

Parsing the Drug Supply Chain Security Act Bar Code

Pharmacists play a crucial role in the healthcare industry, ensuring that patients receive safe and effective medications. However, the drug supply chain is complex and poses many challenges for pharmacists, including the risk of counterfeit drugs and the need for accurate tracking and tracing of medications. To address these challenges, the Drug Supply Chain Security Act (DSCSA) was enacted in 2013.

What is the Drug Supply Chain Security Act (DSCSA)?


The DSCSA is a federal law that was enacted in 2013 with the aim of improving the security of the drug supply chain. The law requires pharmaceutical companies, wholesale distributors, dispensers, and repackagers to implement new measures to ensure the safety and efficacy of medications. <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies>

One of the key requirements of the DSCSA is the use of a 2-D bar code on all packaging that contains specific drug information data in a specific standardized format as specified in the DSCSA law. The DSCSA law requires that each package of medication be labeled with a unique identifier (UI), which can be used to track and trace the product throughout the supply chain. The UI must be in both human-readable and machine-readable format, which is typically in the form of a 2D data matrix bar code. The UI contains the following information about that particular drug package, such as a bottle of pills:

- 1) Global Trade Identification Number (GTIN), which in turn, also usually also contains that drug's 10-Digit NDC Number and the UPC code of that drug package. The GTIN is an international product identification number promulgated by GS1 and used around the world. The GTIN for most US drugs start with the numbers "003" .
- 2) A unique Serial Number assigned by the drug manufacturer specifically for that particular drug bottle or other package – a bottle serial number for a particular bottle of pills, for example (bottle serial number). No two bottles of medication from a particular manufacturer for a particular drug lot have the same serial number. Note that the serial number can be up to 20 alphanumeric characters (which can be problematic for some bar code scanning systems).
- 3) Manufacturer's expiration date for that particular drug bottle or other package;
- 4) Manufacturer's lot number for that particular drug bottle or other package;
- 5) A total of 4 specific 2-digit GS1 Code Application Identifiers (AI) that appear before each of the above data elements contained in the UI. These AI numbers serve as data separators that identify the type of data element following each AI.
 - a) "01" is the AI that appears immediately before the GTIN;
 - b) "21" is the AI that appears immediately before the Serial Number for that package;
 - c) "17" is the AI that appears immediately before the Manufacturer Expiration Date; and
 - d) "10" is the AI that appears immediately before the Manufacturer's Lot Number.

Putting this all together, below is an example of the DSCSA structure (*Parentheses, bolding, and enlarged font are added for emphasis.*):

DSCSA bar code



This is what appears when the **DSCSA bar code** is scanned to Note Pad for risperiDONE 1mg:

0100327241001505213019755265341726053110DJ11102

Below is the breakout of the information:

GTIN Number	Serial Number	Expiration Date	Batch/Lot Number
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(01) 00327241001505 (21) 301975526534 (17) 260531 (10) DJ11102

***Note:** There is *no* officially adopted standard for the order in which the information contained in the DSCSA bar code is displayed when scanned. Most drug manufacturers input the information as GTIN + Serial Number + Expiration Date + Batch/Lot Number. All manufacturers lead with GTIN, in some instances, the other information is in a different order.

<u>Application Identifiers:</u>	<u>Sample Drug Info:</u>
AI for GTIN Number:	(01) 00327241001505 (14 numeric characters)
AI for Serial Number	(21) 301975526534 (up to 20 alphanumeric characters)
AI for Mfg Expiration Date	(17) 05/31/2026 (<i>format is YYMMDD</i>)
AI for Mfg Batch/Lot Number	(10) DJ11102 (up to 20 alphanumeric characters)

Advantages for Pharmacists of Bar Code Labeling Software that utilizes the DSCSA Bar Code

Bar code labeling software that utilizes the data contained in the DSCSA bar code can provide many advantages for pharmacists, including:

1. Improved Patient Safety

The DSCSA was enacted to improve the safety and efficacy of medications, and using software that can parse out the information contained in the DSCSA bar code is a crucial component of this effort. By ensuring that each package of medication has a unique identifier that can be easily tracked and traced throughout the supply chain, pharmacists can have greater confidence that the medications they are dispensing are safe and effective.

2. Increased Efficiency

Bar code labeling software that can read and understand the data in the DSCSA bar code can also improve the efficiency of pharmacy operations. By automating the process of creating and printing labels, pharmacists can save time and reduce the risk of errors. This can be especially beneficial for pharmacies that have a high volume of prescriptions to fill.

3. Enhanced Inventory Management

Software that utilizes the DSCSA bar code can also provide pharmacists with better visibility into their inventory. By tracking each package of medication with a unique identifier, pharmacists can easily identify which products are in stock, when they were received, and when they expire. This can help prevent expired medications from being dispensed and ensure that inventory levels are optimal.

4. Compliance with the Law

Perhaps the most significant advantage of compliant bar code labeling software for pharmacists is that it ensures compliance with the DSCSA. Failing to comply with the law can result in significant penalties, including fines and the revocation of licenses. By using compliant software, pharmacists can rest assured that they are meeting the law's requirements and avoid the risk of noncompliance.

How to Choose Compliant Bar Code Labeling Software

When choosing bar code labeling software that can read and utilize the DSCSA bar code, there are several factors that pharmacists should consider. These include:

1. Ease of Use

Pharmacists should look for software that is easy to use and integrates well with their existing systems. The software should be user-friendly and require minimal training to use.

2. Compliance with the DSCSA

Pharmacists should ensure that the software is compliant with the DSCSA's standards for bar code labeling. This includes ensuring that the software can create and print labels that include a unique identifier in both human-readable and machine-readable format that meets the requirements of the DSCSA, including the ability to create a unique serial number for each label being printed as required by the DSCSA.

3. Integration with Inventory Management Systems

Pharmacists should also look for software that integrates with their existing inventory management systems. This can help streamline operations and provide better visibility into inventory levels.

4. Customer Support

Finally, pharmacists should look for software that offers strong customer support. This can be especially important in the event of technical issues or other problems. The software provider should offer timely and effective support to ensure that any issues can be resolved quickly and efficiently.

The Drug Supply Chain Security Act (DSCSA) has brought significant changes to the pharmaceutical industry, including the requirement for bar code labeling software that can read and utilize the data contained in the DSCSA bar code and also print DSCSA compliant labels. For pharmacists, using compliant software can provide many advantages, including improved patient safety, increased efficiency, enhanced inventory management, and compliance with the law. When choosing bar code labeling software, pharmacists should look for software that is easy to use, complies with the DSCSA's standards, integrates with inventory management systems, and offers strong customer support. By using software that fully utilizes the DSCSA bar code and the data contained in it and that complies with the requirements of the DSCSA, pharmacists can help ensure the safety and efficacy of the medications they dispense and avoid the risk of noncompliance with the law.