This policy is applicable to the following Henry Ford Health System business unit(s):

- [ ] Henry Ford Hospital
- [x] Henry Ford Medical Group
- [x] Community Care Services
- [x] Behavioral Services
- [ ] All of the Above

**OBJECTIVE:**
(1) To ensure that JCAHO standards are met
(2) To enhance patient safety by requiring documentation of all medications dispensed to the patient
(3) To ensure that all applicable state regulations regarding dispensing of medications are met.

**Philosophy:**
Although sample medication may be helpful in patient care, drug samples:

- increase the cost of drugs for all patients who pay for their medications
- sometimes allow patients to receive improperly labeled, packaged, outdated and unrecorded drugs, and suffer possible adverse outcomes.
- provide access to prescription drugs by unauthorized personnel who may self-administer them without medical supervision. The Ambulatory Pharmacy and Therapeutics Committee discourages the use of sample medications unless they are properly controlled.

**Definition:**
Medication is any agent used in the prevention, treatment, or mitigation of disease. "Sample Medication" referred to in this policy include prescription legend and OTC drugs only which are provided at no charge by drug company representatives. Topical products listed as OTC in the Facts & Comparison reference (updated monthly) are exempt. Sample medications are provided by drug company representatives to promote the sale of the drug.
Policy:

The Ambulatory and Inpatient Pharmacy and Therapeutics Committees discourage the use of sample medications except for selected clinics/providers who comply with the legal and regulatory issues governing the labeling, stocking, dispensing, and recording of sample medications as outlined in the procedures below. Sample OTC and legend drugs are prohibited from all HFMG ambulatory care sites except where approved by the Ambulatory Pharmacy and Therapeutics Committee as sample medications meeting the intent of the special cause exclusionary provision.

Sample Medication Procedures:

1. Special Cause exception to stock samples is requested by completion and forwarding of the request to the Ambulatory Pharmacy and Therapeutics Committee Secretary.

2. Only drugs approved for sampling may be dispensed as samples by approved clinics. Medications denied HFMG formulary status may not be sampled.

3. Ambulatory Pharmacy personnel work with the requestor to assure adherence to regulatory and legal requirements.

4. Sample medications must be checked monthly, by clinic nursing staff to assure that only non-expired drugs are stocked and dispensed.

5. The triplicate sample medication log form is used to maintain a permanent record of the sample medications dispensed.

6. All special cause variation sample medications must be signed out on the SAMPLE MEDICATION FORM in the clinic. One copy of the triplicate form must be attached to the sample medication that goes home with the patient; one copy is put in the patient’s medical record and the original remains on the log book.

7. Each medication that leaves the clinic with a patient must be labeled with the following information:
   - name of the patient
   - name and strength of the drug
   - lot number of the drug
   - patient specific directions for use of the drug (or Pharmacy-generated drug information sheets)
   - expiration date of the drug (one year from date of dispensing if not otherwise noted)
   - name, address and telephone number of dispensing physician (can be satisfied by attaching your business card)

8. As a part of the note dictated into CarePlus™, providers will indicate the name and strength of the sample medication, specific directions for use, lot number and date of dispensing for all sample medications given to the patient.

10. In the hospital, nurses may only administer medications that are dispensed and labeled by the Inpatient Pharmacy. Sample and other free medications are not permitted on the inpatient nursing units.

11. Pharmaceutical company representatives may only distribute special cause variation sample medications that have been approved by the Ambulatory Pharmacy and Therapeutics Committee.

12. Free supplies of drugs are to be distributed or mailed to hospital staff only if specifically requested by the physician. Unsolicited sample supplies are unauthorized.

13. Sample medication should be stored in a locked area in the clinic nursing station. The clinic nurse is responsible for key access to sample storage areas. Sample storage areas must be locked during non-clinic hours. Medical service representatives are not authorized to have access to drug sample storage areas. **Samples cannot be stored in physician’s offices or other health care provider’s offices.**

14. The physician, dentist, or registered nurse (under the direction off a physician or dentist) shall be responsible for the storage of samples in the clinic.

15. A designated approved individual in concert with the physician or other licensed prescriber shall be responsible for special cause variation samples in the clinic. Special cause variation sample medications may be removed from storage areas by personnel licensed to prescribe.

16. No controlled drug samples shall be permitted.

17. Topical products listed as OTC in the Facts & Comparison reference (updated monthly) are exempt from the sampling requirements outlined herewithin and do not require documentation on the HFHS Sample Medication triplicate forms nor auxilliary labeling other than the manufacturer’s label.
18. Free samples of drugs may **only** be used under medical supervision. Physician, dentist, podiatrist or optometrist (within scope of practice) consent is required before free medication may be dispensed. The nurse is not legally authorized to label or dispense special cause variation sample medications to patients for use away from the clinic.

19. Sample medications, no longer needed, should be forwarded to Pharmacy for disposition.

20. Patients are not to be charged for sample medications.

21. Infractions of this policy shall be reported to The Ambulatory Pharmacy and Therapeutics Committee.

22. A copy of this policy shall be posted in each clinic sample storage area and distributed to vendor representatives.

23. Each clinic is responsible for assuring compliance with this policy in a manner acceptable to JCAHO, the Public Health Code and applicable state laws.

24. Due to the changing medical economic forces impacting HFMG, approved sample medications will be subject to periodic review of the Ambulatory Pharmacy & Therapeutics Committee.

25. Every effort will be made to assist clinic personnel in complying with the requirements. However, should attempts fail, sample medications will be removed from the clinic facilities upon notification of the Regional Chief Medical Officer.
Clinic Procedures:

1. Sample Medications Prescription Form must be filled out for each special cause variation sample medication dispensed from the clinic.
   a) First copy (White) labeled medication with dosing instructions
   b) Second copy (yellow) to the chart (Office note dictation into CarePlus™ acceptable.)
   c) Provider name and address should be affixed to samples
   d) Patient information
   e) Expiration date of medication
   f) Third copy (pink) remains in log book

2. The Nursing staff are not authorized to package or dispense sample medications for patient use following the clinic visit.

3. Nursing or pharmacy staff may be responsible for patient instruction on how to use special cause variation sample medications.

4. Nursing or pharmacy staff check expiration date of special cause variation sample medications in clinic storage areas and removes drugs that are about to expire or have expired in conjunction with monthly medication center reviews.

5. Nurse secures special cause variation sample medication storage area during hours when the clinic is closed.

6. Nurse posts a copy of the sample medication policy in each clinic sample storage area.
Appendix A

Sample Medication
Documentation for Special Cause Variation

**Definition:** Special Cause Variation is defined as a high-risk patient population or situation with the likelihood of a poor outcome without the sample medication. (e.g. oral contraceptives in a teenage high-risk pregnancy clinic).

**Process:** Please complete the following information. All of the following information must be provided prior to evaluation. Upon receipt, it will be reviewed by the Ambulatory Formulary Committee. You will be notified in writing by Dr. Barkley (Chairperson).

1. **Description of the Population or High Risk Situation**

2. **Justification for the Need for Sample Medications**

3. **Name of Drug or Drugs Needed**

4. **Description of the Process To Ensure Compliance with State Laws and JCAHO Regulation**

5. **Name and Telephone Number of the Person Responsible for Assuring Documentation and Compliance with State and JCAHO Regulations**

Please fax completed form to Dr. Barbara Zarowitz, 248-642-6094.