
GEORGIA DEPARTMENT OF PUBLIC HEALTH DRUG DISPENSING PROCEDURE

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TABLE OF CONTENTS

DRUG DISPENSING PROCEDURE	4
The Drug Dispensing Procedure Signature Page	4.1
A. Definitions	4.2
B. General Requirements	4.4
C. Drug Storage and Record Keeping	4.5
D. Outdated, Deteriorated, Returned and Recalled Drugs	4.8
E. Inventory	4.9
F. Labeling and Appropriate Containers	4.9
G. Client Counseling Components	4.11
H. Drug Programs/Contracts	4.13
I. Dispensing/Administering of 340B and 340B PVP	4.15
J. Additional Information	4.16

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DRUG DISPENSING PROCEDURE

The following procedure is for the proper procurement, storage, record keeping, labeling and handling of drugs and/or devices by authorized agents or employees of the **Georgia Department of Public Health** and the County Boards of Health.

Licensed Pharmacist:

Print name _____

Signature _____ Date _____

Licensed Physician:

Print name _____

Signature _____ Date _____

DRUG DISPENSING PROCEDURE

All registered professional nurses or physician's assistants who dispense dangerous drugs and/or devices under the authority of an order issued in conformity with a nurse protocol or job description and as an agent or employee of **the Department of Public Health** or any county board of health, shall meet the same standards and comply with all record-keeping, labeling, packaging, storage and all other requirements for the dispensing of drugs imposed upon pharmacists and pharmacies with regard to such drugs and/or devices, as outlined by the following dispensing procedure. **This procedure applies to all drugs and devices within the district, whether purchased through state or local funds. The Pharmacy Director for the Department of Public Health, or a qualified designee, may make periodic on-site visits to health districts and/or local health departments to provide technical assistance and review drug use, storage and handling.**

A. DEFINITIONS

For the purpose of this dispensing procedure, the following definitions apply:

1. Administer or Administration
Administer or administration means to give a unit dose of any drug or to perform any medical treatment or diagnostic study. O.C.G.A. § 43-34-23(a)(1).
2. Dangerous Drug
Dangerous Drug means any dangerous drug as defined in O.C.G.A. § 16-13-71, but does not include any controlled substance or Schedule I controlled substance. **See also O.C.G.A. § 43-34-23(a)(3).** Dangerous drugs are required to bear upon the package, the words "Caution Federal Law Prohibits Dispensing Without Prescription", "Rx only," or words of like import. These drugs may also be referred to as "Legend" drugs.
3. Device
Device means an instrument, apparatus, contrivance or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician". O.C.G.A. § 26-4-5(9).
4. Dispense
"Dispense" means to issue one or more doses of any drug in a suitable container with appropriate labeling for subsequent administration to, or use by, a patient. O.C.G.A. § 43-34-23 (a)(3.1)
5. Dispensing Procedure
Dispensing Procedure means a written document signed by a licensed pharmacist and a licensed physician that establishes the appropriate manner under which drugs may be dispensed pursuant to O.C.G.A. § 43-34-23(a)(4).

6. Distribute
Distribute means the delivery of a drug or device other than by administering or dispensing. O.C.G.A. § 26-4-5(11).

7. Job Description
Job description means a document, signed by the primary supervising physician and the physician assistant, in which the primary supervising physician delegates to that physician assistant authority to perform certain medical acts and which describes the professional background and specialty of the primary supervising physician and the qualifications including related experience of the physician assistant; and includes a general description of how the physician assistant will be utilized in the practice. A job description shall not be required to contain every activity the physician deems the physician assistant qualified to perform but shall confine the activities of the physician assistant to those in the scope of practice of the primary supervising physician. O.C.G.A. § 43-34-102(4).

8. Nurse
Nurse means a person who is a registered professional nurse licensed as such under **Article 1 of Chapter 26 of Title 43**. O.C.G.A. § 43-34-23(a)(6).

9. Nurse Protocol
Nurse protocol means a written document mutually agreed upon and signed by a nurse and a licensed physician, by which **document**, the physician delegates to that nurse the authority to perform certain medical acts pursuant to subsection (b) of O.C.G.A. § 43-34-**23**. These acts shall include, without being limited to, the administering and ordering of any drug. O.C.G.A. § 43-34-**23(a)(7)**.

10. Order
Order means to select a drug, medical treatment or diagnostic study through physician delegation in accordance with a nurse protocol or a physician's assistant's job description. Ordering under such delegation shall not be construed to be prescribing nor shall ordering of a drug be construed to authorize the issuance of a written prescription. O.C.G.A. § 43-34-23(a)(8).

11. Practitioner or Practitioner of the Healing Arts
Practitioner or Practitioner of the Healing Arts means a physician, dentist, podiatrist or veterinarian, and shall include any other person licensed under the laws of Georgia to use, mix, prepare, dispense, prescribe and administer drugs in connection with medical treatment to the extent provided by the laws of Georgia. O.C.G.A. § 26-4-5(33).

12. Prescription Drug Order
Prescription Drug Order means a lawful order of a practitioner for a drug or device for a specific patient; such order includes an electronic visual image prescription drug order and an electronic data prescription drug order.
O.C.G.A. § 26-4-5(36).

B. GENERAL REQUIREMENTS

1. Although the **Department** 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, biologicals (vaccines and diluents), and related items. Furthermore**, all biologicals (vaccines and diluents) must be handled and stored according **to any specifics related to the individual vaccine listed in 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>.
2. **The District Health Director or licensed physician signing this agreement shall designate a secure lockable area, room(s), which shall be known as the medication room(s) which is devoted to business related to pharmaceuticals and medical devices. Also, they shall designate a person in charge of the medication room(s). The District Health Director shall keep this information current and on file, available upon request. All drugs should be kept out of reach of unauthorized staff and patients.**
3. **A hard copy and/or computer or electronic access to current medication reference materials must** be available in all health departments and/or health centers (at a minimum, **a hard copy or electronic version of Drug Facts and Comparisons [eFacts and Comparisons], American Hospital Formulary Service or Lexi-Comp Drug Information Handbook [Lexi-Comp Online].**)
4. 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:
 - a. A prescription from a licensed practitioner authorized to prescribe.
 - b. An order issued in conformity with a nurse protocol or job description.
5. A registered professional nurse or physician's assistant is only authorized to dispense pursuant to an order issued in conformity with a nurse protocol or job description, not a prescription or an order written on a chart or phoned in by a physician.

6. The telephone number of a poison center shall be conspicuously posted in the medication room and pharmacy areas (e.g., Georgia Poison Center 1-800-222-1222).

C. DRUG STORAGE AND RECORD KEEPING

1. All drugs shall be stored in designated areas known as the medication room, 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 **either a thermometer or an electronic temperature monitoring device that monitors the unit's internal temperature. The temperature must be recorded by a clinic employee. Documentation shall be made twice daily by initialing a temperature log during clinic hours to insure the proper temperature range specified for those particular drugs. The document must provide the printed employee name and identifying initials. Temperature logs must be kept on file for three years.**

NOTE: Refrigerators/freezers can be monitored with an external electronic temperature monitoring device which electronically monitors internal temperatures with a temperature probe (e.g., Sensaphone).

- b. All pharmaceuticals are to be stored and maintained at the correct temperature according to the individual product package insert for 24 hours a day, seven days a week. Extreme changes in temperature have the potential to change the effectiveness and/or stability of the drug. All pharmaceuticals that are improperly stored must be immediately segregated from stock and labeled unusable. See Section D. OUTDATED, DETERIORATED, RETURNED AND RECALLED DRUGS.
 - c. 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). **All access entries to the medication room(s) must be locked at all times prohibiting outside entry. Security of the medication room(s) must be maintained 24 hours a day. Authorization to the medication room(s) must be reserved to those employees performing functions**

requiring access such as dispensing and inventory management and control.

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

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

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

3. **Upon receipt of pharmaceuticals and/or medical devices, invoices must be signed and dated. Any discrepancies must be clearly noted on the invoice and reported within one business day to the distributor. Resolution must be noted on the invoice. All invoices must be maintained on file for five years. For purchases made by the State Office of Pharmacy, signed and dated invoices must be submitted to the State Office of Pharmacy within 72 hours of receiving the product.**
4. **Records of dispensing are to be made and kept by the dispensing facility for two (2) years in a secure location and retrievable upon request. Dispensing records may be manual hard copy on a *Drug Dispensing Sign-out Sheet* or electronic print version.**

Required documentation **for dispensing records** when a drug or device is dispensed pursuant to an order issued in conformity with a nurse protocol includes:

- a. **Patient's name and address.**
- b. Name, strength, **and dosage form** of drug dispensed **with the National Drug Code (NDC) number**
- b. Quantity dispensed.
- c. Date dispensed.
- d. **Name of the nurse ordering and dispensing.**
- e. **Name of practitioner (delegating physician).**
- f. Lot number and expiration date, per legal requirements

g. **Identifying serial number (prescription number).**

If using an electronic dispensing record in place of the manual *Drug Dispensing Sign-out Sheet*, the electronic dispensing record should clearly identify who is ordering the pharmaceutical or medical device and ideally the computer entry person, if other than the person ordering. The electronic dispensing records must be printed in hard copy every twenty-four (24) hours and filed in a secure location. The electronic dispensing print-out record must be readable without the aid of a special device. The dispenser(s) is/are responsible for verifying completeness and accuracy of the entries to the system, and must provide documentation that medication order information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

5. A running inventory of drugs received, **dispensed**, and removed from designated storage areas must be verified by actual count **at least** monthly. **Discrepancies in inventory should be researched and findings should be clearly noted. Reconciliation should occur immediately if variances are found. If a manual and an electronic inventory are kept simultaneously, then both inventories must be the same.**
6. 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). **Districts that contract for local retail or hospital pharmacy services must keep contracts on file with a copy of a current pharmacy license. The District/County must ensure no drug diversion and no violations of federal or state laws or regulations.**
7. 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 the Department of **Public** Health 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 **Department** of Public Health or any County Board of Health. Prescriptions and/or orders 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.
8. No health center in which drugs are handled shall operate in any manner or dispense any drugs under unclear, unsanitary, overcrowded, unhealthy 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.

9. Drug samples are forbidden in public health facilities unless a written **district** procedure **approved by the State Office of Pharmacy** 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 least monthly** and remove from stock all outdated, **improperly stored**, 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, **improperly stored**, deteriorated, unused or overstocked drugs from inventory **and label unusable. For vaccines, contact the Immunization Program for guidance.** 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 documentation is required to be sent to the State Office of Pharmacy **to ensure that credit is applied to the appropriate state account. For any drugs purchased by the county or district, documentation must be retrievable and available upon request.** 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, improperly stored, 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. **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. **Documentation must be submitted to the State Office of Pharmacy upon request.**

4. 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, **including all clinics/medication rooms**, must be **conducted, documented, and signed** at the end of each fiscal year. **An attached template is on page 4.19 as a guide, “Annual Drug Inventory”.** This inventory must include all drugs 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 must be maintained on file at the district level for a period of two (2) years **and a copy must be submitted by the second week of July to the State Office of Pharmacy on an annual basis.** 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) month 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). **O.C.G.A. § 31-12-3.1**

F. LABELING AND APPROPRIATE CONTAINERS

1. All drugs and/or devices for use in the health department shall be in appropriate containers (manufacturer’s original package or prescription vial), including the use of:
 - a. Child-proof containers.
 - b. Light-resistant and moisture-proof containers.
 - c. Adequately-labeled containers to identify, at a minimum, the brand name or generic name, strength, lot number and expiration date.

2. Any drug and/or device issued or dispensed to the client for self-administration shall be in appropriate containers (manufacturer's original package or light resistant prescription vial, both with child-proof caps, unless a waiver is on file for non-safety caps) and labeled with the following information:
 - a. Name, address and telephone number of the health district, health department or health center.
 - b. Date and identifying serial number (at minimum, the three (3) digit county code and any other necessary identifying numbers).
 - c. Full name of the client.
 - d. Name of the drug and strength.
 - e. Name of drug manufacturer (optional).
 - f. Directions for use to the patient.
 - g. **Name of delegating physician.**
 - h. The expiration date of the drug.
 - i. Such other accessory cautionary information as may be required or desirable for proper use and safety to the client.
 - j. **FDA labeling requirement:**
For drug products dispensed in health departments, it is a requirement to provide the FDA Side Effect Statement, "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088." Each authorized dispenser or pharmacy must distribute the side effects statement with each prescription drug product dispensed. One or more of the following options to distribute the side effects statement must be selected:
 - 1) **Distribute the side effects statement on a sticker attached to the unit package, vial, or container of the drug product;**
 - 2) **Distribute the side effects statement on a preprinted pharmacy prescription vial cap;**
 - 3) **Distribute the side effects statement on a separate sheet of paper;**
 - 4) **Distribute the side effects statement in consumer medication information; or**
 - 5) **Distribute the appropriate FDA-approved Medication Guide that contains the side effects statement.**
3. All drugs must be identified up to the point of administration to, or use by, the client. Therefore, the nurse should **READ LABELS THREE TIMES.**
 - a. When the drug is selected from the storage area.
 - b. When preparing, labeling, dispensing or administering the product.
 - c. When returning the original container or package to the storage area, or discarding it.

4. The contents and the label of every drug must be verified by the licensed individual authorized to dispense, issue or administer drugs before each drug is given to the client.
5. **When a dispensing nurse uses any person to assist in the measuring of quantities of medication and the typing of labels, excluding the dispensing of drugs, the dispensing nurse must be physically present in the dispensing area and actually observing the actions of such person in doing such measuring and typing, and the dispensing nurse must be the verifier of the contents and the label.**

G. CLIENT COUNSELING COMPONENTS

The following client counseling components are a requirement of the Omnibus Budget Reconciliation Act of 1990, and the Georgia State Board of Pharmacy Rules and Regulations. The purpose, in part, is to enhance the public health and welfare by requiring that consultation be offered to clients regarding their medications and various conditions that could affect or be affected by the use of those medications.

1. Client Records
 - a. A client record system shall be maintained for clients for whom Prescription Drug Orders are dispensed or for whom drugs are dispensed under the authority of a nurse protocol or job description. The client record system shall provide for the immediate retrieval of information necessary for the nurse or physician's assistant to identify previously dispensed drugs. Such client's record shall contain, at a minimum:
 - 1) Full name of the client for whom the drug is intended,
 - 2) Date of birth,
 - 3) Client's gender,
 - 4) Address of the client (and telephone number if available).
 - b. Unless the client or the client's agent refuses such information, the nurse or physician's assistant dispensing under the authority of a nurse protocol or job description shall make a reasonable effort to obtain from the client or client's agent and record:
 - 1) Any known allergies, drug reactions or idiosyncrasies;
 - 2) Chronic conditions or disease states of the client;
 - 3) The identity of any other drugs, including over-the-counter drugs, or medical devices currently used by the client.

If the client or the client's agent refuses to provide such information as listed above, it should be documented with the client's or client's agent's signature.

- c. The nurse or physician's assistant dispensing under the authority of the nurse protocol or job description shall make a reasonable effort to obtain, record and maintain a list or record of all drug orders obtained by the client at the site where the drug was dispensed within the preceding two (2) years, showing the following information:
 - 1) Name and strength of the drug.
 - 2) Quantity and date dispensed.
 - 3) Name of the nurse or physician's assistant ordering and dispensing the drug.
 - 4) Comments from the nurse or physician's assistant relevant to the individual's drug therapy, including any other information peculiar to the specific client or drug.
- d. A client record shall be maintained for a period of not less than two (2) years from the date of the last entry in the profile record.

2. Prospective Drug Review

For the purpose of promoting therapeutic appropriateness, before ordering a drug(s) from a nurse protocol or job description and before dispensing any such drug(s), the nurse or physician's assistant shall, at a minimum, review the client's records and each drug(s) ordered to identify:

- a. Drug over-utilization or under-utilization.
- b. Therapeutic duplications.
- c. Drug-disease contraindications.
- d. Drug-drug interactions.
- e. Incorrect dosage, dosage form or duration of therapy.
- f. Drug-allergy interaction(s).
- g. Clinical abuse or misuse.

Upon recognizing any of the above, the nurse or physician's assistant ordering the drug shall take appropriate steps to avoid or resolve the problem including, if necessary, consultation with the delegating physician.

3. Client Counseling

- a. Before dispensing a drug and/or device which has been ordered under the authority of a nurse protocol or job description, and following a review of the client's record, the nurse or physician's assistant shall

personally offer to discuss matters which will enhance or optimize drug therapy with each client, or caregiver of such client. Such discussion shall include appropriate elements of client counseling, based on the professional judgment of the nurse or physician's assistant. Such elements may include but are not limited to the following:

- 1) The name, strength and description of the drug.
 - 2) The dosage form, dose, route of administration and duration of drug therapy.
 - 3) Intended use of the drug and expected action or result.
 - 4) Any special directions and precautions for preparation, administration and use by the client.
 - 5) Common, severe side effects, adverse effects or interactions, and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
 - 6) Techniques for self-monitoring drug therapy.
 - 7) The proper storage of the drug.
 - 8) Follow-up information regarding the need for continued drug therapy, if applicable.
 - 9) Action to be taken in the event of a missed dose.
 - 10) Comments relevant to the individual's drug therapy, including any other information peculiar to the specific client or drug.
- b. Additional forms of client information may be used to supplement verbal client counseling when appropriate or available.
- c. **Documentation of drug and/or device counseling must be clearly noted in the client's chart.**

H. Drug Programs/Contracts

1. 340B Drug Pricing Program

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals. Source: U.S. Department of Health and Human Services, Health Resources and Service Administration, Office of Pharmacy Affairs. More information is located at <http://www.hrsa.gov/opa/>

Eligible programs (covered entity) within Public Health:

- a. A family planning project receiving a grant or contract under Sec. 1001 PHSA (42 USCS § 300).
- b. An entity receiving a grant under subpart II of part C of Title XXVI of the Ryan White Care Act (RWCA) (relating to categorical grants for outpatient early intervention services for HIV disease) - Early HIV Intervention Services Categorical Grants (Title III of the RWCA).
- c. A State-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the RWCA.
- d. An entity receiving funds under section 318 (42 USCS §247c) (relating to treatment of sexually transmitted diseases) or section 317(j)(2) (42 USCS§247b(j)(2)) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary.

2. 340B Prime Vendor Program (PVP)

The program is free and voluntary to facilities that are already 340B eligible. The 340B PVP provides additional savings to 340B participants registered with the Prime Vendor. The program provides access to 340B sub-ceiling prices for drug products, favorable rates to access multiple wholesale distributors, and access to other related value-added products. The PVP is free to all 340B covered entities, but the covered entity must enroll in the PVP. More information is located at <https://www.340bpvp.com/public/default.asp>

3. Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)

MMCAP is a voluntary group purchasing organization operated and managed by the State of Minnesota serving government-authorized healthcare facilities. The state of Georgia is a MMCAP participant. The Department of Administrative Service (DOAS) is the administrator for Georgia. The goal of MMCAP is to provide member organizations the combined purchasing power to receive the best prices available for pharmaceuticals, hospital supplies, and related products. More information is located at <http://www.mmd.admin.state.mn.us/mmcap/background.htm>

I. Dispensing/Administering of 340B and 340B PVP Products

- 1. 340B and 340B PVP purchased products may only be administered/dispensed to a patient of the covered entity. The Office of Pharmacy Affairs has published final notice of guidelines on definition of a patient to allow a clearer understanding of which individuals may receive prescribed medications purchased at the legislatively mandated discount of [Section 602](#) of the [Veterans Healthcare Act of 1992](#).**

In summary, an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and**
- The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and**
- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.**

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a State operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

For more information, please refer to the October 1996 Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 [Patient and Entity Eligibility](#).

- 2. 340B PVP may contract to allow use of pharmaceutical products to clients that do not meet the patient definition. The 340B PVP will provide notification on each product in this category to the participating 340B PVP entities.**

J. ADDITIONAL INFORMATION

1. The Prescription Drug Marketing Act (PDMA)

The Prescription Drug Marketing Act (PDMA) of 1987 establishes legal safeguards for prescription drug distribution to ensure safe and effective pharmaceuticals. It was passed in response to the development of a wholesale sub-market (known as the "diversion market") for prescription drugs. More information is located at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm201702.htm>

2. The Robinson-Patman Act

The Robinson-Patman Act (15 U.S.C. 13 (a)-(f)) specifically makes it unlawful for "[One engaged in commerce to discriminate in price between different purchasers of commodities of like quality and grade where the effect may be substantially to lessen competition.]"

3. The Food and Drug Administration

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title (or volume) of the CFR is revised once each calendar year. A revised Title 21 is issued on approximately April 1st of each year.

CFR 21 is downloaded from the files of the Government Printing Office (GPO) and contains the most recent revision. The CFR at GPO, both current and historical, can also be searched directly at <http://www.access.gpo.gov/nara/cfr/index.html>.

- a. To report non-emergencies about medical products: medicines, medical devices, blood products, biologics, and special nutritionals:

The FDA's MedWatch program allows healthcare professionals and consumers to voluntarily report a serious **adverse event**, **product quality problem or product use error**, that they suspect are associated with the drugs, **biologics**, medical devices, **and dietary supplements** they prescribe, dispense or use. These problems include serious adverse reactions and events, product quality problems and product use errors. Reporting can be done online, by phone, or by submitting the

MedWatch 3500 form by mail or fax. Visit the MedWatch site, <http://www.fda.gov/medwatch/>, for more details.

- b. To report non-emergencies about vaccines:

Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System, which is maintained by FDA and the Centers for Disease Control and Prevention. The vaccine reporting form may be found at <http://vaers.hhs.gov>; a copy of the form may also be obtained by calling 1-800-822-7967 or at the FDA website, <http://www.fda.gov/>.

4. To report accidental poisonings:

Georgia Poison Center
80 Jesse Hill Drive, SE
PO Box 26066
Atlanta, GA 30335-3801

Emergency Phone: 1-800-222-1222

TTY/TDD: (404) 616-9287

Administrative Phone: (404) 616-9237

FAX: (404) 616-6657 (administrative) or (404) 616-9288 (Poison Center)

Website: www.georgiapoisoncenter.org

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