Professional Medical Device & Drug Sample Policy
For Public Health Clinics

1.0 PURPOSE

To establish a procedure to provide vendor-supplied samples of medications or personal medical devices without charge to patients in compliance with federal and state laws and regulations.

2.0 DEFINITIONS

2.1 "Personal Medical Device (PMD)" means a medical device that a patient can take home. These include blood glucose monitors, blood pressure monitors, etc.

2.2 "Medication Sample" means a medications or personal medical device provided by a manufacturer free of charge for the purpose of encouraging ongoing use by patients.

3.0 POLICY ELEMENTS

The distribution of vendor-supplied medication and personal medical device samples are only allowed if in compliance with this policy.

4.0 PROCEDURE

4.1 Control of Samples

- **A.** Samples will be used for patients of Public Health (PH). The use of samples by employees who are not patients of the Public Health Clinic are not allowed.
- **B.** Samples will be kept in a secure limited access storage area and segregated and easily identifiable from regular pharmacy inventory. The area must be locked when unattended. Industry representatives will not have access to the storage area without supervision of appropriate personnel.
- **C.** Authorization to distribute approved samples is contingent on continued compliance with the procedures outlined in this policy for the control of samples.
- **D.** Each Public Health Clinic utilizing approved samples shall designate a Pharmacist, Physician, Physician Assistant or Advanced Practice Registered Nurse operating under O.C.G.A. 43-34-25 who is responsible for ensuring compliance with all policies and procedures related to these product categories and are also responsible for the oversight of recordkeeping.
- **E.** Samples may not be acquired for personal use by practitioners or staff.

4.2 Storing, Handling, and Dispensing of Samples

A. Practitioners are prohibited from storing samples in their offices.

B. Samples must be provided to the patient at no cost.

C. All samples must be labeled with the following information: patient name, medical record number (MRN), practitioner's name, date, directions for use, purpose of treatment, drug/device name, quantity dispensed, and clinic name, address, and phone number. All of the above must also be recorded on the dispensing log. There must be a dispensing log for each medication sample and maintained for 2 years.

D. The information shall be entered into the patient's medical record to document receipt of an approved sample at the time of dispensing. If a sample is dispensed at a mobile or temporary location, then entry of information must occur within 24 hours.

E. Samples may be dispensed only with the consent and supervision of a Physician, Physician Assistant or Advanced Practice Registered Nurse operating under O.C.G.A 43-34-25 when acting within their prescribing authority of the state of Georgia.

F. Samples may be placed for use within a designated medication dispensing unit.

G. Samples may be removed from inventory and assigned to a practitioner for use on a mobile unit or temporary event-based location to be dispensed to patients.

- **i.** A sign out log will be kept at the facility. The date and location of inventory removal, drug/device name, strength, and quantity will be noted on the log. The log must be signed by the receiving practitioner.
- **ii.** The drug coordinator, pharmacist or another practitioner must co-sign the log to verify the information is documented accurately. A copy of the form must be provided to the receiving practitioner. If samples are retrieved from an automatic dispensing unit, the receiving practitioner is not required to obtain a copy.
- **iii.** Samples provided but not used must be returned to the designated inventory at the end of each day by the receiving practitioner. Return of samples from the mobile unit or temporary event location must be verified and documented by either the drug coordinator, pharmacist, or another practitioner prior to returning to designated inventory.
- **iv.** The returning practitioner with either the drug coordinator, pharmacist or another practitioner must reconcile the copy of the sign out sheet and the dispensing log with the original sign out log that was maintained at the clinic. They must co-sign to verify the information is accurate upon return and there are no inventory discrepancies. For samples being returned to an automatic dispensing unit, the pharmacist or drug coordinator would ensure reconciliation the following morning.
- **v.** Record keeping discrepancies must be resolved within 24 hours by the practitioner who signed out the samples. Failure to resolve

discrepancies will be reported to the next superior manager and reported to the State Office of Pharmacy.

4.3 Inventory Management of Samples

A. A specific person must be assigned responsibility for monthly inspections of samples.
B. The Public Health Clinic must follow all policies listed in the Drug Dispensing Procedure with a focus on storage, handling, removal, and distribution of drugs.
C. All medications in the Public Health Clinic must be stored according to manufacturer's instructions and checked monthly for outdates, deterioration and appropriate storage location. All areas in which medications are stored, including refrigerators and freezers, must be inspected.
D. A monthly review of sample stock inventory will be conducted in conjunction with the District Pharmacist or District Drug Coordinator. An inventory log must be maintained for 6 years. The sample inventory log is intended to provide the Public Health Clinic with a methodology to track the sample medications dispensed as well as aid staff in identifying those that have expired and require disposal.
E. The storage area must not be subject to extreme temperatures. Room temperatures must be monitored and maintained to ensure that all medications are stored per the manufacturer’s recommendations. All refrigerators and freezers containing medications must have daily temperature checks. For medications requiring refrigeration or freezing, processes need to be in place to notify the District Pharmacist or District Drug Coordinator if there has been a refrigerator or freezer electricity malfunction when the clinic is closed. Logs of these checks should be maintained for 2 years.
F. Samples must be well-organized by drug or drug category and segregated and easily distinguished from regular pharmacy inventory. Medications with similar names or similar packaging should be in separate areas.
G. Lighting in the storage room must allow easy reading of medication names and dosages.

4.4 Regulatory Compliance Inspections

A. Regulatory compliance inspections will be performed not less than bi-monthly by the District Pharmacist or District Drug Coordinator for the purpose of verifying compliance with dispensing procedures and medical record documentation requirements.
B. All samples will be checked for expiration dates and proper storage. Expired items or those that will expire prior to the next inspection will be removed and sent back to the reverse distributor for destruction on the appropriate local account utilizing appropriate documentation records.

C. Quarterly reports will be provided to the State Office of Pharmacy and non-compliance and corrective action shall be documented.

D. Failure to comply with procedures for handling and dispensing samples may result in the removal of all such medications and personal medical devices from the clinic permanently as determined by the State Office of Pharmacy. Clinics that fail to implement procedures for handling and dispensing samples or clinics unable to comply with procedures will not be able to stock and dispense samples.

E. Clinics dispensing samples must comply with all labeling, storage, and handling procedures required by the Georgia Board of Pharmacy and respective licensing board of the practitioner.

F. All samples of oral medication must be dispensed in child-resistant containers. The patient or patient representative may waive this requirement by signing a waiver statement.

4.5 Procedure for Request of Samples

A. Public Health Clinics are not authorized to receive samples of controlled substances.

B. A manufacturer's sales representative may distribute a dangerous drug as a complimentary sample only upon the written request of a practitioner as defined by O.C.G.A. §16-13-21(23).

> "Practitioner" means:
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> **(A)** A physician, dentist, pharmacist, podiatrist, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;
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> **(B)** A pharmacy, hospital, or other institution licensed, registered, or otherwise authorized by law to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;
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> **(C)** An advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25. For purposes of this chapter and Code Section 43-34-25, an advanced practice registered nurse is authorized to register with the DEA and appropriate state authorities; or
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> **(D)** A physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician assistant is authorized to register with the DEA and appropriate state authorities.

C. A practitioner’s authority to request, receive, and dispense prescription drug samples is determined by the limitations, if any, placed upon that practitioner’s prescribing authority under State law.

D. The request shall contain the names and addresses of the supplier and the requestor and the name and quantity of the specific dangerous drug requested.
E. Samples can only be distributed to the licensed practitioner or to the pharmacist upon the written request of a licensed practitioner.
F. The industry representative will be responsible for logging the generic name, brand name, company name, representative's name, delivery date, clinic location, quantity, lot number and expiration date on a form maintained in the individual Public Health clinic.
G. Representatives are responsible for ensuring that the remaining shelf life for samples is at least 6 months.
H. Industry representatives will be responsible for notifying the District Pharmacist or District Drug Coordinator of any manufacturer recalls.

4.6 Recall Process for Medication Samples

A. A practitioner notified of a recall regarding samples received must provide the information to the District Pharmacist or District Drug Coordinator.
B. The District Pharmacist or District Drug Coordinator must notify all clinics of a recall.
C. The recalled stock will be located, removed, and processed following the instructions contained within the recall notice.
D. The District Pharmacist or District Drug Coordinator will notify the designated practitioner at all locations and provide information needed to address the recall along with the name and phone number of the pharmacy personnel managing the recall.
E. If a Class I patient-specific recall is required, Public Health Clinic staff must contact the patient and inform the patient of the recall.
F. The clinic personnel contacting the patient must provide the patient with any information or instructions provided by the FDA regarding the recall.

4.7 Compliance

A. A copy of this policy must be available in each clinic sample storage area.
B. Violations of this policy and corrective actions shall be reported to the State Office of Pharmacy within 30 days of the discovery of the violation.