

Rx for mitigating risk



Using a starter free drug program through a non-commercial pharmacy can serve patients and mitigate regulatory risk for manufacturers at the same time

Cardinal Health Specialty Solutions



The OIG confirms

that using a *non-commercial* specialty pharmacy as part of a free drug program adds a deeper layer of protection against inducement to mitigate the risk of fines and penalties.

No one wants to hear the news: a new and horrific diagnosis that threatens not only a patient's life, but also the financial security of the patient's family. The drug therapy will cost nearly \$20,000 a month and there could be a delay in treatment for insurance authorization of up to 30 days—or more. For the best efficacy, the patient needs to start the drug now. The doctor, patient and drug manufacturer need to turn somewhere for help, but where without breaking the bank or incurring hefty penalties?

A Risk-Laden Approach

To prevent gaps in care, providers and drug manufacturers have been working together for the good of the patient. At the same time, they need to consider—and meet—stringent regulatory requirements. Often, in situations where a patient is in need of life-saving therapies, drug manufacturers have quietly stepped in, working in the background with a commercial specialty pharmacy to provide free drugs until a patient's coverage is verified or other funding is acquired.

But here's the problem: while manufacturers clearly have their hearts in the right place by putting the needs of the patient first, the regulatory risk of this approach can substantially outweigh their goodwill. These risks can impact the manufacturer's financial health considerably by exposing them to the perils of incurring fines, sanctions and other penalties for anti-kickback and inducement violations.

How can manufacturers confidently do the right thing— help patients in need while mitigating regulatory risk at the same time? Today, a more effective and compliant solution is the unique Sonexus™ Access & Patient Support Free Drug program from Cardinal Health Specialty Solutions. This program addresses the key elements of traditional programs with the added benefits of distribution through a non-commercial pharmacy.

The Prescription for a Better Way to Mitigate Risk

Sonexus™ Access & Patient Support services from Cardinal Health was the first to offer a free drug program through a *non-commercial* pharmacy. This regulatory advantage, combined with unprecedented patient access and support, meets the needs of both manufacturers and patients and continues to blaze the trail for innovative and compliant free drug programs. The degree of separation from a commercial environment adds another level of security to clear the regulatory hurdles of kickback and inducement concerns for free drug distribution.

In fact, the Sonexus™ Free Drug model has been publicly supported by the regulatory authorities themselves. In 2015, an advisory opinion issued by the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) affirmed that free drug programs that combined time limits and billing controls effectively addressed the perception of inducement. Additionally, they noted that the use of a non-commercial pharmacy further reduces even the inference of inducement: the free drug would not be used to influence future purchase of that or any other drug as no commercial transactions will take place beyond participation in the free drug program.

In effect, a free drug program supported by a non-commercial specialty pharmacy is a more effective, risk mitigating approach to structuring and distributing a free drug patient assistance program to those in need than a traditional free drug program offered through a commercial pharmacy.

To understand the criticality of the design of a compliant free drug program, we need to take a closer look at the purpose of the program itself, its inherent risks and why including a non-commercial pharmacy builds another level of compliance into the program design.

What are Free Drug Programs?

Free drug programs were created by drug manufacturers to fill the gap created by delays during the insurance authorization process, as well as to serve those who are uninsured or underinsured. Through these programs, the manufacturer provides free drugs to patients meeting certain criteria while coverage issues are resolved.

Understanding the Inherent Risks

Understanding inducement, real or perceived, is the key to understanding regulatory compliance surrounding free drug programs. Can the free drug program “induce” or encourage a patient or provider to use the dispensing pharmacy to purchase the same or other drugs or products in the future? Specifically, the regulations guarding against inducement are:

- 1 Anti-Kickback Statute:** Prohibits compensation to **induce** or reward referrals of items or services that are reimbursable by a federal or state healthcare program. This includes the transfer of anything of value—indirectly or directly, overtly or covertly, in cash or in kind.
- 2 Beneficiary Inducement Civil Monetary Penalty (CMP):** Prohibits compensation likely to **induce** or influence a patient’s selection of a particular provider, practitioner or supplier of any item payable by a federal or state healthcare program. This includes the transfer of items or services “for free” or for other than fair market value.

For manufacturers, to simply avoid offering free drug programs altogether is not the right thing to do. Neither is the other pathway manufacturers’ often take—providing free samples directly to physicians. Not only does a free sample program not relieve the risk of inducement, it can open the door to other risks.

A manufacturer must implement the sample program without bias to doctors or specialists, as appropriate, without regard to how much of their product the physician actually prescribes. If any preferential treatment is shown to a doctor that prescribes more of the manufacturer’s product, the manufacturer would be at risk for violating the Anti-Kickback statutes and subject to fines and penalties.

Tracking drug samples in the channel can be a particular challenge. Even with the best documentation in place, manufacturers may not be able to get a clear picture of which patients are receiving their drug: are the samples going to new patients only or to the same patients repeatedly?

Free samples can accidentally get mixed in with reimbursable inventory. Even with the tightest inventory control and reconciliation processes in place, manufacturers can’t be certain that an insurance claim may slip through and be submitted in error for the free drugs. If a claim is submitted, the manufacturer could be in direct conflict with the Beneficiary Inducement Civil Monetary Penalty requirement.

Free Drug Program eligibility requirements

- ❑ Drug prescribed by physician
- ❑ On-label indication
- ❑ Patient has commercial or government health insurance or may be under or uninsured
- ❑ For the insured, delay in insurance of at least five business days

Matters can get even worse with a free sampling program. Manufacturers must guard against the potential for misbranded, adulterated and expired drugs reaching patients, too. The Prescription Drug Marketing Act of 1987 addresses the dangers of counterfeit and adulterated drugs specifically. If adulterated drugs get into a free sampling program, the manufacturer can incur additional monetary and civil penalties on top of inducement consequences.

With so many exposures to consider, where can a manufacturer turn for help with a free drug program that offers a deeper level of compliance? Until recently, the only option was to use a commercial specialty pharmacy. By following specific guidelines these pharmacies meet compliance standards to mitigate the *actual risk* of inducement. However, by virtue of their retail design, the *perception* of inducement cannot be fully alleviated as the patient may very well purchase future prescriptions or other drug purchases from that very same commercial pharmacy.

A new and more secure option for a free drug program uses a non-commercial pharmacy to add a deeper layer of protection that guards against both *actual* and *perceived* inducement.

Free Drug Programs and Alleviating Inducement

To comply with the Anti-Kickback and Civil Monetary Penalty regulations, a well-designed free drug program from either a commercial or non-commercial pharmacy must:

- **Limit the amount of time on the program to prevent overutilization.** Providing the free drug on a limited time basis ensures appropriate utilization because patient progress on the drug is monitored closely.

Free Drug Programs and Alleviating Inducement *continued*

- **Ensure that no government or commercial healthcare programs are ever billed for the drugs.** “Free” means free: no federal government or other payers, patients or any other third party should ever be billed for the free drugs.
- **Provide no financial incentive to the prescriber** to use the specific pharmacy for this or other drugs or products in the future.

What’s more, using the Sonexus™ Free Drug program and its non-commercial pharmacy brings additional benefits that further reduce the opportunity for actual or perceived inducement for the insured and the uninsured.

- **Not a seeding program:** Eliminating or reducing the cost for initial drug supplies through a traditional free drug program administered by a commercial pharmacy puts a manufacturer at direct risk for sanctions. The patient arrangement in this scenario can be perceived as a way to *induce* a patient to get *ongoing* supplies from that same commercial pharmacy. Using a non-commercial pharmacy to administer a free drug program eliminates this risk because the patient arrangement is limited to the period of the free drug program and only to the specific drug being provided, so no inducement is possible.
- **Unlikely to induce patients to obtain federally reimbursable prescriptions from the non-commercial pharmacy:** A first fill, or starter free drug program for the commercially or government insured helps patients get their therapy without delay even while waiting for the insurance company to authorize treatment. Starter free drug programs are typically limited to 30-day supplies. After that, the patient may have the option to move into a Bridge program or patient assistance program, if they qualify. However, the patient cannot obtain refills from the non-commercial pharmacy for the free drug nor for any other commercially available prescription drugs for that matter. Once the free drug program is complete the pharmacy does not directly market or dispense to patients.

The OIG recognizes the benefits of a well-designed free drug program that includes a non-commercial pharmacy:

- Meets basic regulatory requirements
- Is not a seeding program
- Mitigates the risk of patients obtaining free drugs for federally reimbursable prescriptions
- Reduces the actual and perceived risks of inducement under the Anti-Kickback Statute and the Beneficiary Inducement Civil Monetary Penalty regulations

How Free Drug Programs Work

To understand the workings of a successful free drug program, we need to understand the financial needs of our patients in two scenarios: the commercially or government insured and the uninsured.

Commercially and Government Insured Patients

When a patient is diagnosed with a condition that requires a prescription for a specialty drug, typically, the practitioner will need to submit a prior authorization form to the patient’s payer. A prior authorization may be denied initially, triggering the need for an appeal. Depending on the payer, the authorization and appeal processes can take anywhere from a few days to several weeks. For patients in need of essential therapies, this gap in care can have a serious impact on outcomes.

If the patient doesn’t receive an insurance coverage determination within five business days of the drug being prescribed, the patient’s prescriber or pharmacy can contact the specialty pharmacy to potentially dispense the “first fill” of the drug free of charge until a determination is made. This “quick start” program closes a crucial care gap and gets patients on therapy faster.

After verifying coverage, patients will be assessed for their eligibility into copay and patient assistance programs to help support and/or fully cover the cost of the medications.

After verifying eligibility, the pharmacy will ask the prescriber for a new prescription exclusively for dispensing through the free drug program according to designated time limits. In the case of the non-commercial pharmacy, starter free drug supplies are limited to 30-day supplies. After that, all subsequent prescriptions may be filled by the patient’s commercial specialty pharmacy or the patient may qualify for other patient assistance programs.

During the free drug program, the pharmacy will instruct the patient not to seek reimbursement from an insurance provider. Additionally, for patients on government programs, the non-commercial pharmacy notifies the patient’s Medicare Part D Plan or State Plan that free drugs are being dispensed for which no reimbursement will be sought.

The Uninsured Patient

Uninsured patients are immediately assessed for their eligibility into copay and patient assistance programs, including foundation support, to help offset and/or fully cover the cost of the medications.

Once the source of financial support is determined, the pharmacy will ask the provider for a new prescription exclusively for dispensing through the free drug program.

An uninsured patient can be enrolled in a free drug program for the calendar year. Regular checks and balances are built into the course of the free drug program to reverify benefit eligibility and determine if a transition can be made to commercial insurance at any point.

The Sonexus™ Access & Patient Support Advantage

The Sonexus™ Free Drug program was the first free drug program to include a non-commercial pharmacy. It continues to be the industry-leader in free drug program design. As such, the Sonexus™ Free Drug program addresses the need for an alternative to commercially-dispensed free drug programs that deepens risk mitigation for manufacturers. For the uninsured, Sonexus™ Access & Patient Support connects patients to critical therapies which would otherwise be completely outside the realm of possibility given their current financial and insurance constraints.

The best practices of free drug programs are foundational to the Sonexus™ Free Drug program. Then, the Sonexus™ Free Drug program builds in separation from the commercial process which delivers better control of even the mere perception of inducement and improves speed-to-therapy while patients await insurance authorization.

The Sonexus™ Free Drug program protects every participant in the customer journey: manufacturers, providers, payers and above all, patients. White glove service and superior commitment to quality are included in every program. Patients get unprecedented care that helps *make healthier outcomes possible at a lower risk for the manufacturer.*

A Legacy of Serving Patients in Need

Too often manufacturers aren't recognized for the good they do in providing free drugs to eligible patients. As part of the Sonexus™ Free Drug program, each participating therapy is labeled as "free drug" by the manufacturer granting instant recognition for this invaluable service. At the same time, the Sonexus™ Free Drug program provides manufacturers with stronger guardrails that bring a deeper level of comfort with regulatory compliance.

It's the perfect prescription for mitigating manufacturers' risk.

Ready to lower your risk *while* providing free drugs to patients in need?

The OIG advisory opinion looks favorably on free drug programs dispensed through non-commercial pharmacies

Limits time on free drugs	Not contingent on future drug purchases	Instructs patients not to seek reimbursement	Notifies state and federal programs when applicable
Not advertised directly to consumers	Not a seeding program	Unlikely to induce patients to obtain federally reimbursable prescriptions from the non-commercial pharmacy	

To learn how we can help you

cardinalhealth.com/sonexus | 866.620.9709

About Cardinal Health Specialty Solutions

Cardinal Health Specialty Solutions partners with healthcare providers and pharmaceutical manufacturers to ensure patients have access to the therapies they need. From supporting manufacturers on the path to successful drug commercialization, to delivering the products providers need and the efficiencies they want, we use our expertise to improve specialty care.

Sonexus™ Access & Patient Support is an exclusive line of services that fully integrates direct drug distribution to site-of-care with non-commercial pharmacy services, patient access support and financial programs. Sonexus™ Access & Patient Support services help specialty pharmaceutical manufacturers have a greater connection to the customer experience and better control of product success. Personalized service and creative solutions, executed through a flexible technology platform, mean providers are more confident in prescribing drugs, patients can more quickly obtain and complete therapy, and manufacturers can directly access more actionable insight than ever before.

