TrackTrace RX
TRACEABILITY

Why **dealing with 340B** is important in a drug supply chain?

One of the main concerns that arise out of the implementation of the 340B drug program is the need to maintain a separate inventory to scrutinize the prescription drugs under 340B from among other drugs. An apprehension for supply chain stakeholders and healthcare entities functioning under this program alike, this issue can be eradicated with systematized management of the supply chain on a daily basis; This may include storage of GS1 data that can easily identify which drugs are circulated under the 340B program with a single scan.

The need for effective dealing with 340B drugs in the supply chain is further reinstated by the billing restrictions it has. The Federal Law prohibits using 340B for drugs that are dispensed to Medicaid free-for-service (FFS) patient and are subject to Medicaid rebates, unless the covered entity complies with certain requirements. This law is also known as the 'duplicate discount prohibition' because it intends to protect manufacturers from giving duplicate concession in the form of 340B discount and Medicaid FFS rebate.

How to deal with drugs under 340B?

Effective dealing of the consignments can avoid misplaced or mismatched inventories, apart from saving manufacturers hundreds of dollars that go in duplication of rebates.

AR-enabled multiscanning solutions used for tracking and tracing drugs using the RapidRX technology can be a sure-shot solution in inventory and data management, while making fast error-free sorting of data and consignments possible.

Imagine a way to see through the consignments without even having to open them individually and check with the help of a mobile-edge scanner whether or not it falls under the 340B program; Thus, saving millions that would have gone in manual tallying of the consignments with the EPCIS form.

The Traceability platform is the next big thing that can manage data about a 340B drug effectively, enabling manufacturers to keep a tab on their billing cycle and also ensure that the drugs that reach the end users are safe. Enhanced drug visibility also empowers contract pharmacies distributing 340B drugs to covered entities to ensure that these drugs are not mistakenly diverted to end users who are not covered under the program.

Cloud-base masterdatabase can be used optimally to maintain financial statements and invoices that contract pharmacies share with the covered entities at the end of the year. Some of the other things that can be seamlessly stored include a detailed status report of collections, and a summary of receiving and dispensing records that must be stored under applicable law. On the flip side, covered entities are also responsible for monitoring and ensuring contract pharmacy compliance with 340B programs such as patient definition and the duplicate discount prohibition. This also enables both covered entities and contract pharmacies to be audit-ready at any stage a compliance breach as per the 340B law is discovered.

Who benefits from the 340B program?

The 340 B program has been designed to benefit the manufacturers, the healthcare provider (hospitals and the healthcare providers for the vulnerable and the uninsured) and covered entities (the vulnerable and the needy).

Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Healthcare Act of 1992 requires pharmaceutical manufacturers to enter into an agreement called the pharmaceutical pricing agreement (PPA), with the Department of Health and Human Services (HHS) secretary in exchange for having all their FDA-approved drugs covered by Medicaid and Medicare Part B.

Gauging the benefits that manufacturers get from participating in the 340B program is multi-layered and indirect. Federal Law requires manufacturers who want their drugs covered in the Medicaid program to rebate a portion of drug payments to the government (which is the 340B program). Most of the manufacturers prefer to participate in the Medicaid program because it helps them in regulating the drug prices. How? Medicaid essentially maintains an open formulary in which states are required to provide nearly all prescribed drugs made by manufacturers.

Interestingly, these drugs form the list of outpatient prescription drugs that is being encouraged by the state to the providers to prescribe over other drugs. As per a study by DRUG CHANNELS, purchases by Covered Entities under the 340B program increased from $13.5 billion in 2014 to $61.0 billion in 2019. A consideration of the above-mentioned statistics will tell you the business benefits that manufacturers have inadvertently received from the 340B program.

Eligibility for 340B program

To be eligible under the 340B program, a manufacturer has to meet the following requirements:

- Sign a Pharmaceutical Pricing Agreement and Addendum. (340B Office of Pharmacy Affairs (OPAIS) Account Creation and Manufacturer PPA/PPA Addendum registration tutorial can be found on the 340B OPAIS page.)
- Register with 340B OPAIS and routinely verify that manufacturer information is accurate and up-to-date.
- Submit quarterly pricing data through the pricing component of the 340B OPAIS.
- Comply with all 340B Program requirements.

Some interesting facts:

80% of 340B volume goes through DSH hospitals, even though they make up to 9% of 340B entities.

45% of all medicare acute care hospitals participate in 340 B

64% of hospitals have charity care rates below 2.2% of the national average of hospitals

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