

Medical **Purchasing** Solutions 

Helping Implement Your Repackaged Serialization Services



Table of Contents

The Smart Choice: Outsourcing
Your Repackaged Rx Fulfillment to Medical Purchasing Solutions..... 3

Navigating DSCSA Requirements for Prescription Drug Transactions 4

Repackaged serialized distribution solutions with
Medical Purchasing Solutions..... 5

How it works 6

Additional Benefits of Partnering With Medical Purchasing Solutions..... 7

Quick start guide 8

Partner Services..... 9

Appendix 10

 Appendix A 11

 Appendix B 12

 Appendix C 13

 Appendix D 14

 Appendix E..... 15

DISCLAIMER: The content in this report is intended solely for informational purposes and should not be considered legal advice. We advise consulting your own legal or regulatory counsel for guidance before making any decisions or interpretations regarding the FDA Drug Supply Chain Security Act (DSCSA).

The Smart Choice: Outsourcing Your Repackaged Rx Fulfillment to Medical Purchasing Solutions

Medical Purchasing Solutions is here to help you navigate the challenges and considerations involved in implementing repackaged serialization services. Outsourcing your repackaged Rx fulfillment can streamline your operations, eliminating the complexities of licensing requirements, and technological and process changes and reducing your time to market.

Medical Purchasing Solutions is FDA-registered and holds Verified-Accredited Wholesale Distribution accreditation from the National Boards of Pharmacy. We are a licensed pharmaceutical repackager and wholesaler with expertise in repackaged medications. We adhere to all labeling, tracking and tracing requirements for serialization and distribution of repackaged and Low Unit of Measure (LUM) medications, fully compliant with the Drug Supply Chain Security Act (DSCSA).

Medical Purchasing Solutions offers expert guidance in DSCSA compliance and comprehensive support for your repackaged distribution needs. As our partner, you'll gain full access to our extensive inventory of Rx medications. Additionally, you can choose to have products drop-shipped directly to your customers with proper tracking and tracing, or shipped to your warehouse—whichever best suits your needs.



Compliance Made Simple: Navigating DSCSA Requirements for Prescription Drug Transactions

Traceability at the Unit Level

Under section 505D of the FD&C Act, trading partners are mandated to exchange product tracing information when handling specific prescription drugs. All partners must establish an interoperable, electronic system to capture and retain the necessary tracing information for a minimum of 6 years following the transaction date. This information must be readily accessible to the FDA or other Federal or State officials, particularly in the event of a recall or when investigating a suspect or illegitimate product.

The product tracing standards require unit-level traceability, incorporating aggregation and inference. This means that each transaction must include detailed tracking and tracing at the sellable unit level. For instance, if the sellable unit is a single vial, that vial must be assigned a unique product identifier to ensure it can be accurately traced throughout the supply chain. These tracing requirements also encompass pedigree pass-through, ensuring the integrity of the product's journey from manufacturer to end-user.

Key Considerations

Serialization of single or Low Unit of Measure (LUM) items in accordance with the Drug Supply Chain Security Act (DSCSA) is a complex, costly and labor-intensive endeavor. Key factors to consider include navigating State and Federal licensing and regulatory requirements, registering new NDCs for each repackaging, making significant investments in production and process enhancements, designing compliant labels and packaging and managing inventory effectively.

By November 2023, manufacturers, repackagers, wholesale distributors, and dispensers must be equipped to exchange transaction information, including unique product identifiers and transaction statements, securely, electronically and through an interoperable system.

Repackaged serialized Distribution Solutions with Medical Purchasing Solutions

Warehouse

We're equipped to ship serialized products in bulk directly to your warehouse, making it easy for you to handle distribution on your end. Each unit is individually serialized and comes packaged with the necessary drug insert, so it's ready for you to send out to your customers without any extra steps.

Drop-Ship

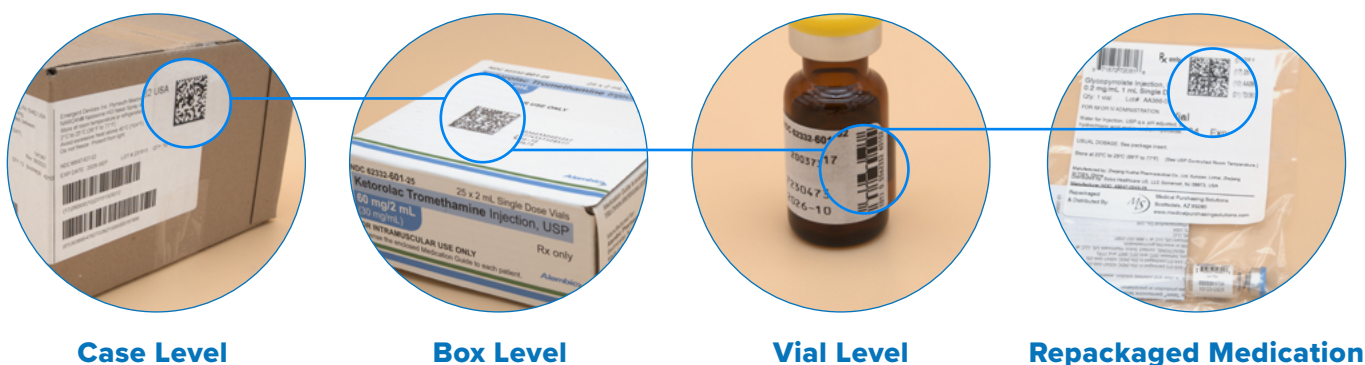
We take the hassle out of distribution by drop-shipping serialized medications directly, ensuring all necessary tracking, tracing and pedigree pass-through documentation is included. We are licensed to distribute products in all 50 states and U.S. territories, so we're here to help you expand your reach through our convenient drop ship program.



How it Works

From bulk shipment to individual units, Young Surgical repackages and relabels medications precisely to meet DSCSA-compliant labeling requirements

1. Case of serialized cartons is received
2. Within that case, the carton of serialized boxed vials is removed
3. From there, the box of 10 vials is separated from the carton
4. Each vial from the box is individually repackaged into an DSCSA compliant package, featuring:
 - a. QR Code
 - b. GTIN
 - c. NDC – Lot Number – Expiration



This single-vial package is now ready to ship to your customer, meeting all of the necessary requirements*, including the relevant drug inserts.

***Safety Data Sheets for all drugs can be found on our website, www.medicalpurchasingsolutions.com**

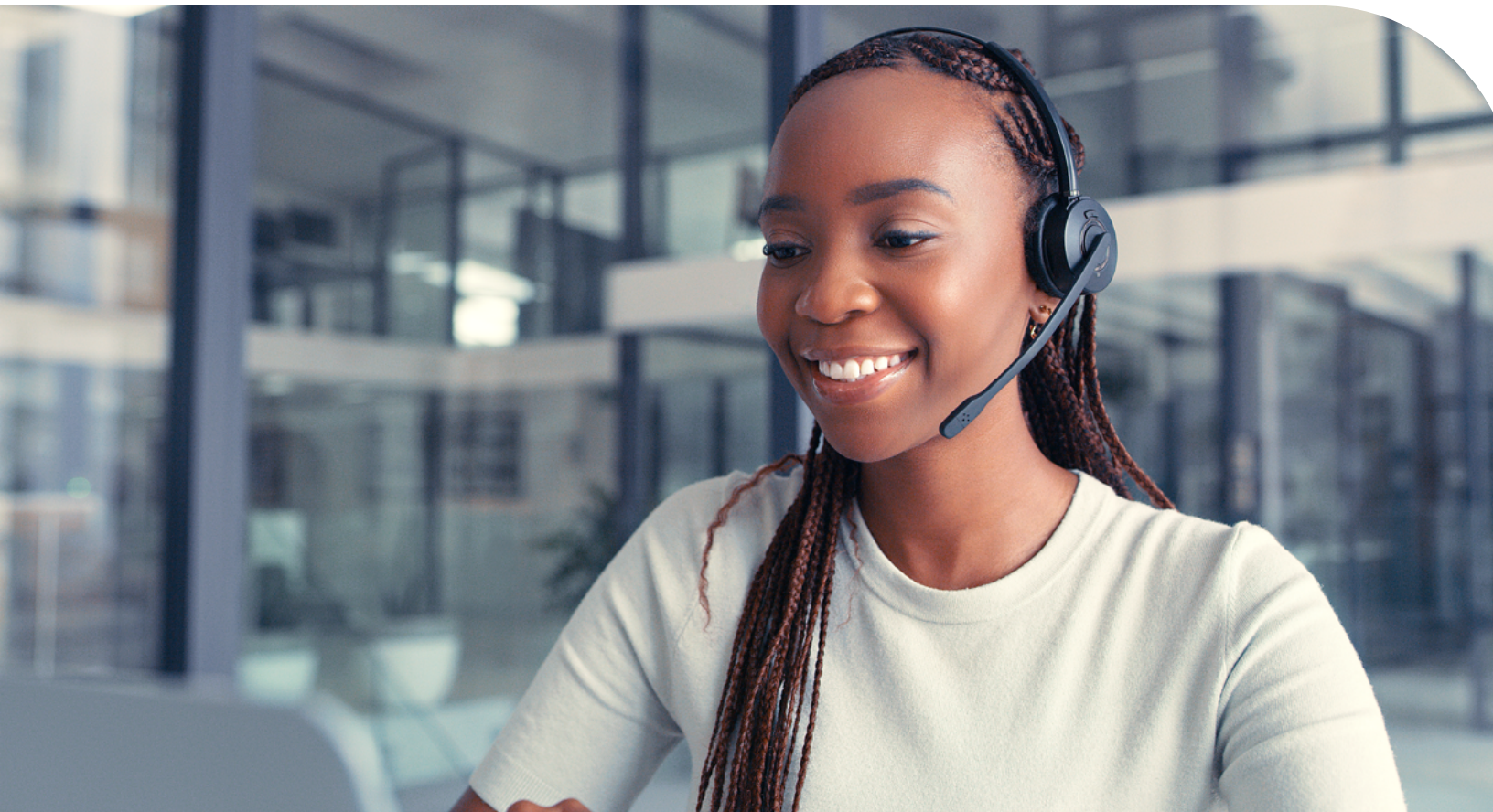
The screenshot displays a detailed Safety Data Sheet (SDS) for Klorolac Tromethamine Injection, USP. The document is organized into sections including: Identification, Hazard Identification, Composition/Information on Ingredients, First Aid Measures, Fire Fighting Measures, Accidental Release Measures, Exposure Controls/Personal Protection, Physical and Chemical Properties, Stability and Reactivity, Toxicological Information, Ecological Information, Disposal Considerations, Transport Information, Regulatory Information, and Other Information. The text is dense and includes various safety warnings, handling instructions, and regulatory references.

Benefits of Partnering with Medical Purchasing Solutions

We've simplified the process of launching a new program, allowing you to bring your product to market more quickly.

1. Personalized packing slips featuring your logo and key contact information for drop-shipped orders
2. Complete access to our service team, there to assist you and your customers with orders and inventory management
3. Pre-written program announcement content ready to share with your customers
4. Ready-to-use FAQs tailored for your customers
5. Pre-crafted content for your website or catalog
6. High-quality product images

For additional information about these services and more, please refer to the Appendix section of this eBook



5 Steps to Getting Started

Partnering with Medical Purchasing Solutions as Your Trusted Choice for Compliant Repackaged Medications Has Never Been Easier

1. Browse the list of Medical Purchasing Solutions's stocked medications and choose the items you'd like to offer. Then, submit your selected list to us.
2. Submit a list of NDCs along with a forecast for any medications that Medical Purchasing Solutions does not currently stock.
3. Choose your preferred shipping and fulfillment method: either drop-shipping directly to your end customer or shipping to your warehouse for distribution (ensuring the ability to pass pedigree and transaction history).
4. Medical Purchasing Solutions will supply you with a price list for both drop-shipped items and warehouse-delivered items.
5. After choosing to partner with Medical Purchasing Solutions, we'll walk you through the implementation process and equip you with all the tools needed for a successful launch.



Additional Partner Services

Medical Purchasing Solutions will lead you through every step of the implementation process, handle all regulatory compliance requirements, and offer dedicated support to both you and your customers.

Streamlining Implementation and Compliance with Medical Purchasing Solutions

Explore the Some of the Services We Offer Our Partners

1. Weekly report on orders and shipping
2. Comprehensive online inventory list with pricing, item numbers, and availability details
3. Tailored packing slips featuring your logo
4. A set of sample tools, including program announcements, FAQs, content, and images, to help you promote your repackaged offerings
5. Management of licensure across all 50 states and U.S. territories
6. Collaborate with your IT team to set up and test EPCIS data
7. License information transfer and validation process
8. Ongoing maintenance of required pedigree and transaction history records
9. Inventory management and sourcing of alternative manufacturers
10. Ensuring compliance with FDA quality and cGMP standards to meet DSCSA requirements

Appendix

Here are samples of the tools and content you'll receive once implementation begins. Feel free to use these resources on your website and in your marketing materials to launch your program and inform your customers.

A. Important DSCSA dates to educate your customers

B. Customer messaging example

C. Program announcement examples

D. Customized packing slip example

E. Customer FAQs



Appendix A

Important DSCSA dates to educate your customers

November 27, 2013

Congress passed the Drug Quality and Security Act (DQSA), which includes Title II, known as the Drug Supply Chain Security Act (DSCSA).

November 2014

The DSCSA requirements started phasing in, initiating a 10-year timeline aimed at transitioning the United States to a serialized traceability model for pharmaceutical drug products.

January 2015

All pharmaceutical suppliers must begin sending DSCSA transaction data, including transaction information, transaction statements, and transaction history for prescription drugs.

July 2015

Wholesale distributors are required to retain DSCSA transaction data for prescription drug purchases for six years from the invoice date.

November 2018

All manufacturers and repackagers must serialize prescription drug products by applying a product identifier (2D barcode) to each individual package and homogenous case.

November 2020

Dispensers are required to purchase and sell only prescription drug products that are encoded with a product identifier and are expected to verify the product identifier when investigating suspect prescription drug products. (However, on October 28, 2020, the FDA deferred this requirement through enforcement discretion until November 27, 2023. The salable verification requirement for the product identifier will not be enforced until November 2023).

November 2023

The FDA DSCSA will continue to phase in product tracing requirements, now including unit-level traceability with aggregation and interoperable electronic systems.

November 2024

The FDA enforcement extension for non-compliance ends on November 27, 2024.

Appendix B

Customer Messaging

The Drug Supply Chain Security Act establishes steps to create an electronic, interoperable system for identifying and tracing specific prescription drugs throughout their distribution in the United States.¹

Key Points to Know About the DSCSA Legislation

- The DSCSA was established to enhance the security of the pharmaceutical supply chain by minimizing the risk of counterfeit, stolen, contaminated, or otherwise dangerous drugs reaching patients and consumers.
- The Drug Supply Chain Security Act (DSCSA) requirements began impacting distributors in November 2019 and will be fully implemented by November 2024.
- As of November 2019, the DSCSA will impact how wholesalers distribute low units of measured prescription drugs and manage the return of prescription drugs.
- The DSCSA mandates the Food and Drug Administration (FDA) to create national licensure standards for wholesale providers and requires these providers to report their licensure to the FDA on an annual basis.

Under the DSCSA, a unique number must be assigned to every individual saleable unit of a prescription drug. However, many pharmaceutical manufacturers have chosen to serialize only at the case or carton level. Starting November 27, 2019, low unit-of-measure quantities, such as vials and individual doses, were no longer allowed for distribution unless they were serialized by the manufacturer.

Due to this change, [COMPANY NAME] can no longer break down larger pharmaceutical packages to sell individual units like vials, as these items do not include a serial number.

To continue providing you with individual prescription drugs, we have established a partnership with a repackager who can deliver the low unit-of-measure services you expect. Our repackaging partner fully complies with the DSCSA's requirements for packaging, tracking, and tracing these smaller quantities.

¹<https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

Appendix C

Program Announcement Example

Important Update on Pharmaceutical Serialization and Pricing

In compliance with the DSCSA, all pharmaceuticals sold must include a serial number. However, manufacturers have chosen not to serialize individual vials, instead opting to serialize only the boxes and cases in which the pharmaceuticals are packaged.

As of November 2019, [COMPANY NAME] can no longer break open pharmaceutical packages to sell individual vials or doses, as these smaller units do not carry the required serial number.

To ensure we continue to meet your needs, we have partnered with a repackager who will break down and serialize each vial or unit as required by the DSCSA.

How does this affect you?

Due to the additional costs associated with repackaging, relabeling, handling, and transportation, there may be an increase in the price of pharmaceuticals sold in individual vials or units.

How will you receive your order?

Low unit-of-measure pharmaceuticals can be stocked at your local distribution center or drop-shipped directly to you. Stocked items will ship at no additional cost, while drop-shipped items will incur a fee of [\$X] for non-refrigerated and [\$X] for refrigerated items.


If you have any questions, please reach out to your [COMPANY NAME] Account Manager.

Appendix D

Customized Packing Slip Example


Personalized packing slip, including your logo and tailored customer message, will be provided.

1234 N. Oak St. Suite 123
City, ST 12345
123-456-7890
800-123-4567
License# XXXXXX
DEA# XXXXXXXX



PACKING LIST
Page 1 of 2

Invoice Number
Invoice Date
Delivery Number









PO Number

Ship To: Customer ID:

GENERAL DENTISTRY
DR. JIM JONES, DDS
1234 N. ELM ST. STE. 123
CITY, ST 12345-1234
US

Quantities				Item ID/NDC	Item Description	UOM	Unit Size
Ordered	Shipped	Remaining	Disp.				
Delivery Instructions:							
Carrier: GROUND				Tracking #:			
7.00	7.00	0.00		PROM625-16L	PROMETHAZINE 6.25MG/5ML SYRUP 16OZ	BTTL	1.0
				BTL			

<p>Lot Number: </p> <p>BZB0007A</p>	<p>Qty: 3.00 BTTL</p>	<p>Expiration Date: </p> <p>04/30/25</p>
<p>Lot Number: </p> <p>BZB0008A</p>	<p>Qty: 3.00 BTTL</p>	<p>Expiration Date: </p> <p>04/30/25</p>
<p>Lot Number: </p> <p>BZB0020A</p>	<p>Qty: 1.00 BTTL</p>	<p>Expiration Date: </p> <p>04/30/25</p>




To access transaction history and serialization data, please go to the link below.




<https://Opus.tracelink.com>

If you do not have a Tracelink account, please Request access to access this portal.
Once an account is created, use the Delivery Number and the Access ID provided.

Delivery Number:

Access ID:

Appendix E

Customer FAQs

Q. What steps should I take to comply with the DSCSA if I am not a dispenser?

A. If you are solely administering prescription drug products and not dispensing them to patients, no additional action is required.

Q. Does the FDA Drug Supply Chain Security Act (DSCSA) cover over-the-counter (OTC) drugs?

A. No, the DSCSA only applies to prescription (Rx) drugs, not to OTC drugs.

Q. How does the DSCSA define a "dispenser"?

A. According to the DSCSA, a "dispenser" includes retail pharmacies, hospital pharmacies, and groups of chain pharmacies under common ownership and control that do not operate as wholesale distributors. It also covers any other individuals legally authorized to dispense or administer prescription drugs, as well as affiliated warehouses or distribution centers under common ownership that do not act as wholesale distributors. It does not include those who dispense products solely for use in animals as per section 512(a)(5).

Q. How can I find out if I qualify as a "dispenser" under the FDA Drug Supply Chain Security Act (DSCSA)?

A. If you're unsure whether you meet the definition of a "dispenser" under the DSCSA, it's best to consult with your regulatory team or legal counsel for clarification and guidance.

Q. Why is my product now being drop-shipped?

A. To meet serialization requirements efficiently, we've partnered with a DSCSA-compliant repackager, making drop-shipping the best option for fulfilling your order.

Q. What is causing the price increase for products sold individually?

A. The price increase is due to the added costs associated with repackaging, relabeling, handling, and transportation.

Q. Will the drop-shipped low unit of measure prescription drugs come with a separate invoice?

A. The end customer will receive a packing slip indicating the items purchased at \$0.00, while the invoice will be sent directly from [COMPANY NAME].

Q. What is the cost of drop-shipping?

A. Drop-ship fees differ depending on refrigeration. Non-refrigerated products carry a fee of [\$X], while refrigerated items have a fee of [\$X].

Q. How will these charges appear on my invoices?

A. Your statements or invoices will show the item price along with a separate line item for the drop-ship fee.

Q. Does the FDA Drug Supply Chain Security Act (DSCSA) cover over-the-counter (OTC) drugs?

A. No, the DSCSA only applies to prescription (Rx) drugs, not to OTC drugs.

Q. How does the DSCSA define a "dispenser"?

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Q. What is the expected delivery time for drop-ship orders?

A. Drop-shipped prescription drugs are sent via UPS ground, with delivery times varying by location but generally arriving within 7 days.

Q. Can repackaged items be returned?

A. Unfortunately, unit-dose prescription drugs are non-returnable.

[] represent information to denote organizational specific content.



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