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Pharmaceutical Samples

The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing to physicians.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

A Toolkit for Academic Medical Centers

I. Introduction

Of the \$29 billion spent by the pharmaceutical industry to promote its products, over 60 percent, or about \$18 billion a year goes to “free” samples.¹ Samples encourage physicians and patients to rely on medications that are expensive, but often not more effective than other available drugs. Research has shown that samples can increase physician prescribing of the marketed product,^{2,3} independent of the effect of detailing by industry sales representatives.⁴

Samples serve two distinct marketing purposes. Physicians value samples and are willing to spend time with sales representatives to get them.⁵ Secondly, samples serve as “starter” medications – an enticement to prescribe new, heavily marketed and generally more expensive medications. Once therapy has been initiated, patients and their insurers are likely to continue to pay for the new, costly drugs.⁶

Studies indicate that the majority of pharmaceutical samples are not dispensed to low-income or uninsured patients.^{7,8} Nevertheless, many physicians use samples, in part, to provide medications to needy patients. However, the inconsistent availability of samples may limit the utility of this approach.

Influential guidelines in the *Journal of the American Medical Association* call on academic medical centers to prohibit the direct provision of pharmaceutical samples to physicians, instead establishing a system of vouchers for low-income patients or other arrangements that distance the company and its products from the physician.⁹

Drawing on the experience of leaders at academic medical centers with strong conflict-of-interest policies, this “best practices” document outlines some practical considerations for academic medical centers engaged in reviewing samples policy.

This toolkit is one in series prepared by the Prescription Project to assist medical schools and teaching hospitals developing new policies to address the conflicts of interest that arise from pharmaceutical and medical device industry marketing. For further assistance or more information, please email policy@prescriptionproject.org.

II. Policy Considerations

Developing a samples policy requires consideration of the marketing impacts of samples, the needs of under-insured patients, patient safety concerns associated with dispensing samples, compliance with accreditation standards and the invisible overhead costs associated with logging, tracking and dispensing medications from a traditional sample closet.

In recent years, numerous clinics, health systems and medical schools have decided to forgo industry samples.^{10 11} These include the Cambridge Health Alliance in Cambridge, MA, and the University of Michigan Hospitals and Health Centers, which are both Medicaid Disproportionate Share Hospitals (policies below). While the Michigan policy permits samples under specific circumstances and subject to “special cause” approval, the provision is rarely used.

In the absence of samples, access to medication can be facilitated through prescribing generic drugs (including \$4 prescriptions available from major chain pharmacies), accessing state and institutional assistance programs, use of favorable pricing available through federal 340B programs (primarily in public hospitals and clinics) and pharmaceutical industry prescription assistance programs (PAPs).*

- One medical center streamlined the use of PAPs by designating two full-time pharmacy technicians to help identify needy patients and handle all applications. These employees are charged with understanding the convoluted and continually changing nature of the applications (which are made purposely difficult) so that each individual nurse and physician does not have to learn all the rules and processes.
- The same medical center has established a fund made up of charitable donations to help pay for free medications to needy patients.

A sample-free policy is not always practical or politically feasible. In such cases, institutional policies should be designed to eliminate the marketing function of samples, while ensuring that samples continue to be available to patients in need. The elements of such a policy should include:

- Physicians may not directly accept samples from industry representatives
- All samples remain under the control of the pharmacy department to ensure inventory integrity
- Samples are not for personal use by physicians, their families or staff

Recently, the University of Pittsburgh Schools of the Health Sciences and the University of Pittsburgh Medical Center adopted stringent policies for relationships with industry.¹² In the course of developing samples policy, the school investigated the experience of other medical centers, including:

- The *Hospital of the University of Pennsylvania (HUP)* Drug samples were prohibited several years ago due to patient safety concerns; they were replaced with a voucher system.
- *Geisinger Medical Center* has banned samples on campus because of the burden of required inventory tracking. Half of employed physician practice sites have lost their sample privilege for failing to maintain documentation.

* While these programs only provide brand-name drugs, they do cut the link between individual MD and the industry (for more, see The Prescription Project. Fact sheet: Industry Prescription Assistance Programs)

- The *University of Wisconsin Hospital and Clinics* utilizes a combination of starter supplies, exempt samples [i.e. samples permitted under specified conditions] and vouchers to meet the needs of clinic patients. There are strict procedures governing their use and documentation.
- *Brigham and Women's Hospital in Boston* disassembled their centralized sample distribution center several years ago. The resource utilization (space, human, and time due to volume of paperwork) was not seen to be justified. The facility administration supported expansion of the free care and indigent care programs and samples were subsequently eliminated.

The proposed University of Pittsburgh samples policy establishes a centralized distribution process for medication samples. Pharmaceutical companies will be asked to deliver samples directly to the central pharmacy, rather than to physician offices. Physicians who have agreed to comply with institutional samples policy will make weekly orders of samples from the central pharmacy. A procedure is established to track inventory and dispensing. Physicians who have not agreed to comply with institutional samples policy will not be permitted to distribute samples. The center estimates the new samples distribution system will require a budget of \$83,000 to \$163,000, mostly for pharmacy technician time.

Joint Commission (formerly JCAHO) Hospital Accreditation Standards¹³ for samples require that samples be stored and dispensed with the same protections required for medications dispensed by the pharmacy. Samples require proper labeling and tracking and must be retrievable in the event of a recall. Prescription Project interviews indicate that many AMCs eliminated samples to ensure patient safety and compliance with Joint Commission standards, since guaranteeing proper sample management in each clinic and department was difficult (see Joint Commission standards, below).

III. Example Policies

Cambridge Health Alliance (Cambridge, MA)

The distribution of drug samples by staff of the inpatient and outpatient units is not allowed within CHA. The Department of Pharmacy is responsible for providing drugs to patients through various means to ensure that the needs of the CHA indigent patient population are met.

University of Michigan Hospitals and Health Centers

I. Policy Statement

Drug samples, while convenient for patients, entail regulatory concerns, safety risks for patients, and encourage prescribing of high cost, non-preferred medications. Therefore, with limited exceptions, sample medications are not permitted in UMHHC facilities. Vouchers for starter medications approved by the Ambulatory Formulary Committee may be dispensed to patients as an alternative. Non-approved vouchers are not permitted in UMHHC facilities.

Drug samples shall not be made available for use by inpatients.

The policy regarding the distribution of drug samples shall be controlled by the Executive Committee on Clinical Affairs. Visitation of Ambulatory Care Site personnel and control of drug samples/vouchers shall be monitored jointly by the site personnel and the Department of Pharmacy Services.

II. Policy Purpose

This policy and these procedures have been developed to provide:

- A. Guidelines restricting the use of samples in ambulatory clinic sites.
- B. A mechanism for enforcement of these guidelines

III. Definitions

Drug Samples: Prescription and non-prescription medications which are provided to the sites by pharmaceutical representatives for complimentary distribution to patients, as starter doses.

UMHCC Sites: Applicable to all UM Hospitals and Health Centers where care is provided to patients.

Pharmaceutical Sales Representatives (PSR): A representative of a pharmaceutical manufacturer who visits the ambulatory care sites for the purpose of soliciting the use of, or providing information about, pharmaceutical products. Representatives who visit UMHHC facilities for the sole purpose of initiating or monitoring research studies are exempt from these guidelines.

IV. Policy Standards

- A. Sample medications are not permitted in UMHHC facilities except as noted below. This includes both patient care and non-patient care areas.
- B. Vouchers approved by the University of Michigan Health System's Ambulatory Formulary Committee may be distributed by UMHHC ambulatory care sites in order for patients to receive complimentary starter medications from a pharmacy of their choice. The Ambulatory Formulary Committee will determine a formulary of UMHS-preferred medications, which then may be available through vouchers. Only vouchers approved by the Ambulatory Formulary Committee are permitted to be used by UM clinicians at UMHHC.
- C. Non-approved vouchers may not be distributed by PSRs to UMHHC ambulatory care sites, nor dispensed by UMHHC personnel at UMHHC sites.
- D. Under special circumstances in which there is a legitimate clinical need, with the approval noted below, sample medications may be permitted in UMHHC. Specific requests to have physical samples in a UMHHC clinic must be made on the Special Cause Sample Request Form (Exhibit A), and be approved by the Ambulatory Formulary Committee and the Site Medical Director.

V. Procedure Actions

- A. Participating pharmaceutical companies may distribute UMHS Ambulatory Formulary Committee-approved vouchers to UMHHC clinics through their sales representatives. These vouchers are for generic medications or brand drugs that are designated as "preferred" by the Ambulatory Formulary Committee.
- B. PSRs may not distribute non-approved vouchers or coupons within UMHHC sites, or to UMHS clinicians.
- C. If a clinic medical director believes there is a clinical need to maintain some physical samples, a request will be made to the Ambulatory Formulary Committee and Site Medical Director using the Special Cause Sample Request Form. If the request is approved, the succeeding steps must be followed:
 - 1. A formulary of approved sample products must be approved for the clinic. Samples of only those products are permitted at the site.

2. The approved products must be reviewed annually by the medical director.
 3. Samples must be stored in a locked secure area. PSRs are not authorized to have access to drug sample storage areas.
 4. When samples are received from the manufacturer, they must be recorded on the Sample Drug Log-in Form (Exhibit B).
 5. The sample drugs must be inspected by the clinic medical director or designee monthly, and a copy of this review sent to the Department of Pharmacy Services (Exhibit C).
 6. In the event of a drug recall, the Department of Pharmacy Services will notify the clinic. The clinic medical director or designee must review sample inventory and return recalled drugs to the pharmacy.
 7. When dispensing a sample medication to a patient, the physician must select the drug, dose and quantity of medication to be dispensed. This must be recorded in the patient's medical record. The physician must review the dose-pack and patient label with written instructions prior to the medication being dispensed to the patient. Distribution of sample medications for purposes other than starter doses is prohibited by the Michigan Public Health Code.
 8. The physician may delegate to a medical assistant or nurse the following steps:
 - a. complete the Sample Drug Sign-Out Log (Exhibit D)
 - b. Complete the Sample Medication Label (Exhibit E)
 - c. Document the patient waiver of a child-proof container
 - d. Obtain final approval from the physician before dispensing
 - e. Provide patient education regarding the medication
- D. The Department of Pharmacy Services will inspect the sample medication storage, log, and dispensing process at least annually. If adherence to this policy is not being met, the privilege of maintaining samples will be revoked.
- E. If PSRs distribute non-approved samples or vouchers to a UMHHC site, the UMHHC reserves the right to take disciplinary action against the representative and/or company including prohibition from visiting UMHHC facilities.

Policy 05-03-024 - Exhibit A
Special Cause Sample Request Form

Definition: Special Cause is defined as a patient population or situation with the likelihood of a poor outcome without the sample medication (e.g., eye drops following ophthalmologic surgery or procedures).

Process: The following information must be completed prior to evaluation. The submitted form must be approved by the Department Chair and the Ambulatory Formulary Committee.

- 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 Process to Ensure Compliance with Michigan Public Health Code and JCAHO

5. Name of Person Responsible for Assuring Documentation and Compliance with Policy

Approved:

_____	_____	_____	_____
Requestor	Date	Requestor	Date

 Chair Date
 Ambulatory Formulary Committee

Joint Commission standards for sample medication distribution

Q. What issues must our organization consider relating to sample medications?

A. The following issues:

- Patient-specific medication information must be available in some fashion (MM.1.10)
- Medication must be safely stored (MM.2.20)
- Medication orders must be written clearly (MM.3.20)
- There must be a written order for every medication (IM.6.20)
- Medications are appropriately labeled, Element of Performance #3 at a minimum - this information is usually included on the container (MM.4.30)
- You must be able to retrieve sample medications if recalled, discontinued, or expired (MM.4.70 and MM.4.80)
- As with any medication, you must monitor the effect (MM.6.10)
- As with any medication, you must address actual or potential adverse drug events and error (MM.6.20)
- As with any medication, if appropriate to the patient's needs, education is provided (PC.6.10).
- If the patient is transferred to another Provider, setting, level of care, a complete list of current medications, must be communicated (National Patient Safety Goal 8B).

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