



# Samples:

## Best Practices for Academic Medical Centers\*

### The Problem:

**P**harmaceutical representatives provide free drug samples to physicians in order to encourage the uptake of specific products. Samples influence prescribing behavior: physicians who accept samples are more likely to deviate from current clinical recommendations when prescribing drugs, thus placing patients at risk. The vast majority of physicians report having accepted industry samples at some point in their careers.<sup>1</sup>

Ostensibly, samples can be used to benefit low-income patients who would otherwise struggle to afford a particular drug. In practice, however, low-income and uninsured patients are less likely to receive samples than high-income patients and patients with insurance.<sup>2</sup> Furthermore, samples often never reach patients at all, and are instead used by physicians or hospital staff or their relatives.<sup>3</sup> Patients who do receive samples may discontinue treatment entirely if they are not able to afford the medication once the sample supply runs out.<sup>4</sup>

Sample medications present more hazards than pharmacy-issued medications. Sample distribution can endanger patients, as it bypasses the usual professional oversight and pharmacy protocols that ensure the proper use and storage of drugs.<sup>5, 7</sup> Furthermore, the drugs that are provided as samples tend to be new, costly drugs that lack the established safety records of pre-existing alternatives.<sup>8</sup> Once therapy has been initiated, patients and their insurers may continue to pay for the more expensive drug, rather than a generic alternative. The additional cost of long-term treatment with these drugs usually exceeds any initial savings.<sup>9</sup> In general, physicians who accept samples are less likely to prescribe drugs in accordance with clinical guidelines and are more likely to prescribe newer, more expensive drugs.<sup>10, 11</sup>

The direct provision of samples to physicians undermines evidence-based clinical practices. In order to protect the best interests of patients, AMCs must impose limits on the use of samples.

### Best Policy Practices:

#### Model Policy

Baylor University:

The policy prohibits covered individuals from accepting drug samples. Clinical sites that accept samples “must set up a central repository to distribute the drug samples and to facilitate timely patient access to optimal therapeutics”. These restrictions minimize the risk to patients, while still preserving the availability of samples.

<http://www.bcm.edu/pdf/coipolicy.pdf>

\*These recommendations come out of an ongoing study by Columbia University's Center on Medicine as a Profession. The researchers will update their recommendations regularly to incorporate new policies and findings. These materials were made possible by a grant from the state Attorney General Consumer and Prescriber Education Grant Program, which is funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.

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## **Samples must only be accepted and managed by a pharmacy or other central repository.**

Individuals, departments, and divisions must not be permitted to accept samples directly. All samples should be managed by a central repository such as a pharmacy, where they can be inventoried and distributed properly. This policy limits contact between physicians and vendors, eliminates the safety concerns regarding sample distribution, and mitigates biased prescribing while also ensuring that samples will remain available to patients who need them.

## Implementation:

In recent years, numerous clinics, health systems and medical schools have chosen to prohibit samples entirely in order to avoid the challenges associated with proper sample management.<sup>12, 13</sup> In these instances, some institutions have adopted alternate methods of expanding access to medication. Strategies include: accessing state and institutional assistance programs, taking advantage of favorable pricing available through federal 340B programs (primarily in public hospitals and clinics), and employing pharmaceutical industry prescription assistance programs (PAPs) or voucher systems that subsidize drugs for low-income patients.<sup>14</sup> ■

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**Figure I.**

