District 2 Public Health
Protocol for Transporting Dangerous Drugs

Purpose:

The purpose of this protocol is to define the parameters, accountability standards and the training required for the transport of dangerous drugs by public health personnel.

Public Health Personnel Who May Transport Dangerous Drugs

Public Health recommends that the following be permitted to transport dangerous drugs (including vaccines):

- **Physicians;**
- **Pharmacists, in accordance with the requirements of O.C.G.A 43-34.26.1;**
- **RNs and LPNs in accordance with OCGA 43-34-23 (delegation of authority via nurse protocols); OCGA 43-34-26.1 (delegation of authority via Influenza Vaccine Protocol Agreements);**
- **APRNs in accordance with the requirements of OCGA 43-34-25 (delegation of authority via APRN Protocol);**
- **Physicians Assistants in accordance with OCGA 43-34-23 (delegation of authority via job description);**
- **Drug manufacturer, wholesaler, distributor, or supplier, per OCGA 16-13-72; and**
- **Public Health employees*, such as Immunization Program field staff and District Drug Coordinators, assigned job responsibilities for transporting dangerous drugs to meet specific program requirements, must comply with the training and accountability standards defined within this protocol. Public Health employees assigned job responsibilities for transporting dangerous drugs must meet the following criteria:**
  - **Have a signed job description (Attachment 1) which documents specific job responsibilities for transporting dangerous drugs to meet specific program requirements and which require compliance with the following performance standards:**
    - **OCGA 16-13-72 (Sale, distribution, or possession of dangerous drugs) {Attachment 2}; and**
    - **Centers for Disease Control and Prevention Vaccine Storage and Handling Toolkit at www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf (Attachment 3)**
    - **Sections B, C, D, and E of the Drug Dispensing Procedure, in the General Guidelines Section of the District 2 Nursing Protocols (Attachment 4, sections attached).**
  - **Complete a Transporting Dangerous Drugs Training Program, as approved by the Division of Public Health, once annually.**
  - **Receive approval from the District Health Director or Program Director to transport vaccines and dangerous drugs.**

- **Comply with the job responsibilities for transporting dangerous drugs, as documented per job description, and in accordance with a performance review completed annually.**
- **Signed an acknowledgement statement prohibiting the transport of dangerous drugs to their home or any other site other than a Public Health Clinic site or site receiving state supplied vaccine.**

<u>Accountability Standards</u>

Public Health personnel who transport dangerous drugs must comply with all standard operating procedures related to the storage and handling of dangerous drugs, including the following:

1. **Overseeing proper receipt and storage of vaccine and drug shipments**
2. **Preparing vaccine and drugs for transport**
3. **Assuring appropriate storage of drugs and vaccine per manufacturer's recommendations**
4. **Monitoring temperature and the environment of drug and vaccine storage and containers**
5. **Using appropriate refrigerator/freezer or other storage environment**
6. **Monitoring expiration dates of vaccine and drug stock**
7. **Disposing of any spoiled or expired vaccine or drug**
8. **Using proper containers for transport of drugs and vaccines**
9. **Documenting transport and receipt of drugs and vaccines.**

Any infractions or non-compliance with the standards set forth in the protocol may be subject to disciplinary action in accordance with established policies and procedures for employee performance review.

The approving District Health Director or Program Director must:

1. **Be available during the time drugs are transported.**
2. **Be accessible by phone for reporting any theft, damage, temperature excursions, and interruptions to the cold chain and/or violations in the storage requirements per package inserts.**
3. **Comply with the CDC guidelines Vaccine Toolkit.**

District 2 Public Health
Training Plan for
Protocol for Transporting Dangerous Drugs

All new public health employees will receive training on the "Protocol for Transporting Dangerous Drugs" during orientation. Current employees will receive initial training by the County Nurse Manager during their monthly local staff meeting and annually, thereafter, per state mandate.

The County Nurse Manager will be responsible for completing and documenting the Transporting of Dangerous Drugs training annually during the local county staff meeting. All county and district staff attending the meeting will be trained and sign the District 2 Transporting Dangerous Drugs Acknowledgement Form. The required training components are listed in the attached "Protocol for Transporting Dangerous Drugs".

Clinical staff (RNs, LPNs, APRNs) will sign and date the Acknowledgement Form that is required (attached). Original signature sheets will be maintained in each nurse protocol book with a copy sent to the District Office, Attention: Drug Coordinator. Forms will be checked during Quality Assurance audits. Signature sheets should be maintained like protocol signature sheets for a period of 5 years.

Non clinical staff will complete training and also sign the Acknowledgement Form that is required (attached). Each employee will maintain their original signature sheet in their employee file and the supervisor will maintain a copy of their signature sheet in the supervisory file *or* in a notebook with copy of protocol (preferred). A copy of each non clinical staff's signature sheet should be sent to the District Office, Attention: Drug Coordinator. The signature sheets will be checked during Quality Assurance audits. Signature sheets should be maintained like protocol signature sheets for a period of 5 years.

District 2 Public Health
Acknowledgment of Completion
Transporting Dangerous Drugs

I, _____, acknowledge that I have read and understood the following training components required for public health employees transporting drugs:

- **OCGA 16-13-72 – pertaining to the sale, distribution, or possession of dangerous drugs (Attachment 2);**
- **CDC Vaccine and Storage Handling Toolkit (Attachment 3)**
- **District 2 Public Health Drug Dispensing Procedure – Sections B, C, D, E (Attachment 4)**

I further acknowledge that I have discussed the requirements for transporting dangerous drugs with a supervisor and had the opportunity to ask questions to clarify any components of this requirement.

I further acknowledge that I am prohibited from transporting dangerous drugs to home or any other site other than a public health clinic or site that received state supplied vaccine.

Having read and understood the requirements associated with transporting dangerous drugs, I agree to be bound by the terms set forth in the training components, applicable documents and directives of supervisors and approving authority.

_____ _____

Employee Signature **Date**

_____ _____

Trainer or Supervisor Signature **Date**

_____ _____

Transport approved by:
District Health Director or designee **Date**

ATTACHMENT 1

Job Description/PMF:

Each person who may transport drugs must have the following statement included in their annual performance review form:

As assigned and/or required, transport drugs per compliance with the District 2 Public Health Protocol for Transporting Dangerous Drugs. Annually, review the protocol and sign acknowledgement form.

ATTACHMENT 2

O.C.G.A. § 16-13-72

GEORGIA CODE

*** Current through the 2009 Regular Session ***

TITLE 16. CRIMES AND OFFENSES
CHAPTER 13. CONTROLLED SUBSTANCES
ARTICLE 3. DANGEROUS DRUGS

O.C.G.A. § 16-13-72 (2009)

§ 16-13-72. Sale, distribution, or possession of dangerous drugs

Except as provided for in this article, it shall be unlawful for any person, firm, corporation, or association to sell, give away, barter, exchange, distribute, or possess in this state any dangerous drug, except under the following conditions:

(1) A drug manufacturer, wholesaler, distributor, or supplier holding a license or registration issued in accordance with the Federal Food, Drug, and Cosmetic Act and authorizing the holder to possess dangerous drugs may possess dangerous drugs within this state but may not distribute, sell, exchange, give away, or by any other means supply dangerous drugs without a permit issued by the State Board of Pharmacy. Any drug manufacturer, wholesaler, distributor, or supplier holding a permit issued by the State Board of Pharmacy may sell, give away, exchange, or distribute dangerous drugs within this state, but only to a pharmacy, pharmacist, a practitioner of the healing arts, and educational institutions licensed by the state, or to a drug wholesaler, distributor, or supplier, and only if such distribution is made in the normal course of employment;

(2) A pharmacy may possess dangerous drugs, but the same shall not be sold, given away, bartered, exchanged, or distributed except by a licensed pharmacist in accordance with this article;

(3) A pharmacist may possess dangerous drugs but may sell, give away, barter, exchange, or distribute the same only when he compounds or dispenses the same upon the prescription of a practitioner of the healing arts. No such prescription shall be refilled except upon the authorization of the practitioner who prescribed it;

(4) A practitioner of the healing arts may possess dangerous drugs and may sell, give away, barter, exchange, or distribute the same in accordance with Code Section 16-13-74;

ATT 2

(4.1) A physician in conformity with Code Section 43-34-23 may delegate to a nurse or a physician assistant the authority to possess vaccines and such other drugs as specified by the physician for adverse reactions to those vaccines, and a nurse or physician assistant may possess such drugs pursuant to that delegation; provided, however, that nothing in this paragraph shall be construed to restrict any authority of nurses or physician assistants existing under other provisions of law;

(4.2) A registered professional nurse licensed under Article 1 of Chapter 26 of Title 43 who is employed or engaged by a licensed home health agency may possess sterile saline, sterile water, and diluted heparin for use as intravenous maintenance for use in a home health setting, and such nurse may administer such items to patients of the home health agency upon the order of a licensed physician. The State Board of Pharmacy shall be authorized to adopt regulations governing the storage, quantity, use, and administration of such items; provided, however, nothing in this paragraph or in such regulations shall be construed to restrict any authority of nurses existing under other provisions of law;

(5) A manufacturer's sales representative may distribute a dangerous drug as a complimentary sample only upon the written request of a practitioner. The request must be made for each distribution and shall contain the names and addresses of the supplier and the requestor and the name and quantity of the specific dangerous drug requested. The written request shall be preserved by the manufacturer for a period of two years; and

(6) Such person, firm, corporation, or association shall keep a complete and accurate record of all dangerous drugs received, purchased, manufactured, sold, dispensed, or otherwise disposed of and shall maintain such records for at least two years or in conformance with any other state or federal law or rule issued by the Georgia State Board of Pharmacy.

HISTORY: Code 1933, § 79A-703, enacted by Ga. L. 1967, p. 296, § 1; Ga. L. 1972, p. 948, § 2; Ga. L. 1975, p. 690, § 1; Ga. L. 1982, p. 3, § 16; Ga. L. 1996, p. 356, § 6; Ga. L. 1998, p. 219, § 1; Ga. L. 1999, p. 643, § 5.2; Ga. L. 2003, p. 140, § 16; Ga. L. 2009, p. 859, § 5/HB 509.

ATTACHMENT 4

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B. GENERAL REQUIREMENTS

Although the Division of Public Health and the county boards of health may stock drugs and related supplies which are not considered dangerous drugs (e.g., ferrous sulfate tablets, reagent strips), the storage, record keeping and inventory control requirements shall apply to all drugs and related items. All biologicals (vaccines and diluents) must be handled and stored according to the storage and handling guidelines located in the Georgia Immunization Program Manual. The manual may be accessed on line at http://health.state.ga.us/publications/manuals.asp.

A current drug reference book should be available in all health departments and/or health centers. (At a minimum, Drug Facts and Comparisons [eFacts and Comparisons], American Hospital Formulary Service or Lexi-Comp Drug Information Handbook.)

All drugs or devices which bear, or are required to bear, upon the package, the words "Caution, Federal Law Prohibits Dispensing Without Prescription", "Rx only" or words of like import, shall be issued pursuant to one of the following:

1. A prescription from a licensed practitioner authorized to prescribe.

2. An order issued in conformity with a nurse protocol or job description.

A registered professional nurse or physician's assistant is only authorized to dispense pursuant to an order issued in conformity with a **standard** nurse protocol or job description, not a prescription or an order written on a chart or phoned in by a physician.

C. DRUG STORAGE AND RECORD KEEPING

1. All drugs shall be stored in designated areas within the facility that are sufficient to insure the proper sanitation, temperature, light, ventilation, moisture control, segregation and security. These conditions must also be considered when drugs are being distributed/transported from one area/facility to another area/facility.

   a. All drugs requiring refrigeration must be stored in a refrigerator designated for drug use. The refrigerator and/or freezer must have a thermometer and the temperature must be checked and recorded on a routine basis to insure the proper temperature range specified for those particular drugs.

   b. Store drugs for external use apart from drugs for internal use or injection (segregate at least by using different shelving or bins).

2. All drugs shall be stored in a secured area (under lock and key when not in actual use). Access to drugs should be only to specifically authorized personnel, as indicated by written policy and procedure, and the area should be sufficiently secure to deny access to unauthorized persons.

   Whenever more than one authorized person has access to drugs from a common inventory, one person shall be designated "in charge" of said inventory. All authorized persons "in charge" 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.

   This system of accountability must exist for all drugs and include at a minimum, the name of drug and strength, the amount of drug, the date and signature of authorized persons or other information as indicated by written policy and procedure for drug accountability.

3. Required documentation on a *Drug Dispensing Sign-out Sheet* when a drug is dispensed pursuant to an order issued in conformity with a nurse protocol includes:

   a. Name and strength of drug dispensed.
   b. Quantity dispensed.
   c. Date dispensed.
   d. Record of nurse dispensing.
   e. Name of patient.
   f. Lot number and expiration date, per legal requirements.

4. A running inventory of drugs received, and drugs removed, from designated storage areas must be verified by actual count on a monthly basis.

5. Districts that contract for local retail or hospital pharmacy services must ensure that a list of state supplied drugs dispensed from the pharmacy location to public health clients is forwarded to appropriate district staff or state program on a monthly basis (e.g., SHAPP).

6. All records pertaining to drug accountability (from ordering and receipt of drug to actual patient administration) must be kept on file. The Georgia Drugs and Narcotics Agency and its inspectors shall have the authority to conduct inspections or audits on all drugs received and/or disposed of by an agent or employee of the Division of Public Health of the Department of **Community Health** or any county board of health. Prescriptions and/or orders issued in conformity with a **standard** nurse protocol shall be kept on file for a minimum period of two (2) years from the date they are filled. Refer to the Public Health Record Retention Policy for specific program requirements that may be more stringent.

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7. No health center in which drugs are handled shall operate in any manner or dispense any drugs under unclean, unsanitary, overcrowded, unhealthful conditions or under any condition that endangers the health, safety or welfare of the public. All drugs shall be kept beyond the normal reach of small children.

8. Drug samples are forbidden in public health facilities unless a written procedure has been established for their use by a licensed physician and a licensed pharmacist.

D. OUTDATED, DETERIORATED, RETURNED AND RECALLED DRUGS

1. Examine drug stock at regular intervals of not more than six (6) months duration and remove from stock all outdated and deteriorated drugs. Stock must be rotated so the shortest dated stock will be used first. No outdated or deteriorated drug may be kept in stock for patient use. Under no circumstance shall any drug be dispensed or administered that bears a date of expiration that has been reached or that is in a deteriorated condition.

2. Remove all outdated, deteriorated, unused or overstocked drugs from inventory. The district pharmacist or district/county drug coordinator will be responsible for compiling and sending the required documentation to the drug manufacturer, drug wholesaler or the reverse drug distributor (i.e., Guaranteed Returns) for handling the drugs appropriately. For any drug purchased through the State Office of Pharmacy, prior notification and a copy of the prepared documentations is required to be sent to the State Office of Pharmacy. The proper documentation should be kept on file for a minimum of two (2) years. Information on drugs purchased or supplied with state or federal funds must be submitted upon request. Documentation should include the following:

   a. Name and strength of the drug, expiration date, lot number, unit or size and quantity of drug returned.
   b. The name and street address of the clinic/county/district returning drugs.
   c. The date of the return.
   d. The reason the drug is being returned (e.g., out-of-date, deteriorated, discontinued, unused, overstocked).

Depending on the drug and/or the contract, an exchange for fresh stock, a return for credit or a return for "destruction only" may occur.

3. The District/County Drug Coordinator or the District Pharmacist shall ensure that any drugs/vaccines at the district level requiring destruction shall be destroyed in accordance with current pharmacy rules and regulations that apply to non-controlled substances. A record of the destruction should be kept on file for a minimum of two (2) years and a copy sent to the Pharmacy Director of the Division of Public Health with the following information:

   a. Name and strength of the drug, expiration date, lot number,

manufacturer, and quantity destroyed.

b. The name, address and organizational code of the district.
c. The date the drug was destroyed.
d. The reason the drug is being destroyed.
e. The name and title of the person, in print and signature, destroying the product.

4. Drug Recalls
If a drug recall for pharmaceutical supplies purchased by the Office of Pharmacy is issued by a manufacturer or other authorized agency, the district pharmacist or drug coordinator will be notified of the procedure to follow to insure that all recalled public health issued drugs are removed from stock at the state, district and county level. For pharmaceutical supplies purchased by the district or county, the district pharmacist or drug coordinator would work with the drug manufacturer or wholesaler and pull any recalled drugs.

5. See the Georgia Immunization Program Manual, Storage and Handling Guidelines regarding the disposition of outdated, expired or wasted vaccines. The manual is located at http://health.state.ga.us/publications/manuals.asp.

E. INVENTORY

1. Annual Inventory
An inventory of all drugs and/or devices in each health district must be taken at the end of each fiscal year for auditing purposes. This inventory must include all drugs purchased for use in public health whether these drugs are located in the district, the county health department or a local retail or hospital pharmacy. The completed annual inventory form must be maintained on file at the district level for a period of two (2) years. Inventory information on drugs purchased or supplied with state or federal funds must be submitted upon request.

2. Each health district should maintain a supply of drugs on hand within the district, adequate to supply the needs of the district, but not to exceed a three (3) months' supply. Inventory levels for each drug should be established, and then reviewed and adjusted on a routine basis to maintain proper inventory control.

3. Vaccine inventory must be documented and managed in the Georgia Registry of Immunization Transactions and Services (GRITS).