., a drug warehouse) must meet the storage provisions in this section.
 - (3) **Inventory Requirements:** Pharmaceuticals stored in any off-site location (i.e., a drug warehouse) are subject to all the inventory management and control provisions of this policy.

8. **Security of Pharmaceuticals and Devices:** Drug storage areas must remain secured at all times when not in use. The names of all individuals with security access to the drug storage area will be documented on a CHD memorandum of record, authorized by the CHD administrator/director. This memorandum will be updated as necessary, maintained in the official records of the CHD and readily accessible to pharmacy personnel.

- a. **Access to Drug Storage Areas:** Access to the drug storage areas must be restricted to personnel authorized to handle drugs.
- b. **Access to Licensed Pharmacy:** In CHDs with a licensed pharmacy, the pharmacy must be secured when not in use or in the absence of a registered pharmacist employed by the CHD. No one is allowed to be in the pharmacy unless a registered pharmacist employed by the CHD is present on the premises and is on duty.

9. Inventory Management

a. Inventory Control Components

- (1) **Stock Control Level:** Each CHD must establish and maintain a stock control level (**NOT TO EXCEED A TWO-WEEK SUPPLY**) for each medication carried in inventory. Re-evaluation of stock control levels must be monitored to ensure that appropriate levels are maintained and overstocking is avoided.
- (2) **Actual Inventory on Hand:** The actual inventory quantity of a product on the shelf at the time the monthly inventory is taken should equal the total for the last entry on that product's manual or electronic inventory record. By compartmentalizing the drug inventory (i.e., maintaining separate logs for separate drug storage locations) an inventory discrepancy can be isolated to a particular area. This reduces the staff time required to reconcile an inventory discrepancy.
- (3) **Reorder Point:** Local CHD procedure shall establish a reorder point that triggers the ordering process for that facility.

- b. **Stock Rotation:** CHDs should use drug inventory on a first-in-first-out (FIFO) basis, based upon the drug expiration date.

c. Verifying Receipts and Disbursements

- (1) **Pharmaceuticals Received by the CHD from the BPHP:** Upon receiving drugs from the BPHP, or from an order placed with BPHP but shipped by the wholesaler or manufacturer, CHD personnel must compare the DOH shipping list with the products and quantities received. At a minimum, two (2) DOH personnel shall verify the shipment and certify the receipt.

Any discrepancies (including shortages, overages, or incorrect product) between the listed quantity shipped and the actual quantity received must be noted and the BPHP notified the same day 850-922-9036. Copies of the invoices/packing slips will be scanned and emailed. If the invoice is a Cardinal invoice and the product was ordered from BPHP, then the invoice should be submitted to cardinal.invoices@flhealth.gov and if the invoice is from another vendor and the product was ordered from BPHP, then the invoice should be submitted to HDSHP.InvoicesBulk@flhealth.gov, as documentation of the discrepancy. This documentation must be signed by both parties responsible for the receiving, dated with the receiving date and the discrepancy noted.

- (2) Ordering and Receiving Controlled Substance Drugs:** Any drug that is defined as a controlled substance will be ordered and received under the direct supervision of the CHD pharmacist (in CHDs with a licensed pharmacy), the CHD physician (whose license and DEA registration for licensed drugs to be stored and/or administered) or their designee. See [Appendix K](#) for Controlled Substance Registration information.
- (3) Pharmaceuticals Received from Other Sources:** For products procured locally by the CHD and not through the BPHP, receipts from the wholesale distributor or drug manufacturers, including pharmaceutical transfers from another CHD or health care entity, must be checked against the included packing list, invoice, or transfer document. At a minimum, two (2) personnel will verify the shipment and certify their receipt. A copy must be retained by the CHD.
- (4) Pharmaceuticals Returned to Other Sources:** Pharmaceutical returns to the reverse drug distributor must be performed in accordance with the vendor's established return policy. CHD personnel responsible for returning these pharmaceuticals will sign and date the accompanying form as certification of the return. Pharmaceutical transfers to another CHD or health care entity will use a shipping list as described above.
- (5) Pharmaceuticals Distributed to CHD Clients:** Pharmaceuticals administered, dispensed, issued, or otherwise distributed to CHD clients will be entered into the appropriate pharmaceutical record form and the quantity disbursed reduced from the CHD pharmaceutical inventory in order to maintain an accurate perpetual inventory

balance.

d. Taking Inventory

(1) Drugs Exempt From Inventory

- (a) Manufacturer's Drug Samples:** These products are the personal property of the requesting physician. Drug samples may not be sold. Physicians must store their drug samples separately from the CHD drug inventory, and are required to keep a separate inventory record of sample drugs. For non-controlled substances the general drug record retention provisions in Florida Administrative Code, rule 61N-1.012 (1) apply.
- (b) Client-Specific Prescriptions:** CHDs will establish a tracking system for the receipt and distribution of any client-specific prescription obtained from the BPHP.
- (c) Client-Specific Manufacturer's Indigent Drug Compassionate Care or Client Assistance Program:** CHDs will establish a tracking system for the receipt and distribution of any client-specific prescription obtained from a drug manufacturer through a licensed pharmacy.

(2) Maintenance of Separate Inventories: Drugs obtained from the BPHP must be stored and properly inventoried separately from drugs obtained from other sources. All drugs that have been procured or obtained through 340B PHS pricing must be segregated and inventoried separately from non-PHS priced drugs. Drugs for PHS eligible programs can only be dispensed or administered to program eligible CHD clients.

(3) The 340B covered entity will document evidence to support the criteria for inventory management:

- (a)** It must regularly evaluate 340B utilization reports to identify and correct discrepancies.
- (b)** For additional information review the CHC Comprehensive 340B Policy and Procedure Manual located at:
https://docs.340bpvp.com/documents/public/resourcecenter/CHC_PolicyManual.docx.

(4) Inventory Frequency for CHD Sites: All CHD sites shall inventory all drug products, including any vaccines or immunizations in possession of the CHD, regardless of source, and an inventory shall be conducted monthly to establish the quantity of drug products to be ordered from the BPHP, the wholesale distributor or drug manufacturers. In addition, to monitor for diversion of non-controlled substance or “program” medication, the CHD pharmacist, physician (whose license and/or DEA registration licenses drugs to be stored/administered) or designee, and CHD business manager or designee will conduct quarterly inventories of selected medication to compare and reconcile with pharmacy and physician inventory and dispensing/administration records.

(5) Annual Written Inventory for All CHDs: A written inventory listing all drug products, including any vaccines in the CHD possession, with respective quantities on hand at the time of inventory and respective inventory values obtained from associated acquisition costs must be prepared in all CHDs annually no later than the close of business on the last working day of June. Each CHD shall retain a copy of this inventory. A sample physical inventory form is located in [Appendix B](#).

The annual physical inventory will be conducted by the joint involvement of the CHD business manager, or other delegated CHD staff, and pharmacy staff (in those CHDs with a licensed pharmacy); or CHD business manager, or other delegated CHD staff member, and the CHD physician, whose license and/or DEA registration licenses drugs to be stored /administered (in those CHDs without a licensed pharmacy).

(6) CHD Inventory Value Report: An Inventory Value report indicating the total asset value of the CHD drug inventory, including any vaccines or immunizations in the CHD’s possession, as of June 30, must be forwarded to the DOH Bureau of Finance and Accounting, Office of Policy and Systems in Tallahassee by the subsequent July 14 of each year.

(7) Controlled Substances Inventory: A complete, monthly inventory of all controlled substances will be conducted according to section 893.07, Florida Statutes.

In the event of a discrepancy, the CHD pharmacist, physician or designee will review the results of each day’s activity (inventory) as reported on the computer database

system or written Inventory Record report. All inventory discrepancies will be investigated and reported (a DOHP 5-6; Incident Reporting Form may be used to document such a discrepancy). Significant loss of a controlled substance must be reported to the DEA. See 21 CFR section 1301.76.

For Schedule II Controlled Substance Discrepancy reports, the CHD pharmacist, physician, or designee will immediately notify the CHD administrator/director.

- (8) Inventory Adjustments:** All inventory adjustments will be carefully checked and appropriate entries made on the drug record to explain such adjustments. [Appendix A](#) illustrates the basics of an administration/inventory control logbook page.
- (9) Insurance Coverage on Pharmaceutical Inventory:** A CHD must maintain adequate insurance protection against loss for all drug products, including any vaccines, in its possession. The CHD's business manager will reevaluate the level of coverage and protection at least once annually following the submission of the end of fiscal year pharmaceutical inventory value report.
- (10) Unusable or Unserviceable Drugs:** Drugs rendered unusable from the event (damaged, unable to maintain within temperature requirements, exceeded manufacturer's expiration date, etc.) shall be kept in quarantine from useable pharmaceutical inventory.

e. Designated Drug Quarantine Area for Non-usable Pharmaceuticals

Each CHD shall establish a minimum of two (2) designated, clearly marked and defined quarantine areas for non-usable pharmaceuticals.

A drug quarantine section shall be clearly marked and designated separate and apart from any other place where drugs are stored so that products therein shall not be confused with usable products being held for distribution. There should be two (2) quarantine areas:

- (1) Drugs Received from the BPHP:** Any drug received from the DOH BPHP and placed in quarantine will be segregated from other usable inventory and from other quarantined drugs.

- (2) **Drugs Received from Other Sources:** Any drug received from a source other than the DOH BPHP and placed in quarantine will be segregated from other usable inventory and from other quarantined drugs.
- (3) **Inventory Accountability Options for Record Maintenance:** Drugs in quarantine are still considered to be part of a CHD total drug inventory until they have been returned or destroyed. If not part of the active inventory, then a reference list of drugs in quarantine shall be maintained. Documentation of a drug's return or destruction must be maintained with other inventory records throughout the mandatory record retention period.

The Physical Inventory report, [Appendix B](#), must reflect the inventory quantities and values of both usable and non-usable drugs.

10. Pharmaceutical Returns and Disposal Policy

- (1) **Pharmaceuticals Returned to the BPHP:** Any controlled substance pharmaceutical being returned to the BPHP must be completely segregated or returned separately from any other items being returned. The sending CHD must produce a shipping list to identify each controlled substance being returned, the NDC number, the quantity being returned, and the reason for return.

Before returning any pharmaceuticals to the BPHP, CHD personnel should compare the entries on the drug shipping list against the actual products and quantities being returned. CHD personnel responsible for returning these pharmaceuticals will sign and date the completed shipping list as certification of the return. A copy must be retained by the CHD. Refer to G.1 Return and Disposal Policy. Returning outdated or deteriorated pharmaceuticals is an essential function. Establishing proper inventory management controls will aid the CHD in reducing the expenses associated with this process.

A contracted reverse drug distributor is available through the current Group Purchasing Organization (GPO) Agreement and must be used to return and/or dispose of drugs. Drugs returned through the GPO Contracted Reverse Distributor (CRD) are governed by law and the procedures outlined in this policy and procedure. The processing fee for the CRD will be deducted from the issued credit. The CRD must be licensed as a Reverse Distributor in Florida under Chapter 499, Part I, Florida

Statutes. If the CRD is not located in state, it must be licensed in the jurisdiction where it receives DOH's reverse distributed prescription drugs.

An invoice listing the drug name, NDC number, and quantity returned must accompany all returns processed through the CRD. A copy of this shipping document must be retained by the CHD for audit purposes, and a copy of this shipping document must be forwarded to the BPHP Business Office at the BPHP Business Office.

Questions regarding controlled substances may be addressed to the appropriate [DEA Offices](#). CHDs must follow the internal tracking number procedures.

- (a) **Outdated Pharmaceuticals:** Expiration dates for pharmaceuticals will be checked in CHDs without a licensed pharmacy at least monthly. All outdated products will be removed and segregated from active stock and placed in the appropriate designated quarantine area. Outdated pharmaceuticals should be returned at least monthly.

Outdated products shall never be sold, administered, issued, dispensed, or distributed to the public. Expired prescription drugs may not be donated for charitable purposes.

- (b) **Deteriorated Pharmaceuticals:** Any non-expired pharmaceutical product that has been subjected to improper storage conditions, contaminated in any way, adulterated, or deemed to be unusable for any reason other than being considered excessive stock shall be segregated from active stock and placed in the appropriate designated quarantine area.

- (2) **Procedures for the Return and Disposal of Unusable or Unserviceable Drugs from BPHP:** CHDs must adhere to procedures in disposing of unusable or unserviceable drugs ([Appendix L](#)). An unusable or unserviceable drug includes expired or damaged drug and any BPHP-dispensed or CHD-dispensed client medication not having left the confines of the CHD pharmacy or drug storage area; but does not include overstock. To ensure that any credit issued is applied correctly, drug returns to the CRD or to the BPHP must include the BPHP's or CHD appropriate wholesale distributor account number. No

expired, damaged or otherwise adulterated drug may be returned directly or indirectly to the BPHP.” See section 499.006, Florida Statutes, for definition of “adulterated.”

An invoice listing the drug being returned, the quantity of the drug being returned, the date of the return, and the account to which any issued credit is to be applied will accompany all drug returns either to the BPHP or to the CRD ([Appendix L](#)). All prescription drug returns must comply with the audit trail requirements of Section D. 4. 2. of this Policy and Procedure, and must include the manufacturer’s or repackager’s name and lot number for each drug.

Controlled substances being returned must be segregated and not co-mingled with other drug items being returned.

- (a) **Service Option Available from Contract Reverse Distributor:** For an additional service fee applied to any credit issued, a CRD field representative will assist with the preparation of shipping labels and invoice documentation required for drugs being returned to the CRD, including any applicable DEA 222 forms that must accompany the return. A copy of the return invoice must be forwarded to the BPHP Business Office.
- (b) **BPHP Return Merchandise Authorization (RMA) Number for CRD Returns:** If a CHD chooses not to use a CRD field representative, the CHD must contact the BPHP Business Office to obtain a RMA number. This is a DOH internal tracking number only, but no RMA number will be issued until an invoice of drugs to be returned is forwarded to the BPHP Business Office.

This invoice may be sent by regular U.S. mail, fax, or email. Upon receipt of the invoice and the assignment of a MRA number through the PFS the BPHP Business Office will contact the CRD and have a shipping label sent to the CHD.

CHDs should receive a MRA number from the BPHP Business Office by the close of business the next business day following the CHD request.

- (3) **Return of Repackaged Drugs from the BPHP:** Repackaged drugs obtained from the BPHP must be

returned to the BPHP for disposal. No credit will be issued.

- (4) **Return of Manufacturer's Drug Samples:** Out-of-date or otherwise unusable manufacturer's drug samples are to be returned to the manufacturer or distributor of that drug.
- (5) **Disposal of Client Medications:** Medications dispensed to a specific client by any pharmacy or dispensing physician or practitioner and thus having become the personal property of that client may neither be entered or reentered into a CHD pharmaceutical inventory nor reused for or redispensed to another client.

Any prescription dispensed to a CHD client by the BPHP, CHD pharmacy, or a non-DOH pharmacy for a medication that is no longer part of that client's drug therapy regimen should not be retained by CHD staff. No credit will be issued to the CHD, and the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP) CRD is entitled to bill the CHD a disposal fee. Clients should be directed to an entity in Florida with a license to arrange for the disposal of their medications.

All unclaimed pharmaceuticals obtained from BPHP must be returned through the PFS to BPHP within 90-days.

Dispensed prescription drugs may not be donated for charitable purposes.

- f. **Drug Recalls:** Recall notification for drugs procured from the BPHP will be distributed to all CHDs through a PFS announcement. These recalled drugs should be returned directly to the BPHP using the PFS RMA procedure, unless otherwise instructed, for replacement or credit. Recalls for drugs purchased from any other source shall be handled in accordance with the recall notice.

E. Section 5: Procurement and Distribution of Pharmaceuticals and Vaccines by CHDs

- 1. **Procurement of Controlled Substances:** Health care practitioners must comply with regulations related to the prescription of controlled substances set forth in section 456.0276, Florida Statutes, and where necessary, follow the CDC's guidelines for prescribing opioids.
- 2. **Procurement by CHDs**
 - a. **Bulk Pharmaceuticals:** Bulk pharmaceuticals are available to CHDs through the BPHP in the program areas identified in this

policy. The current BPHP's PFS lists the available products.

(1) Procurement from the BPHP

- (a) Ordering Information from the BPHP:** CHDs may order drugs using the on-line order forms listed at [BPHP Online Order](#).
- (b)** CHD staff must pay special attention to the product's unit of issue when ordering bulk drugs from the BPHP. Failure to order properly may result in a serious under or over shipment of product.
- (c) Order Frequency:** Orders should be submitted to the BPHP on a semi-monthly or as needed basis.

- (2) Procurement from vendors other than the BPHP:** CHDs may elect to procure drugs in addition to those obtained from the BPHP. Drugs are procured from the wholesale distributor. All procured drugs must be listed on an approved formulary.

b. Individual Clients' Prescriptions from the BPHP

- (1) The BPHP dispenses drugs for individual CHD clients in the following program areas:
- AIDS Drug Assistance Program (ADAP)
 - Epilepsy
 - Family Planning
 - Tuberculosis (including Directly Observed Therapy)
 - Insulin
 - Phenylketonuria
 - Sexually Transmitted Diseases

Guidelines have been established by each program entity regarding requirements. Consult these individual program guidelines for specific program requirements.

- (a) Security and Confidentiality of Client-Specific Prescriptions:** CHD staff shall consider all information contained in a client's prescription form as confidential. The prescription shall be kept in a secure location with access limited only to authorized personnel until it is sent, if at all, to the

BPHP for filling and dispensing.

- (b) Requirements for all Client-Specific Prescriptions:** All prescriptions submitted to the BPHP for dispensing must contain all of the following information:
- 1) Client's name
 - 2) Client's date of birth
 - 3) Client's address
 - 4) Physician's state license number
 - 5) Physician's DEA number if the prescription is for a controlled substance
- (c) Initiating Therapy with Program Covered Pharmaceuticals:** If the medication is obtained from BPHP, it is the responsibility of the CHD to arrange or provide medication dosage coverage for a client until the client's prescription is received from the BPHP unless that prescription is written for an eligible program whose distribution is restricted to being dispensed only by the BPHP.
- Under no circumstance shall a client-specific prescription drug be used to initiate therapy for any client other than the client to whom that prescription was originally dispensed.
- (d) Specific Requirements for Client-Specific Epilepsy Medication from the BPHP:** The BPHP dispenses Epilepsy Program medication for eligible program clients. Prescriptions for non-controlled epilepsy medications shall be submitted via e-Prescribe or on an Epilepsy Medication Request Form ([Appendix M](#)). CHDs are responsible for utilizing the most recently available form for prescriptions.
- BPHP will mail all epilepsy drugs to the client's home address. Exceptions will be considered on a case-by-case basis. The CHD representative must contact BPHP prior to submitting the Epilepsy Medication Request Form for exception authorization.
- (e) Specific Requirements for Directly Observed Therapy (DOT) or Directly Observed**

Preventative Therapy (DOPT): The BPHP offers a medication dispensing service for the treatment of TB in the form of individual packs that can be administered daily, biweekly, triweekly as prescribed by practitioner. To utilize this service the CHD must submit a DOT Multi-Dose Order Form to the BPHP. Prescriptions for DOT will be mailed to the CHD TB Program coordinator or representative.

There are several TB treatment medications that require approval from the TB Physicians Network prior to dispensing for the treatment of individuals diagnosed with TB. Please refer to the TB Program's procedures for the specific restricted treatment regimens at [IOP 230-01-18](#).

- (f) Specific Requirements for Client-Specific Insulin Medication from BPHP:** BPHP dispenses Insulin Program medication for eligible program clients. Prescriptions for insulin formulary drugs must be submitted to BPHP along with the completed Insulin Distribution Program Application and the completed Client Medical Profile ([Appendix C](#)).
- (g) Maximum Allowable Prescription Quantities for Client-Specific Prescriptions from the BPHP:** BPHP will dispense a 30-day supply of medications for client-specific prescriptions for the ADAP Prescriptions, Epilepsy, Insulin, TB, and Family Planning medications will be dispensed either 30-day or 90-day supply as prescribed.
- (h) Refill Requests for Client-Specific Prescriptions from the BPHP:** Each individual CHD is responsible for establishing and maintaining a system for obtaining prescription refills for individual client prescriptions from the BPHP. Prescription refills for drugs for ADAP, TB, Family Planning, Epilepsy, Insulin, STDs (DOH and Department of Corrections) Program eligible clients must be submitted via the PFS or via the BPHP Interactive Voice Recognition (IVR) System that can be reached at 800-554-4584.

Prescriptions are valid for a maximum of one (1) year from the date of the original written date except for controlled substances (section 893.03, Florida Statutes), which are valid for only six (6)

months from the date written. After these respective times, a new prescription must be submitted to the BPHP.

- (i) Filling of “Faxed” Client-Specific Prescriptions at the BPHP:** The BPHP will only accept pre-authorized, original fill, faxed client-specific prescriptions for program drugs provided that the prescription is signed by a licensed physician, physician assistant or advanced nurse practitioner for a DOH eligible client. If the prescription appears forged or questionable the pharmacist will fill based on his or her discretion, see Prescription Fax Form, [Appendix N](#).
- (j) Submission of Electronic Client-Specific Prescriptions to the BPHP:** BPHP has ability to receive client-specific prescriptions via e-Prescribing and the Health Management System (HMS) portal. All CHDs must submit prescriptions via electronic data exchange using one of the above methods.
- (k) Supportive Information and Documentation for Client-Specific Prescriptions**

 - 1) Client Information Sheet:** Information sheets for client-specific prescriptions concerning the prescribed drug will be sent with the original fill and each subsequent refill.
 - 2) Client Medication Profile, DOH Form 2069:** All CHD clients’ receiving prescriptions from the BPHP in Tallahassee (e.g., HIV/AIDS, Insulin, Epilepsy, Family Planning, and TB) must sign DOH Form 2069 ([Appendix C](#)), which requests that their prescriptions be shipped to the CHD.

Regardless of the option selected, the client must complete the name and address section, and sign and date the form in the space provided at the bottom of the page. The BPHP requires this authorization for audit purposes. DOH Form 2069 should accompany the initial new client’s prescription(s) sent to the BPHP.

The CHD should retain a copy of the completed form and forward the original to the BPHP. The client's personal and medical information should be reviewed at least annually or sooner if there is a change in the client's medical or personal information. Any change to the information in any of the sections of this form should be forwarded to the BPHP as soon as possible.

Personal and medical client information entered onto the client profile is considered confidential. It shall be kept in a secured location with access limited to authorized personnel only.

- 3) **Offer to Counsel Signature:** Clients picking up prescriptions at the CHD must sign the receipt as proof that they have been informed of the counseling service available, via 800-554-4584. An offer to counsel signature log [Appendix D](#), must be maintained by the CHD and sent to BPHP on a weekly basis.

(I) **Questions Pertaining to Client-Specific Prescriptions**

- 1) **Questions by CHD Staff:** CHD staff having questions concerning client prescriptions dispensed by BPHP should contact BPHP staff at 850-922-9036, select option 2.
- 2) **Questions by CHD Clients:** CHD clients receiving prescriptions dispensed by the BPHP in Tallahassee have the right to receive counseling regarding their medications, Florida Administrative Code, rule 64B16-27.400(4). A toll-free number 800-554-4584 is provided for clients to contact the BPHP during regular business hours (8:00 am - 5:00 pm, Monday-Friday, excluding state holidays).

- (3) **Prepackaged Drug Products from the BPHP (Issuance Program):** Prepackaged pharmaceuticals may be ordered from the BPHP utilizing the PFS. See Definitions, SECTION IV.

- (a) **Conditions:** A registered nurse or a licensed physician assistant working in and employed by a CHD is authorized to issue medications when all the following conditions are met. See section 154.04, Florida Statutes, and Florida Administrative Code, rules 64F-14.001 and 14.002.
- 1) **Formulary Requirements:** The formulary shall be comprised of medications recommended by the Pharmacy and Therapeutics Committee and approved by the Surgeon General and Secretary. The Surgeon General and Secretary's approval will serve as final approval by the DOH. No controlled substances shall be included in this formulary.
 - 2) **Ordering Procedures:** Medications shall be ordered from the BPHP in conformance with approved protocols, which must require the medications to be prepackaged and pre-labeled with the appropriate dosage instructions. The pharmaceuticals for this program are available for ordering through the PFS.
 - 3) **Protocols:** The protocols must be signed by the supervising physician and the CHD director/administrator, however, only one signature is necessary when the CHD director/administrator is the supervising physician. The protocols shall be reviewed at least annually and each time there is a change in supervising physician and/or CHD director/administrator. See Definitions, SECTION IV.

All registered nurses or licensed physician assistants who issue medications shall do so as part of their duties as an employee, and sign and date the protocols or a statement acknowledging that they are familiar with the protocols.
 - 4) **Issuance Program:** When medications are issued, the licensed registered nurse or licensed physician assistant shall note the name and amount of medication issued, and

the date of delivery on the client's record, and sign the entry. The drug issued shall be entered into the appropriate drug record log and reduced from inventory. The record must be generally retained for three (3) years or six (6) years if federal program funds were used to procure the drugs.

(b) Incident Reporting: All untoward or unusual incidents, pursuant to this section, shall be reported in accordance with DOHP 5-6, Incident Reporting on a [DOH Incident Report](#). The untoward or unusual incidents to be reported shall include but not be limited to:

- 1) Issuance of an incorrect medication;
- 2) Issuance of an inappropriate dosage;
- 3) Issuance of a medication that is not consistent with approved protocols; or
- 4) Inappropriate labeling of repackaged medications.

(c) Issuance Program Formulary: The medications, approved by the Surgeon General and Secretary for the Issuance Program, are listed in [Appendix F](#).

3. Vaccines and Immunizations from the BPHP (Vaccines for Children): All orders for immunizations through the Vaccines for Children (VFC) Program must be submitted directly to the Bureau of Epidemiology, Immunization Section, not to the BPHP for processing.

4. Distribution by CHDs

a. Dispensing/Issuing

- (1) Dispensing/Issuing Authority for Pharmaceuticals:** Either a pharmacist or a practitioner authorized by law to dispense drugs may dispense pharmaceuticals in a CHD. A licensed registered nurse and a licensed physician assistant may issue medications in accordance with section 154.04, Florida Statutes.
- (2) Pharmacist (RPh) Dispensing:** A Florida licensed pharmacist employed by the CHD or working under contract with a CHD may dispense pharmaceuticals pursuant to chapters 465 and 893, Florida Statutes, and Florida Administrative Code Rule 64B16-27.

- (3) **Physician (MD/DO) Dispensing:** A physician employed by a CHD must comply with all other regulations as set forth in section 465.0276, Florida Statutes.
- (a) **Dispensing Drug Samples:** A physician may dispense a drug sample in the manufacturer's labeled package containing the physician's name, client's name, and date dispensed.
- (b) **Dispensing All Other Drugs:** If drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container bearing the following information: The practitioner's name, client's name, date dispensed, name and strength of the drug and the directions for use.
- (c) **Dispensing of Prescriptions:** A licensed practitioner must complete a prescription or medication order for any prescription dispensed. Each prescription written for dispensing must contain the following information: The client's name and address, date prescribed, name, strength, quantity of medication, directions for use, authorized practitioner's name, clinic identification (i.e., name, address, city/state, telephone number) and refill instructions, if appropriate, section 456.42, Florida Statutes, must be followed.
- (d) **Physician's Check of Finished Medication Product(s) in CHDs without a Pharmacy:** In CHD sites without a pharmacy, if the on-site physician is not the person preparing or obtaining the medication, or is not the preparer of the label, the physician must check the prescription contents and label for completeness and accuracy before the prescription is delivered to the client or his/her agent. The prescriber or registered nurse shall initial the prescription label before it is delivered to the client or his/her agent because:
- a. The physician is the only person having the authority to dispense;
 - b. The registered nurse has the ability to order and deliver;
 - c. This is verification of the final step in the quality control process; and

- d. This is the last opportunity for the physician to change the medical order as originally written (e.g., change in medication, change in directions, change in quantity, etc.).

- (4) **Labeling of Prescriptions:** The label affixed to a container used in dispensing non-controlled substances shall contain at a minimum the following information: A prescription number (or other prescription identification adequate to readily identify the prescription); client's name; authorized practitioner's name; directions for use; name; strength; and quantity of medication; name; address and phone number of facility; date of the original filling or the refill date; and product expiration date.

If necessary, list any appropriate warnings or cautions as to use, side effects, or storage requirements.

As stated in this policy and procedure, a prescription number should be recorded in the prescription files of the facility where it is dispensed and a clear concise warning that it is a crime to transfer any prescribed medication to any person other than the client for whom prescribed.

- (5) **Record Filing Requirements:** The original drug order, consisting of a prescription or a medication order entered in a client's medical record is to be filed and kept in the pharmacy or clinic. The record must be generally retained for three (3) years or six (6) years if federal program funds were used to procure the drugs.
- (6) **Use of Original Containers:** Original containers of medications will be used whenever possible.
- (7) **Reconstitution of Medications:** See sections 465.003(18), and 499.003, Florida Statutes.
- (8) **Expiration Dates:** Medications with the shortest remaining expiration date will be used first.
- (9) **Dispensing Requirements for TB DOT or DOPT Medications:** A registered pharmacist or a practitioner authorized to dispense must dispense all prescriptions or medical orders for clients on DOT or DOPT.
 - (a) **In CHDs with a Licensed Pharmacy:** In a CHD with a licensed pharmacy, the local pharmacy may prepare DOT/DOPT medication(s) or these

prescriptions may be submitted to the BPHP for dispensing.

- (b) **In CHDs without a Licensed Pharmacy:** A CHD without a licensed pharmacy will use BPHP's DOT/DOPT Program.
- (c) **Prescriptions for TB DOT/DOPT filled at the BPHP:** CHDs may obtain client-specific DOT/DOPT prescriptions that are dispensed from the BPHP. For biweekly and triweekly unit dose prescriptions, CHDs may obtain a 30-day supply of DOT/DOPT client-specific medication(s) in individual blister packs by using the DOT Multi-Dose Order Form.

- b. **Recording and Reporting Medication Errors:** All medication errors, as defined in DOHP 5-6, shall be reported on a [DOH Incident Report](#).
- c. **Client Medical Records:** For all 340B PHS drugs dispensed/administered/issued, the CHD must comply with Health Resources Services Administration (HRSA), Office of Pharmacy Affairs (OPA) client and contracted pharmacy definitions, as well as documenting that PHS drugs were provided only to PHS eligible clients. Visit the [HRSA OPA Client Definition and Contracted Pharmacy](#) for better clarification. The Issuance Program of 340B PHS program prescriptions (e.g., Family Planning, TB and STD) must also comply with the HRSA OPA client definition cited above.

F. Section 6: General Topics

1. **Standardized, Approved Drug Formularies:** All CHD drug formularies will be sent to the DOH BPHP and reviewed by the DOH Pharmacy and Therapeutics (P & T) Committee. The P & T Committee will certify that all drugs provide appropriate, consistent and equitable drug therapy, meeting the clinical needs of the clients we serve in an effective, efficient, and fiscally responsible manner. The P & T Committee will review and certify formularies on a monthly basis or as required. Drugs must be listed on an approved formulary in order for a CHD to order or procure the same.
2. **Procurement and Distribution of Primary Care Pharmaceuticals:** CHDs may order drugs for use in their Primary Care Program from the wholesale distributor or as otherwise stipulated in the Group Purchasing Organization (GPO) Agreement. See [Bureau of Public Health Pharmacy SharePoint](#) site.
3. **Procurement and Distribution of Sample Pharmaceuticals:** CHDs may also utilize pharmaceutical samples for required primary care drugs

from manufacturers' representatives in accordance with the respective manufacturer's policy, but these must only be obtained upon the written order of a practitioner authorized to dispense. Samples are the personal property of the requesting physician and are not considered to be part of a CHD drug inventory. See sections 499.028(3),(9), and (10), Florida Statutes.

- 4. Inspection of CHD Facilities:** All CHDs must be open to inspection by the representative of any agency authorized to inspect for compliance with sound pharmaceutical practices as dictated by appropriate laws and regulations. See Chapters 465, 499, and 893, Florida Statutes.

The CHD pharmacy manager (in a CHD with a licensed pharmacy) or CHD business manager (in a CHD without a licensed pharmacy) shall maintain a documents list indicating the physical location of all documentation (e.g., invoices, issue documents, transfer documents, et al.) that might be required during an audit or inspection. This list shall also include the physical location of the most recent complete physical pharmaceutical inventory conducted in the CHD.

- 5. DOH Quality Improvement Reviews:** The DOH shall require that a consultant pharmacist conduct a periodic inspection of each CHD in meeting the requirements of section 154.04(1)(c)5, Florida Statutes.

Individual CHDs will be contacted by a consultant pharmacist from the BPHP to schedule the on-site quality improvement review.

- 6. Prepackaged and Repackaged Pharmaceuticals for Dispensing**

- a. Drugs Prepackaged For Dispensing:** All drugs prepackaged at CHD pharmacies must be processed in compliance with applicable state regulations and must be used only for dispensing at the site where they are prepared.

A licensed practitioner shall oversee and be responsible for the prepackaging process and confirm that correct procedures, accuracy, and labeling are maintained. The transfer of prepackaged drugs for any reason to another CHD location, site, facility, or clinical area requires special license(s).

Drugs prepackaged for dispensing on the premises must include the following minimum information:

- (1) The quantity of contents;
- (2) The common (generic) name of the drug;
- (3) The strength of the drug;
- (4) The dosage form;

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- (5) The expiration date;
- (6) The manufacturer's or internal lot number; and
- (7) The manufacturer's name.

- b. Drugs Repackaged for Dispensing or Issuing:** Repackaged drugs used at CHDs must be purchased from a manufacturer specifically licensed to repackage pharmaceuticals and to conduct business within the state of Florida. Repackaged pharmaceuticals used in the Issuance Program must be procured from the BPHP.

Issuance Program drugs should never be distributed from the CHD that received them from the BPHP. They should only be provided to a client at the CHD that ordered them through the Issuance Program. Aside from the Issuance Program, DOH drugs are transferred by CHDs to other entities who are contract providers to DOH for DOH clients.

The repackaged drug products at the BPHP are primarily intended for use in the Issuance Program. They may also be used as starter packs for program drugs (e.g., Family Planning, Insulin, TB, STD) to cover the time interval between the submission of a prescription to the BPHP for filling and the prescription's arrival at the CHD. Repackaged medication from the BPHP should not be used for the continued filling of a client's prescription(s). Client-specific prescriptions for program drugs should be forwarded to the BPHP.

- 7. Continuous Quality Improvement Programs in CHD Pharmacies:** All CHD licensed pharmacies will establish a Continuous Quality Improvement Program as required in Florida Administrative Code Rule 64B16-27.300.
- 8. In-House Pharmacy Services Infrastructure and Purchasing:** A CHD, as part of its infrastructure, may organize a licensed in-house pharmacy operation in one of several arrangements. The structure chosen, however, may or may not restrict the CHD access to contract pricing, through the GPO Agreement, and its ability to access 340B PHS pricing for pharmaceuticals. The name in which the pharmacy license is issued becomes a critical element. For the purposes of this section, "purchasing" includes obtaining program pharmaceuticals through the BPHP via a CHD program allocation.
- a. Career Service Organization:** A CHD in-house pharmacy organized around Career Service or OPS personnel will have the pharmacy license issued in the name of the CHD. As a health care entity, the CHD and CHD pharmacy will have full access to all state pharmaceutical contracts and 340B PHS pricing where it is

applicable. The CHD and CHD pharmacy are responsible for inventory management and control, including proper documentation and audit trails, for all pharmaceuticals purchased, received, returned, distributed, transferred, administered, issued, or dispensed.

- b. Contracted Pharmacy Personnel Organization:** A CHD may elect to contract for in-house pharmacy personnel services only with one or more individuals or with a company. The pharmacy license is issued in the name of the CHD, and as a health care entity the CHD and CHD pharmacy will have full access to all state pharmaceutical contracts and 340B PHS pricing where it is applicable. The CHD and CHD pharmacy are responsible for all inventory management and control requirements detailed in this policy, including proper documentation and audit trails, for all pharmaceuticals purchased, received, returned, distributed, transferred, administered, issued, or dispensed.
 - c. Fully Contracted Pharmacy Services Organization:** A CHD may elect to contract or outsource its entire in-house pharmacy services operation with a single company (contractor), which is responsible for supplying pharmacy personnel and services. The contractor does not have access to pharmaceuticals supplied through the BPHP, the GPO Agreement or 340B PHS pricing. To obtain access to these pharmaceuticals and special pricing, the CHD (not the contractor) would order any required pharmaceuticals and thereafter transfer these pharmaceuticals to the contractor using a restricted pharmaceutical drug distributor – Government Program License. The contractor is responsible for inventory management and control, including proper documentation and audit trails, for all pharmaceuticals received, returned, distributed, transferred, administered, issued, or dispensed. A CHD contract manager for pharmacy services is responsible for ensuring that the contractor follows established policies and procedures, including HRSA OPA rules, if 340B PHS drugs are dispensed (see also Contracted Pharmacy). The CHD contract manager is responsible for executing a DOH contract, which includes all HRSA OPA required terms and conditions as a prerequisite to 340B PHS eligibility.
- 9. Changes in DEA Status:** A change in a CHD DEA status occurs whenever there is a change in location or a change in the registrant's information. A DEA registration number is location specific, therefore if a CHD has a DEA number registered to its medical director or other authorized physician at a specific address and changes location, a new DEA registration containing the new information must be obtained. If a CHD has a DEA number registered to its medical director or other authorized physician at a specific address and the medical director or

other authorized physician ceases to be a CHD employee or ceases to be the authorized physician of record, a new DEA registration in the name of the new medical director or other authorized physician must be obtained. Changes in the DEA status will also affect a CHD's ability to order scheduled drugs. Drug wholesalers will refuse to ship scheduled drugs to a CHD or CHD pharmacy when they become aware of an unreported change in DEA status, that is, the CHD DEA registration information on file with the wholesaler is no longer valid.

10. **CHD Satellites' "Drop-Ship Only" Accounts for Pharmaceuticals Subject to Special Shipping Requirements:** CHD satellite operations neither ordering nor possessing controlled substances but having to receive drugs subject to special shipping requirements (e.g., Varivax ®) may utilize the CHD medical director's state medical license number to register a "drop-ship only" account with the wholesale distributor. Other non-controlled substance drug shipments may be received by these satellite operations in accordance with the DOH's policy regarding the transfer of CHD drugs. See [Bureau of Public Health Pharmacy SharePoint](#) site.

Controlled substances may only be ordered and received by a CHD (or a CHD satellite location) having a wholesale distributor account referencing the DEA number of an authorized physician of record at that CHD or CHD satellite location.

11. **Track and Trace to Dispensers from Wholesalers who are Purchasing Directly from Manufacturers:** Florida Administrative Code Rule 61N-1.030(1)(b), is applicable to wholesale distributors who purchased the subject drug directly from the manufacturer, the exclusive distributor of the drug for the manufacturer or a repackager who purchased the drug from the manufacturer. Transaction documentation that must be provided includes: Transaction Statement (TS); Transaction History (TH); and Transaction Information (TI). These items are defined in Florida Administrative Code Rule 61N-1.028. They are required to be provided to a dispenser on one document, which can be in electronic format or on paper.

G. Section 7: Public Health Preparedness

1. **Emergency Support Function 8 (ESF8) Public Health and Medical Services:** ESF8 provides the means for a public health response, triage, treatment and transportation of victims of a disaster or catastrophic incident; assistance in the evacuation of victims/residents out of the disaster area before, during and after the event; immediate support to hospitals, nursing homes and assisted living facilities; provision of emergency behavioral health crisis counseling (i.e., critical incident stress debriefing); special needs sheltering and care; and the re-establishment of all health and medical systems. Assistance in pre-event evacuation may also be provided whenever clients are affected, or pre-established plans

for health care institutions have failed. Pre-event evacuation orders may also be issued when the Governor, state coordination officer, or their designee determines that it is in the best interest of the health, welfare, or safety of the population in the potential area of impact, by means of an executive order.

2. **Expectations of Pharmacy Services at CHDs in Preparation for and During a Declared Emergency**

a. **Preparation**

- (1) Anticipate pharmaceutical needs that may be required in the event of a disaster (for example, special needs shelter [SpNS] clients). Refer to Bureau of Preparedness and Response (BPR) for the response basics guideline.
- (2) Emergency Support Function 8 provides the means for a SpNS. Refer to the [Special Needs Shelter Program](#) for more information.
- (3) Participate in local, county, and regional all-hazards planning (i.e., strategic national stockpile, special needs sheltering, CHEMPACK).
- (4) Share information on resources that may be available in disaster response for mutual aid (pharmaceuticals, personnel, expertise, and equipment such as mobile pharmacies) with the BPR.
- (5) Have a personal disaster plan. Refer to the BPR [Family Preparedness Guide](#) or go to www.floridadisaster.org for an interactive website to develop your family disaster plan.
- (6) Ensure that pharmacy/pharmaceutical needs are covered in the CHD Continuity of Operations Plan (COOP). Requirements for inventory control, security, and temperature control are easily overlooked by those who do not normally handle and plan for pharmaceuticals. Include information on storage location(s) and contingency plans/locations for storage of pharmaceuticals in COOP.
- (7) Comply with the DOH's training policy regarding the National Incident Management System.
- (8) Incident Command System training requirements. See [DOHP 300-1-16](#).

b. **During a Disaster:** A disaster may be declared by a Governor's

executive order in the event of a disaster (or, in the case of a hurricane, in the anticipation of the event) that overwhelms the local capacities. The declaration gives the Governor additional authorities to expedite response to ensure the protection of life and property in the state of Florida. Such a declaration may suspend operation of targeted state drug laws and drug related licensure laws to facilitate distribution of state owned pharmaceuticals to need locations.

The DOH is the lead agency that coordinates ESF8 Public Health and Medical services in a disaster. Response is not limited to the normal operations of the CHDs, but is expanded to ensure the entire spectrum of health care continuity. For all emergency operation guidance provided below, state prescription drug and licensure laws still apply until such time as they are suspended in an executive emergency order or a supplemental emergency order.

- (1) CHD administrator/director must communicate with their county and state Emergency Operations Centers (EOC). The state ESF8 maintains an email account (stateESF8.planning@flhealth.gov), which is monitored on a daily basis, even in non-disaster times. Please forward information to the planning unit to maintain situational awareness. Anticipate needs (for example, SpNS clients arriving at the SpNS without their maintenance medication, refugees without medical records, reduced staffing), and request additional resources based on those needs.

Provide resources (personnel, pharmaceuticals, equipment) to assist affected counties, as requested by the county or state EOC.

- (2) Align disaster operations to normal procedures as much as possible. It is essential to maintain pharmaceutical integrity, chain of custody (inventory and paperwork), and security.

3. Procurement and Distribution of Pharmaceuticals and Vaccines by CHDs during a Declared Emergency and Recovery

- a. **Use of CHD Inventory for Disaster Response:** CHD must document the use of pharmaceuticals that are used, transferred, or lost during a disaster response. All requests for replacement of pharmaceuticals are submitted through the county, which then forwards the request through the state EOC to the ESF8 representative. For reimbursement purposes, the request for replacement must be submitted (and granted a Mission number) prior to the event closing, so requests should be submitted as

soon as the need for replacement is identified. Include in the request for replacement, the following information:

- (1) Drug name
- (2) Dosage form
- (3) Strength
- (4) Package size
- (5) Disposition of the drugs (used, transferred, destroyed, etc.)
- (6) Location of disposition (CHD, mobile clinic, SpNS, etc.)
- (8) Delivery location and times available
- (9) Points of contact for delivery (names, phone numbers, positions)
- (10) License for receiving product (i.e., physician, pharmacy, etc.)

4. Resources Available for Disaster Response Request through the County or State EOC

a. Federal Resources

- (1) **Strategic National Stockpile (SNS) 12-hour Push Package and Managed Inventory:** Every county has a SNS plan, which is reviewed and exercised annually.
- (2) **CHEMPACK:** CHEMPACK is a component of the Strategic National Stockpile Program, which pre-deploys chemical weapon antidotes to hospitals and first responder agencies.

b. State and Regional Resources

(1) Expertise

- (a) Public Health Preparedness (PHP) unit at BPHP
- (b) Regional emergency response advisors (RERA)
- (c) Regional SpNS coordinators
- (d) The state maintains chemical antidote stockpiles in strategic locations throughout the state (including some in CHDs)

- (2) **Volunteers:** Requests for credentialed medical personnel to assist in disaster response are coordinated through the

county or state EOCs.

- (3) **Medical Reserve Corps:** Requests for credentialed medical personnel to assist in disaster response are coordinated through the county or state EOCs, Everbridge/ServFL.
- (4) **Pharmaceuticals:** Request assistance through the county or state EOCs to supply continued pharmaceutical needs as the event evolves. Inventory documentation (chain of custody) of pharmaceuticals provided through ESF8 is required, from the point the pharmaceuticals are received to the end of the incident. For an event with advanced warning (hurricane), anticipate needs that will arise beginning 72 hours prior to predicted landfall, as well as immediate post-landfall needs.

Requests must document the following: Drug name dosage form; strength; package size; description of need/anticipated need; delivery location and times available; point of contacts for delivery (name, phone numbers, position); and person/license licensed to receive pharmaceuticals (i.e., physician, pharmacy, etc.).

5. Recovery

- a. **Overstock:** Pharmaceuticals purchased by the CHD for disaster anticipation or response that remain unused in the event may be added to the CHD stock. Costs associated with the purchase of these pharmaceuticals will not be reimbursable by FEMA.

Pharmaceuticals provided through the state EOC/ESF8 disposition will be coordinated by the PHP unit at BPHP at the time of the event. Disposition may entail returning pharmaceuticals to BPHP for future response.

b. Unusable or Unserviceable Drugs

- (1) **Quarantine:** Drugs rendered unusable from the event (damaged, unable to maintain within temperature requirements, exceeded manufacturer's expiration date, etc.) shall be kept in quarantine from useable pharmaceutical inventory.
- (2) The return or destruction of quarantined pharmaceuticals will be coordinated by the PHP unit at BPHP at the time of the event.

VI. Distribution List

Deputies
Division Directors
Bureau Chiefs
Children's Medical Services Medical Directors
Children's Medical Services Nursing Directors
County Health Department Administrators/Directors
County Health Department Medical Directors
County Health Department Nursing Directors
County Health Department Business Managers
County Health Department Pharmacy Managers
County Health Department Purchasing Offices
County Health Department Contract Administrators
Executive Office Directors
Policy and Procedures Library
Web Manager

VII. History Notes

DOHP 150-1-01, Pharmacy Services Policies and Procedures for County Health Departments, published in April 2002, replaces HRSM 150-1, Comprehensive Pharmaceutical Services Policies and Procedures Notebook for HRS Public Health Units; DOHP 395-1-08, dated February 2009, replaces DOHP 150-1-01; DOHP 395-1-12, dated July 2012, replaces DOHP 395-1-08; DOHP 395-1-18, dated April 24, 2018 replaces DOHP 395-1-12. The Bureau of Public Health Pharmacy is responsible for this policy and procedures.

VIII. Appendices

The appendices contain DOH forms and sites used by BPHP. The forms listed in the Table of Contents are for information only and may change periodically.