Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools

COMMUNITY CATALYST

COI Toolkit on Samples

I. Introduction

Pharmaceutical companies distribute more than $5 billion in pharmaceutical samples to physicians every year.[1] Samples are a key tactic in pharmaceutical company marketing practices[2] and physicians themselves often cite free samples as the primary reason they allow pharmaceutical sales representatives to meet with them. Samples can potentially benefit patients by allowing them to try a medication for a short time to see whether it works or causes adverse reactions before filling a full prescription. Uninsured and financially stressed patients can receive free samples that they would otherwise be unable to afford. Despite these potential benefits, samples bring with them a host of problems for both patients and the health care system.

In 2009 the Institute of Medicine (IOM) recommended that academic medical centers (AMCs) and teaching hospitals adopt policies prohibiting the use of drug samples, "except in specified situations for patients who lack financial access to medications." The IOM acknowledged a serious societal problem with access to affordable medications, but concluded that drug samples were not the answer.[3] Increasingly institutions are taking action on this difficult issue, and today nearly 30 percent of medical schools prohibit or strictly limit the use of samples.[4 5] In a 2009 national survey, only 44 percent of physicians working in universities or medical schools reported receiving samples, while over 75 percent in solo, two-person, or group practices used samples.[6] It is hoped that the patterns set during physician training will eventually serve to lower physician use of samples in their future practices.

II. Problems with Samples

Industry successfully uses samples to influence prescribing behavior. In a study of teaching hospital residents, those with access to samples in a clinic were more likely to prescribe heavily advertised drugs and less likely to recommend over-the-counter (OTC) or more inexpensive drugs than those who did not have access to samples.[7] Samples influenced prescribing even though residents at this institution were not allowed to have contact with drug sales representatives.

While samples can provide some benefit for low-income patients, research studies have demonstrated that samples are more likely to be given to wealthier, insured patients than to low-income and uninsured patients.[8] This works well as a marketing strategy for the drug company

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Insured patients receive a small supply of free samples and then continue on the brand-name medication for a long period of time, perhaps indefinitely. This can leave the consumer and their insurer paying for a high-cost drug when a more affordable option would have been a better choice from the outset.

Despite short-term savings, patients who receive samples ultimately pay more out of pocket than patients who never received samples.[9] A less expensive, equally effective generic drug may have been available but was overlooked because of the availability of samples. Patients started on samples may not be able to afford to continue them when they have to pay for the prescription themselves, and they may be too embarrassed to inform the prescriber about their financial needs and thus go without treatment.[10]

Because sample supplies are not consistently available, frequently the patient may need to be changed to other samples that are sometimes not even in the same class of drugs. This may lead to therapeutic difficulties in management. When the initial sample is no longer available, prescribers may be tempted to use another sample that is not the preferred treatment, simply because of its availability.[11] [12] Prescribers may also be tempted to use samples for non-FDA-approved indications for the same reason, with devastating consequences.[4] [13]

Institutions and prescribers should also be concerned about other safety concerns as well. Quality control in a "sample closet" is not likely to be as well maintained as quality control in a pharmacy, including proper storage, removal of expired medications, and keeping track of which drug lots were distributed to which patients in case of a recall. Furthermore, prescribers who dispense samples do not have the information that pharmacists have about medications prescribed for the patient by other providers, including the potential drug interactions.

Finally, very new prescription drugs will not have the track record of safety that older drugs in the same class have established, so samples of these types of drugs could pose additional patient safety risks.

Any one of these concerns could be a source of potential liability for any institution that fails to establish and justify a clear policy on the practice of accepting and distributing samples to patients.

III. Justifications for Using Samples

The only ethically defensible reason for using samples is to assist patients who otherwise could not afford to purchase the drugs and where no other low-cost acceptable alternative exists.

Uninsured patients or patients with high-deductibles or high prescription-drug-cost-sharing in their health insurance may not be able to afford their medicine. Low-cost generic alternatives for medications like insulin and other biologics may also be unavailable to this population. Thus, the problems associated with the use of samples must be weighed against the potential for poor health outcomes if the drugs are not made available.

IV. Conditions That Should Be Fulfilled If Samples Are Used

The IOM recommended that academic medical centers should, at a minimum, oversee and restrict the use of samples. The Joint Commission's standards for sample medications, which apply to hospitals, ambulatory health care, and other clinical settings, require proper record keeping of: the name of the drug dispensed; the drug lot number; expiration date; the quantity dispensed; the name of the patient; the name of the prescribing provider; and the date dispensed. Expired drugs must be properly disposed of and the facility must be able to respond to recalls and distribute adverse event information. These requirements were further strengthened in July 2014.[14]

Ideally, institutions should require that drug companies and sales representatives provide all samples to a central pharmacy of the facility in which they will be maintained and distributed to patients. Violations of this practice should be enforced with sanctions against the drug manufacturer.

A licensed pharmacist should ensure that samples have the same safety and quality standards that are applied to drugs that are purchased. This includes overseeing and supervising sample procurement, storage, record-keeping and disposal of expired drugs. Where a central pharmacy and licensed pharmacist are not available, a nurse should be designated to perform these functions. To the greatest extent possible the pharmacist or nurse, rather than the prescriber, should be the only person interacting with pharmaceutical sales representatives.

Samples should be dispensed only to patients who could not otherwise afford to purchase them, due to a lack of insurance, high deductibles or copays, or the financial burden of paying for other medications. Samples should not be used merely for the convenience of the patient or to try out a new drug (a prescription for a small quantity of the new drug should be used for that purpose). Because they accept samples for patient use, institutions should clearly prohibit their redirection and use by any providers or staff at an institution and by their families or friends.

Samples may be used as a bridge for patients who are financially needy while assisting the patients in securing access through other means as described in the next section.

Institutions that opt to allow samples should implement strict controls to manage their use. For example, The University of Pittsburg Medical Center (UPMC), which initially prohibited samples, now makes a limited number available to address access concerns (see policy below). The program is structured to prevent companies from using samples as a means to influence prescribing, such as company representatives gaining entry for closer in-person contact with clinicians. Companies must register with the program and may only provide samples through a UPMC contracted intermediary, not through company sales representatives. Current participation by industry is very low. Physicians register to receive specific samples and must comply with inventory and medical records safety measures. UPMC also provides generic samples to low-income patients through an in-house pharmacy assistance program, a benefit that also discourages the unnecessary use of brand name samples.[15]

"UPMC has designed a central system with limited formulary, making certain products available, such as inhalers, for specific needs expressed by clinicians. This approach eliminates the marketing elements associated with samples, while offering access to necessary medications."

— Barbara Barnes, MD, MS, Associate Vice Chancellor for Continuing Education and Industry Relationships; Associate Dean for CME, University of Pittsburg Medical Center

V. Educate Prescribers and Assist Patients in Securing Access to Low-cost Drugs

To build consensus around policies prohibiting samples and/or to mitigate the demand for samples, institutions should educate their clinical staff and trainees about the cost of medications and affordable options other than samples. For instance, medical school curricula and continuing medical education should address the full range of treatment options, including non-pharmacological alternatives and address unfounded concerns about generic efficacy. The use of generics should be encouraged, including those in the same therapeutic class when no generic is available, such as one of the low-cost generic statins as an alternative to a brand-name statin.

Institutions can also assist patients in gaining access to low-cost medications through existing public and private programs by:

- Assisting patients in the enrollment process for Medicaid, state drug programs, subsidized health insurance through the Affordable Care Act, or industry-sponsored prescription drug Patient Assistance Programs.
- Providing information about the $4 generic drug savings programs widely available at supermarkets and national chain pharmacies.
- Participating in the federal 340B program or directing patients to other facilities that do. This program requires drug manufacturers to provide outpatient drugs to eligible health care organizations at significantly reduced prices. Eligible organizations include: safety-net hospitals, federally qualified health centers, Ryan White HIV/AIDS Program grantees, and certain types of specialized clinics.[16]
- Making their clinical staff and trainees aware of these resources and the staff that can assist their patients.

VI. Model Policies and Noteworthy Practices

The University of Iowa Health Care policy prohibits both samples and manufacturer coupons, in order to better insulate their patients and prescribers from marketing tactics. Also included below are examples of three different approaches by institutions to protect prescribing practices by prohibiting samples except in narrow, defined circumstances. Johns Hopkins prohibits samples, except when they are necessary for patient education (such as inhalers). The University of Central Florida College of Medicine prohibits samples, except in pre-approved instances that would otherwise place vulnerable groups of patients in jeopardy. The University of Pittsburgh Medical Center allows for some samples to be distributed to participating physicians, but manages all samples through a third party, with strict requirements of participating companies.

"As a new medical school, we strive to be a leader in modeling ethical behavior, defining and communicating the standards and rules clearly, and enabling transparent, appropriate dialog and collaborations with industry partners."

— Jeanette C. Schreiber, JD, MSW, Assoc. VP for Medical Affairs, Chief Legal Officer, University of Central Florida College of Medicine

UNIVERSITY OF IOWA HEALTH CARE

Policy and Procedure Manual: Finance-Procurement Services & Value Implementation

7. Additional Pharmacy and Therapeutics Subcommittee and Department of Pharmaceutical Care Requirements: (pg. 5)

a. Industry supplied drug samples, drug containing devices, and vouchers may not be distributed to patients at UI Health Care.

b. UI Health Care faculty, staff, and trainees may not seek or accept industry supplied drug samples for personal or family use.

c. Drug coupons are not permitted to be given to patients at the UIHC.

http://www.uihealthcare.org/uploadedFiles/UIHealthcare/Content/Services/Procurement_Services/Document_Library/Policy_and_Guidelines/Vendor%20Policy%202013.pdf

JOHNS HOPKINS MEDICINE POLICY ON INTERACTION WITH INDUSTRY

d) Pharmaceutical Samples

The practice of accepting free pharmaceutical samples risks interference with one's prescribing practices since industry representatives often provide the newest and most costly drugs. Therefore, free pharmaceutical samples and vouchers for free pharmaceutical samples may not be accepted.

The foregoing will take effect once appropriate procedures are established so that affected providers and clinics can make the necessary changes.

When samples are necessary for patient education (e.g., instructing patients in the use of inhalers), they may be accepted, provided they do not carry the name of a company or the name of the company is covered.

Johns Hopkins faculty physicians and other hospital staff will educate staff and trainees about and inform patients of affordable options for obtaining medicines. Examples are pharmaceutical assistance programs, vouchers, and large retail chains with low-cost medicines.

http://www.hopkinsmedicine.org/Research/OPC/Policy_Industry_Interaction/policy_interaction_industry.html#section_2d

UNIVERSITY OF CENTRAL FLORIDA COLLEGE OF MEDICINE INDUSTRY RELATIONS POLICY AND GUIDELINES

Pharmaceutical Medical Device and Medical Supply Samples

The COM prohibits acceptance of samples of pharmaceuticals medical devices or medical supplies ("Samples") by COM practitioners or faculty members except in limited circumstances as provided in this policy and with prior approval. Samples may be accepted (i) for use in research, provided such use is in a manner that assures full clinical evaluation of its use and adheres to applicable protocols and is approved by the

Associate Dean for Research, and (ii) by a Nurse Manager for patient care under circumstances involving a vulnerable patient population when a COM physician believes lack of provision of samples to their patient would jeopardize their patient's health, provided that the COM physician has requested, and received, a waiver from both the Medical Director and the Director of Quality and Safety of Pegasus Health. The request must outline a clear and convincing benefit to the patient and provide safeguards for the appropriate distribution and control of samples. The request and approval must be documented in writing. No sample may be used personally by COM Personnel. The Pegasus Health Director of Quality and Safety may inspect sample storage areas at any time and may revoke permission if non-compliance is identified.

http://med.ucf.edu/media/2011/08/UCF-COM-Industry-Relations-Policy-and-Guidelines3-4-14.pdf

UNIVERSITY OF PITTSBURG MEDICAL CENTER (UPDATED 2013)

Drug Samples

The provision by manufacturers of "free" samples of prescription drugs can offer benefit to some patients who require trial or starter doses. However, traditional mechanisms for distributing samples require interaction with marketing representatives, providing an opportunity for promotional activities. In addition, the availability of branded samples may lead to inappropriate prescribing of expensive medications in circumstances in which generic substitution is appropriate. In addition, point of care use samples requires compliance with federal requirements for dispensing and inventory management.

UPMC practice sites can request and receive branded samples only through use of the UPMC e-Sample Center, which supports web-based ordering and direct mail shipment of product to the physician. Participating sites must receive training on UPMC dispensing and inventory management procedures and will be subject to ongoing monitoring of compliance. UPMC will monitor the formulary and ordering practices by site.

Practices are permitted to use the MedVantx system, which is designed to advance the appropriate use of generic medications. Over the counter products may also be accepted and distributed by UPMC offices. Free care programs may apply for exemptions that allow for direct receipt of samples under limited circumstances.

(not available on the web)

VII. References

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http://tinyurl.com/AmcModelCoiPolicy

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