Prescription Product Supplier Requirements

Health & Wellness Product Safety
October 2022

At Walmart we are committed to providing our patients with safe, high-quality, affordable medications and healthcare services. As the safety and security of the pharmaceutical supply chain is a shared responsibility, one way this is realized is through collaboration with our suppliers. This document outlines minimum expectations for prescription product suppliers as well as provides useful resources to assure regulatory compliance with applicable provisions of the Drug Supply Chain Security Act.

Prescription Product Suppliers:

Prescription product suppliers are those suppliers that manufacture, package, or distribute a prescription pharmaceutical, dietary supplement or other product that requires a legitimate medical prescription to be dispensed by a licensed healthcare professional.
These products are in contrast to over-the-counter products which can be obtained without a prescription. Such suppliers include, but are not limited to, direct-ship pharmaceutical or medical device manufacturers, bulk pharmaceutical manufacturers, brokers, wholesale pharmaceutical, dietary supplement or device distributors, pharmaceutical, dietary supplement & medical device manufacturers, labelers, repackagers, third-party logistic providers (3PL), or any entity arranging for the purchase of prescription products by Walmart Inc., Sam's Club West, Inc., Sam's Club East, Inc. Wal-Mart Puerto Rico, Inc., our bulk repackaging supplier Gensing King Fisher, and its subsidiaries (collectively referred to as Walmart).

Walmart Pharmacy Distribution Network

The Walmart Pharmacy distribution network includes a network of Walmart owned pharmacy distribution centers located across the U.S. Our distribution centers are VAWD accredited and licensed by applicable State Boards of Pharmacy for intra-company distribution.

Prescription Product Supplier On-boarding

Prescription product supplier on-boarding is required for all suppliers providing prescription pharmaceuticals, dietary supplements, or medical devices directly or indirectly to any of Walmart's Pharmacy Distribution Centers, Walmart Pharmacies, Central Fill Pharmacies, Specialty and Home Delivery Pharmacies, Walmart's bulk repackager, Legacy, or Sam's Club Pharmacies. This includes, but is not limited to, product that is purchased directly or indirectly from a manufacturer or from a third-party wholesale distributor. All information must be provided to Health & Wellness Product Safety for review and approval prior to placing any purchase orders and shipping product. Failure to comply with the following requirements may make your company ineligible to supply to Walmart. Please note, these supplier requirements are in addition to Supplier Requirements listed on corporate.walmart.com/supplier/requirements and **apply to all current and new suppliers.**

New Supplier On-boarding

In order to ship prescription products to Walmart, the supplier must meet or exceed all applicable Federal, State, and local laws and regulatory requirements as well as adhere to any additional requirements stated in the supplier agreement. New suppliers must provide requested information to Health & Wellness Product Safety regarding the manufacture and handling of prescription products. Suppliers may obtain a *Product Information Sheet* from Retail Link following the below path.

Retail Link > Docs > Supplier Replenishment Information > Standard Templates > Product Information Sheet

Information required shall include, but may not be limited to:

- **Facility Disclosure:** Facility disclosure is essential to achieving true supply chain transparency. Each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of the sourced product must comply with applicable U.S. FDA Good Manufacturing Practices and must be disclosed to Health & Wellness Product Safety. This includes all subcontracted facilities or any operations or facilities that are not owned by your company which provide manufacturing, packaging, labeling, storage, distribution, or logistical services.
- United States Food & Drug Administration **(FDA) Drug Establishment Registration or Medical Device Manufacturing Registration** for applicable facilities;
- Applicable **Drug Enforcement Agency (DEA) registration;**
- **Facility Ownership/Business Relationship:** Facility ownership/business entity relationship disclosure is essential for verification of required licenses/registrations;
- **State Board of Pharmacy Manufacturer/Wholesale Drug Distributor license/registration** information for the state in which the applicable facility(s) operates as well as for **AR, CA, GA, IN, and MD**;
- **Authorized Distributor of Record (ADR) or supplier information**
- **New Drug Application (NDA) or Abbreviated New Drug application (ANDA)** number or FDA approval notice;
- **National Drug Code (NDC)** registration information. NDC shall be disclosed in the same format that would be transmitted in the Advanced Shipping Notice (ASN);
- 24 month **recall history** for sourced product;
- Product should be identifiable via the DailyMed website;
- Facility regulatory enforcement/inspection history information for all applicable facilities;

- Third-party U.S. FDA GMP audit/certifications upon request;
- VAWD accreditation, if applicable.

The Product Information Sheet **must** be accurate and complete. Failure to provide complete and accurate information will result in delayed approval and purchase orders and potential denial of purchase orders. Health & Wellness Product Safety will review all supplier/product information and verify applicable licenses and registrations directly with the issuing State and/or Federal agencies. Once verified and approved, the supplier is responsible for disclosing new facility information prior to use of the new facility as well as maintaining accurate facility and registration information with Health & Wellness Product Safety. As always, it is the supplier's responsibility to renew and maintain all required licenses and registrations with the issuing agencies and provide renewal information to Health & Wellness Product Safety immediately upon renewal. Failure to maintain a required license or registration may make your company ineligible to supply to Walmart. & Wellness Product Safety immediately upon renewal. Failure to maintain a required license or registration may make your company ineligible to supplyto Walmart.

DSCSA ASN Data Exchange

Prescription pharmaceutical suppliers must confidentially provide transaction information, transaction history, and transaction statement (Transaction Data, or T3) electronically to Walmart's RXDSCSA Repository to comply with Drug Supply Chain Security Act (DSCSA) requirements for manufacturers, repackagers, wholesaler distributors, and dispensers. The T3 has been exchanged electronically by authorized trading partners using the Advanced Shipping Notice, ASN, since 2016. **Timing** and **accuracy** of the ASN is critical to the success of our pharmacy product flow. Thus we expect transaction data to be transmitted electronically by ASN prior to or upon shipping of product to our pharmacy network. Additionally, pharmaceutical suppliers must have systems and processes in place to monitor and resolve ASN failures to allow for the ASN to be retransmitted prior to freight arriving at our Pharmacy Distribution Centers. Freight received without a complete and accurate ASN cannot be received and will be placed into ***Quarantine*** and may be returned to the supplier.

To avoid prescription pharmaceutical flow disruption, suppliers are advised to adhere to the following expectations:

- **Transmit electronic ASN in advance of shipping freight** to allow for ASN failure resolution and retransmission before freight arrives at the receiving distribution center.

- ASN failures must be addressed timely and retransmitted within a 48 hour time frame. Failure to resolve within 48 hours may result in the product being returned as the supplier's expense.

- **The product information and physical quantity shipped must match the digital record of the T3 in the form of an ASN.** Overages will cause the freight to be placed in *Quarantine* until a corrected ASN is received. PO overages must be corrected within 24 hours to avoid product return. In the instance of an overage of product shipped vs product ordered, an ASN must be sent immediately to Walmart to account for the variance.

- Abide by consistent usage of the correct **receiver ID, 925485USRX,** in the ASN envelope for all **DSCSA ASNs.**

- Suppliers **must pro-actively monitor for any 824 error messages** and react accordingly.

- Suppliers may receive additional technical assistance by contacting **Walmart EDI Support Help-desk at 479-273-8888 or via email at edi@walmart.com.**

Additional technical information may be found by referencing the *DSCSA ASN Guide* published on Retail Link.

Retail Link > Apps > EDI-B2B > Guides > RX DSCSA ASN

DSCSA EPCIS Exchange

On November 27, 2023, trading partners are required to utilize an interoperable electronic approach in (1) exchanging transaction information at the package level, (2) verifying those products at a package level, (3) promptly responding with transaction information and statement in the event of a recall or investigation, (4) facilitating transaction information going back to the manufacturer in the event of a recall or investigation, and (5) accepting saleable returns.

Electronic Product Code Information Services (EPCIS) is a recommended approach by the U.S. Food and Drug Administration (FDA) to all trading partners for the purpose of capturing and exchanging information about products as they are transacted with throughout the supply chain. EPCIS is a globally recognized standard recognized by industry stakeholders as suitable to adopt for DSCSA requirements.

Starting November 2022, Walmart will begin on-boarding current suppliers to EPCIS as a business requirement to supply prescription pharmaceuticals to Walmart. Continuation of current business and all potential new business will be contingent upon the supplier's ability to send accurate and complete EPCIS messaging. Once on-boarded, freight received without complete and accurate EPCIS messaging will not be received, placed into Quarantine, and may be returned at the supplier's expense. For questions regarding EPCIS messaging and on-boarding, email DSCSA101@walmart.com.

Pharmaceutical Packaging and Labeling

Packaging and labeling are details that can be leveraged to reduce costs, improve accuracy and optimize supply chain flow. Thus Walmart has established a standardized approach to packaging and labeling standards that focus on proactive methodologies to drive quality inbound loads into our Pharmacy Distribution Network. You may reference the complete ***DSCSA Labeling Guide*** published on Retail Link.

Retail Link > Academy > Ordering and Replenishment > Shipping, Routing, Packaging, Labeling Guide > Packaging > Secondary Packaging.

Individual Products
Key Focus Points:

- Individual products must meet all U.S. regulatory requirements for prescription products including but not limited to CPSC Child Resistant Packaging requirements, FDA labeling requirements, Tamper Evident Packaging requirements, and U.S. Customs Country of Origin Labeling requirements.

- All prescription pharmaceutical products must meet Drug Supply Chain Security Act Product Identifier and Serialization requirements unless the product is otherwise exempt or grandfathered.

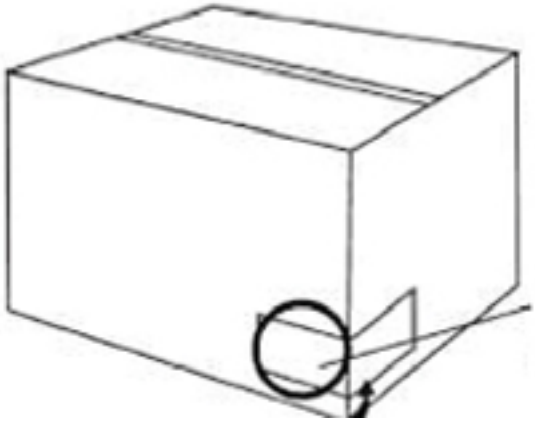
- Products recieved with missing product identifers in both human and machine readable form are subject to Quarantine and return to the supplier at supplier's expense.

Homogeneous Carton. Case, and Pallet Labels
Key Focus Points:

- A combination of both GS1-128 and GS1 Data Matrix should be the symbologies used at the homogeneous shipping case level.

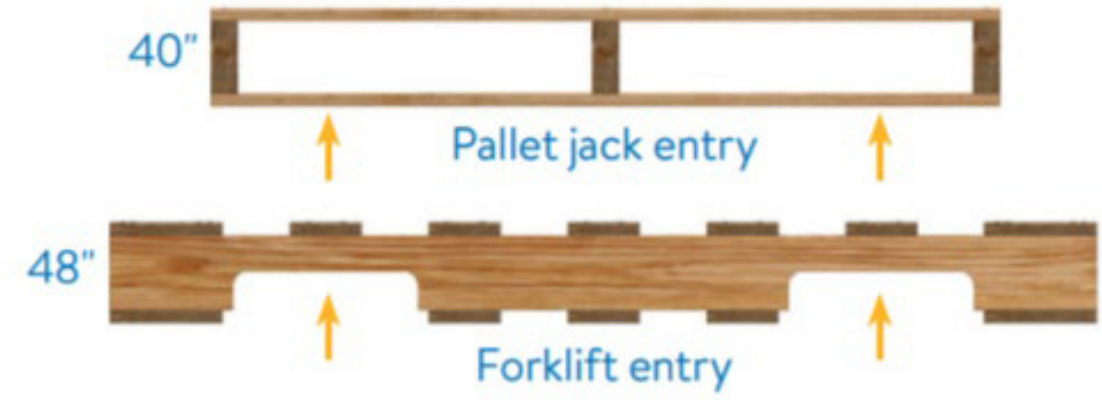
- Product identification labels are required on a minimum of two adjacent sides on each case. A wrap label is acceptable.

- A Serialized Shipping Container Code (SSCC) label must be affixed to each individual shipped case, mixed case, or pallet.



Pallet Requirements
Key Focus Points

- The expected method of shipping into a Walmart Pharmacy Distribution facility is on a 48 X 40 grade A pallet.
- Pallets should be designed to accommodate a standard pallet jack and/or power fork-lift with adequate top board spacing so forklift blades will not affect the freight being shipped.
- Pallets must support the weight of the product being shipped.
- Pallets with broken, split wood and/or exposed nails are not allowed.



Full pallet (48" x 40")

New Prescription Product Approval

Before a current supplier can ship a newly sourced prescription product into Walmart's Pharmacy Distribution Network, the supplier must provide the following information to Health & Wellness Product Safety for verification and approval by completing a Product Information Sheet. Suppliers may obtain a Product Information Sheet from Retail Link following the below path.

Retail Link > Docs > Supplier Replenishment Information > Standard Templates > Product Information Sheet

Information required for the new item shall include, but may not be limited to:

- **Facility Disclosure:** Each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of the sourced product must be disclosed to Health & Wellness Product Safety. This includes all subcontracted facilities or any operations or facilities that are not owned by your company which provide manufacturing, packaging, labeling, storage, distribution, or logistical services.

- United States Food & Drug Administration **(FDA) Drug Establishment Registration or Medical Device Manufacturing Registration** for applicable facilities;

- Applicable **Drug Enforcement Agency (DEA) registration;**

- **Facility Ownership/Business Relationship**: Facility ownership/business entity relationship disclosure is essential for verification of required licenses/registrations;

- **State Board of Pharmacy Manufacturer/Wholesale Drug Distributor license/registration** information for the state in which the applicable facility(s) operates as well as for **AR, CA, GA, IN,** format that would be transmitted in the Advanced Shipping Notice (ASN);

- Authorized Distributor of Record (ADR) status information if applicable;

- **New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)** number or approval information;

- **National Drug Code (NDC)** registration information. NDC shall be disclosed in the same format that would be transmitted in the Advanced Shipping Notice (ASN);

- 24 month **recall history** for sourced product;

- Product should be identifiable via the DailyMed website;

- Facility **regulatory enforcement/inspection history** information;

- Third-party U.S. FDA GMP audit/certifications upon request;

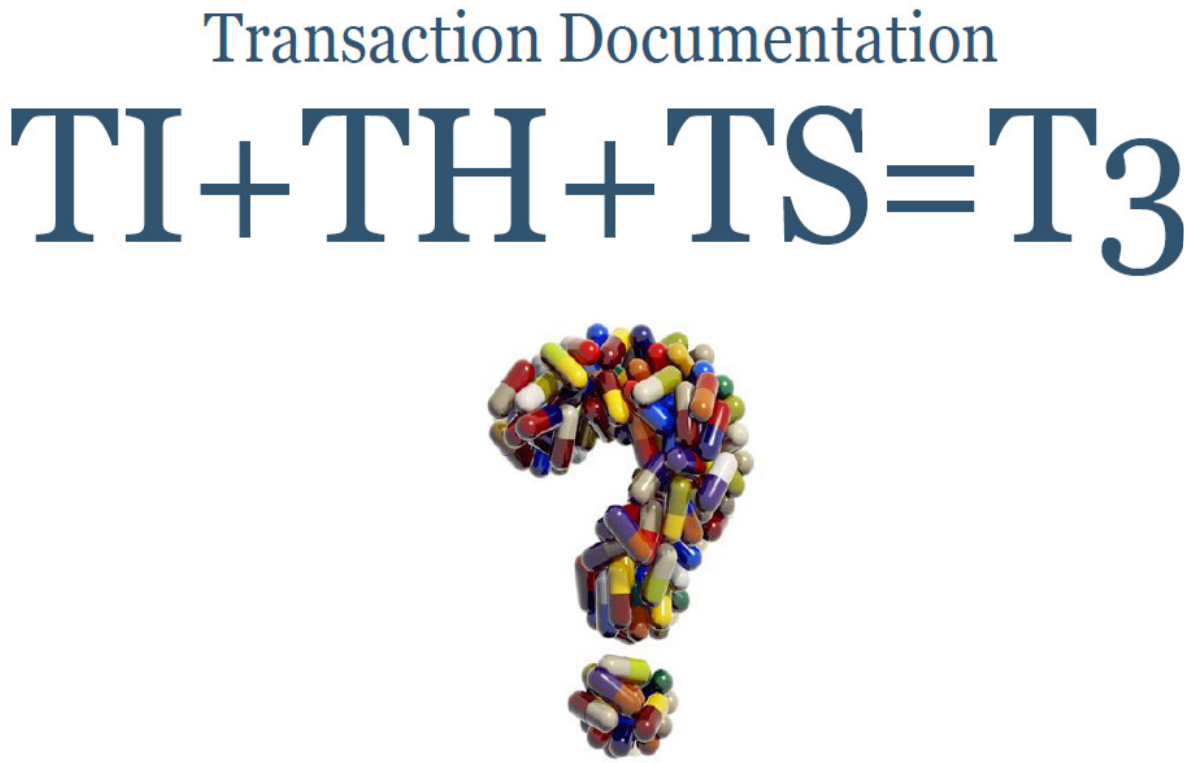
- DEA schedule classification applicable to controlled substances;

The Product Information Sheet must be accurate with all sections completed. Failure to provide complete and accurate information will result in delayed approval and purchase orders. Health & Wellness Product Safety will review all facility/product information and verify applicable licenses and registrations directly with the issuing State and/or Federal agencies. Once verified and approved, the supplier is responsible for disclosing new facility information prior to use of any new facility as well as maintaining accurate facility and registration information with Health & Wellness Product Safety.

As always, it is the supplier's responsibility to renew and maintain all required licenses and registrations with the issuing agencies and provide renewal information to Health & Wellness Product Safety immediately upon renewal. Failure to maintain a required license or registration may make your company ineligible to supply to Walmart.

DSCSA ASN Data Exchange

Prescription pharmaceutical suppliers must confidentially provide transaction information, transaction history, and transaction statement (Transaction Data, or T3) electronically to Walmart's RXDSCSA Repository to comply with Drug Supply Chain Security Act requirements for manufacturers, repackagers, wholesaler distributors, and dispensers. The T3 has been exchanged electronically by authorized trading partners using the Advanced Shipping Notice, ASN, since 2016.



Timing and **accuracy** of the ASN is critical to the success of our pharmacy product flow. Thus we expect transaction data to be transmitted electronically by ASN prior to or upon shipping product to our pharmacy network, Additionally, pharmaceutical suppliers must have systems and processes in place to monitor and resolve ASN failures to allow for the ASN to be retransmitted prior to freight arriving at our Pharmacy Distribution Centers. Freight received without a complete and accurate ASN cannot be received and will be placed into ***Quarantine.***

To avoid prescription pharmaceutical flow disruption, suppliers are advised to adhere to the following expectations:

- **Transmit electronic ASN in advance of shipping freight** to allow for ASN failure resolution and retransmission before freight arrives at the receiving distribution center.

- ASN failures must be addressed timely and retransmitted within a 48 time frame.

- **The product information and physical quantity shipped must match the digital record of the T3 in the form of an ASN.** Overages will cause the freight to be placed in *Quarantine* until a corrected ASN is received. PO overages must be corrected within 24 hours and no more than 48 hours to avoid product return. In the instance of an overage of product shipped vs product ordered, an ASN must be sent immediately to Walmart to account for the variance.

- Confirm consistent usage of the **correct receiver ID, 925485USRX,** in the ASN envelope for all DSCSA ASNs.

- Suppliers must **pro-actively monitor for any 824 error messages and react** accordingly.

- Suppliers may receive additional technical assistance by contacting **Walmart EDI Support Help-desk at 479-273-8888 or via email at edi@walmart.com**.

Additional technical information may be found by referencing the *DSCSA ASN Guide* published in Retail Link.

Retail Link > Apps > EDI-B2B > Guides > RX DSCSA ASN

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DSCSA EPCIS Exchange

On November 27, 2023, trading partners are required to utilize an interoperable electronic approach in (1) exchanging transaction information at the package level, (2) verifying those products at a package level, (3) promptly responding with transaction information and statement in the event of a recall or investigation, (4) facilitating transaction information going back to the manufacturer in the event of a recall or investigation, and (5) accepting saleable returns.

Electronic Product Code Information Services (EPCIS) is a recommended approach by the U.S. Food and Drug Administration (FDA) to all trading partners for the purpose of capturing and exchanging information about products as they are transacted with throughout the supply chain. EPCIS is a globally recognized standard recognized by industry stakeholders as suitable to adopt for DSCSA requirements.

Starting November 2022, Walmart will begin on-boarding current suppliers to EPCIS as a business requirement to supply prescription pharmaceuticals to Walmart. Continuation of current business and all potential new business will be contingent upon the supplier's ability to send accurate and complete EPCIS messaging. Once on-boarded, freight received without complete and accurate EPCIS messaging will not be received, placed into Quarantine, and may be returned at the supplier's expense. For questions regarding EPCIS messaging and on-boarding, email DSCSA101@walmart.com.

Pharmaceutical Packaging and Labeling

Packaging and labeling are details that can be leveraged to reduce costs, improve accuracy and optimize supply chain flow. Thus Walmart has established a standardized approach to packaging and labeling standards that focus on proactive methodologies to drive quality inbound loads into our Pharmacy Distribution Network. You may reference the complete DSCSA Labeling Guide published on Retail Link.

Retail Link > Academy > Ordering and Replenishment > Shipping, Routing, Packaging, Labeling Guide > Packaging > Secondary Packaging.

Individual Products
Key Focus Points:

- Individual products must meet all U.S. regulatory requirements for prescription products including but not limited to CPSC Child Resistant Packaging requirements, FDA labeling requirements, Tamper Evident Packaging requirements, and U.S. Customs Country of Origin Labeling requirements.

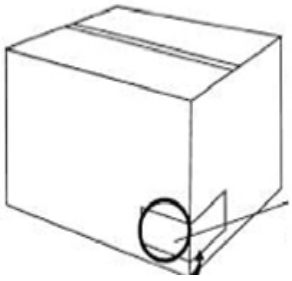
- Additionally, all prescription pharmaceutical products must meet Drug Supply Chain Security Act Product Identifier and Serialization requirements unless the product is otherwise exempt or grandfathered.

- Prescription Pharmaceuticals must contain serialized information on each individual bottle in both human and machine readable format following GS1 industry standards.

Homogeneous Carton Label
Key Focus Points

- A combination of both GS1-128 and GS1 Data Matrix should be the symbologies used at the homogeneous shipping case level.

- Product identification labels are required on a minimum of two adjacent sides on each case. A wrap label is acceptable.

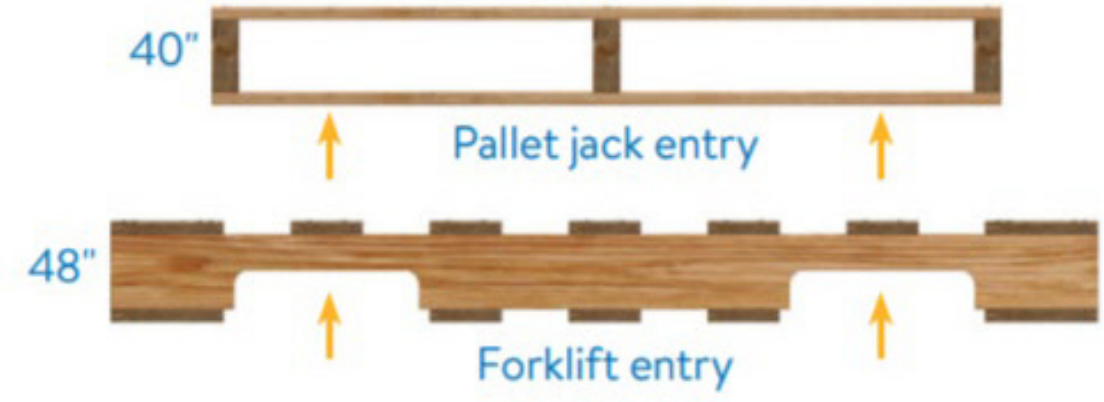


- A serialized Shipping Container Code (SSCC) label must be affixed to each individually shipped case, mixed, case, or pallet.

Pallet Requirements
Key Focus Points

The expected method of shipping into a Walmart Pharmacy Distribution facility is on a 48 X 40 grade A pallet.

Pallets should be designed to accommodate a standard pallet jack and/or power forklift with adequate top board spacing so forklift blades will not affect the freight being shipped.
Pallets must support the weight of the product being shipped.
Pallets with broken, split wood and/or exposed nails are not allowed.




Full pallet (48" x 40")

Direct-to-Store Pharmaceutical Distributors

In addition to receiving prescription products from the Walmart Pharmacy Distribution Network, our pharmacies are serviced by accredited and licensed wholesaler distributors that meet both State Board of Pharmacy and FDA wholesale distributor requirements. These wholesalers distributors are called Direct-to-Store Distributors (DSD).

In order for DSD wholesale distributors to supply prescription products to Walmart Pharmacies or Sam's Club Pharmacies; the distributor must meet or exceed all applicable Federal, State, and local laws and regulatory requirements as well as adhere to any additional requirements stated in an approved supplier agreement.

Additionally, such distributors are responsible for establishing, maintaining, and enforcing policies and procedures that:

- Ensure the integrity, legitimacy, security and authenticity of prescription pharmaceuticals and healthcare product purchases and deliveries;
- Source prescription products from legitimate and verified trading partners;
- Ensure their suppliers are engaged in the lawful distribution of prescription products;
- Ensure verification of vendor and customer licenses/registrations using data from appropriate state and federal agencies, at least annually;
- Ensure all facilities engaged in interstate distribution of prescription products are licensed by the applicable state licensing board as well as hold appropriate DEA registrations; and
- Meet FDA annual prescription pharmaceutical wholesale distributor reporting requirements.

DSCSA ASN Data Exchange

DSD Prescription Pharmaceutical Distributors must confidentially and securely share transaction information, transaction history, and transaction statement (Transaction Data, or T3) electronically to Walmart to comply with Drug Supply Chain Security Act requirements and industry standards for wholesaler distributors and dispensers. T3 has been exchanged electronically by authorized trading partners using the Advanced Shipping Notice, ASN, since 2016. Timing and accuracy of the ASN is critical to the success of our pharmacy receiving processes.

To avoid prescription pharmaceutical flow disruption, DSD suppliers are advised to adhere to the following expectations:

- Transaction Date must be transmitted electronically by ASN prior to or upon shipping product directly to our pharmacies.
- DSD suppliers are expected to share the required NDC-GTIN designations of products that Walmart actively transacts with today to enable successful implementation of our serialization solution. NDCs provided shall be in the same format that would be transmitted in the ASN.
- In the event an ASN is not received before the shipment arrives, the pharmacy will quarantine the order and contact the supplier's customer support hot-line for the respective wholesaler.
- The wholesaler will then be expected to correct and retransmit the ASN by the end of business day to allow the pharmacy to complete receiving the quarantined order.
- Suppliers are expected to provide support and product information necessary for adequate investigation of quarantine product within 24 hours.

Finally, historical Transactional Data must be readily available in retrievable form to each pharmacy to allow reporting pursuant to a legitimate request.

Pharmaceutical Packaging and Labeling

Individual Products
Key Focus Points:

- Individual products must meet all U.S. regulatory requirements for prescription products including but not limited to CPSC Child Resistant Packaging requirements, FDA labeling requirements, Tamper Evident Packaging requirements, and U.S. Customs Country of Origin Labeling requirements.

- Additionally, all prescription pharmaceutical products must meet Drug Supply Chain Security Act Product Identifier and Serialization requirements unless the product is otherwise exempt or grandfathered.

- Prescription Pharmaceuticals must contain serialized information on each individual bottle in both human and machine readable format following GS1 industry standards.

Homogeneous Carton Label
Key Focus Points

- A combination of both GS1-128 and GS1 Data Matrix should be the symbologies used at the homogeneous shipping case level.

- Product identification labels are required on a minimum of two adjacent sides on each case. A wrap label is acceptable.

Mixed Totes or Cases

- All totes/boxes/coolers must be labeled with GS1-128 SSCC label with the appropriate identifiers.

Supplier Resources:

Product Recalls: HWRECALLS@walmart.com

Quarantine Product Investigations: HWSCSAFETY@walmart.com

Product Information Sheet:

Retail Link > Docs > Supplier Replenishment Information > Standard Templates > Product Information Sheet

DSCSA ASN DATA Exchange:

DSCSA ASN Guide:
Retail Link > Apps > EDI-B2B > Guides > RX DSCSA ASN

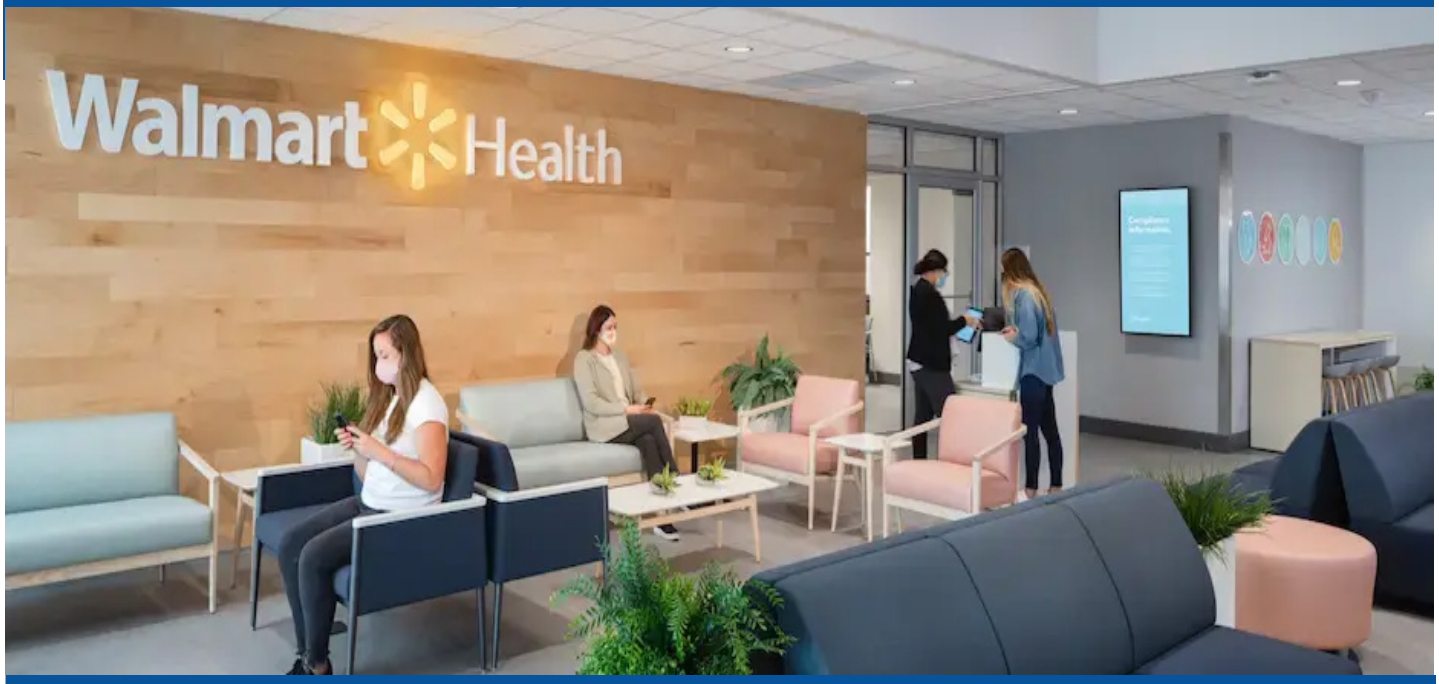
Walmart EDI Support Help-desk at 479-273-8888

DSCSA Labeling Guide:

Retail Link > Academy > Ordering and Replenishment > Shipping, Routing, Packaging, Labeling Guide > Packaging > Secondary Packaging.

EPCIS Specifications:

DSCSA101@walmart.com



Walmart Health Prescription Product Supplier Requirements

Health & Wellness Product Safety
October 2022

At Walmart Health we are committed to providing our patients with safe, high-quality, affordable medications and healthcare services. As the safety and security of the pharmaceutical supply chain is a shared responsibility, one way this is realized is through collaboration with our suppliers. This document outlines minimum expectations for prescription product suppliers as well as provides useful resources to assure regulatory compliance with applicable provisions of the Drug Supply Chain Security Act.

Prescription Product Suppliers:

Prescription product suppliers are those suppliers that manufacture, package, or distribute a prescription pharmaceutical, dietary supplement or other product that requires a legitimate medical prescription to be dispensed or administered by a licensed healthcare professional. These products are in contrast to over-the-counter products which can be obtained without a prescription. Such suppliers include, but are not limited to, direct-ship pharmaceutical or medical device manufacturers, bulk pharmaceutical manufacturers, brokers, wholesale pharmaceutical, dietary supplement or device distributors, pharmaceutical, dietary supplement & medical device manufacturers, labelers, repackagers, third-party logistic providers (3PL), or any entity arranging for the purchase of prescription products by Walmart Health.

Prescription Product Supplier On-boarding

Prescription product supplier on-boarding is required for all suppliers providing prescription pharmaceuticals, dietary supplements, or medical devices directly or indirectly to any Walmart Health Center. This includes, but is not limited to, product that is purchased directly or indirectly from a manufacturer or from a third-party wholesale distributor. All information must be provided to Health & Wellness Product Safety for review and approval prior to placing any purchase orders and shipping product. [1]

Failure to comply with the following requirements may make your company ineligible to supply to Walmart. Please note, these supplier requirements are in addition to Supplier Requirements listed on corporate.walmart.com/supplier/requirements and apply to all

New Supplier On-boarding

In order to ship prescription products to Walmart Health, the supplier must meet or exceed all applicable Federal, State, and local laws and regulatory requirements as well as adhere to any additional requirements stated in the supplier agreement. New suppliers must provide requested information to Health & Wellness Product Safety regarding the manufacture and handling of prescription products. Suppliers may obtain a *Product Information Sheet* from Retail Link following the below path.

Retail Link > Docs > Supplier Replenishment Information > Standard Templates > Product Information Sheet

Information required shall include, but may not be limited to:

- **Facility Disclosure:** Facility disclosure is essential to achieving true supply chain transparency. Each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of the sourced product must comply with applicable U.S. FDA Good Manufacturing Practices and must be disclosed to Health & Wellness Product Safety. This includes all subcontracted facilities or any operations or facilities that are not owned by your company which provide manufacturing,

- United States Food & Drug Administration **(FDA) Drug Establishment Registration or Medical Device Manufacturing Registration** for applicable facilities;

- Applicable **Drug Enforcement Agency (DEA) registration;**

- **Facility Ownership/Business Relationship:** Facility ownership/business entity relationship disclosure is essential for verification of required licenses/registrations;

- **State Board of Pharmacy Manufacturer/Wholesale Drug Distributor license/registration** information for the state in which the applicable facility(s) operates as well as for **AR, CA, GA, IN,** format that would be transmitted in the Advanced Shipping Notice (ASN);

- **Authorized Distributor of Record (ADR) or supplier information;**

- **New Drug Application (NDA) or Abbreviated New Drug application (ANDA)** number or FDA approval notice;

- **National Drug Code (NDC)** registration information. NDC shall be disclosed in the same format that would be transmitted in the Advanced Shipping Notice (ASN);

- 24 month **recall history** for sourced product;

- Product should be identifiable via the DailyMed website;

- Facility regulatory enforcement/inspection history information for all applicable facilities;

- Third-party U.S. FDA GMP audit/certifications upon request.

The Product Information Sheet **must** be accurate and complete. Failure to provide complete and accurate information will result in delayed approval and purchase orders and potential denial of purchase orders. Health & Wellness Product Safety will review all supplier/product information and verify applicable licenses and registrations directly with the issuing State and/or Federal agencies. Once verified and approved, the supplier is responsible for disclosing new facility information prior to use of the new facility as well as maintaining accurate facility and registration information with Health & Wellness Product Safety. As always, it is the supplier's responsibility to renew and maintain all required licenses and registrations with the issuing agencies and provide renewal information to Health & Wellness Product Safety immediately upon renewal. Failure to maintain a required license or registration may make your company ineligible to supply to Walmart Health.

Pharmaceutical Packaging and Labeling

Packaging and labeling are details that can be leveraged to reduce costs, improve accuracy and optimize supply chain flow. Thus Walmart has established a standardized approach to packaging and labeling standards that focus on proactive methodologies to drive quality inbound loads into our Pharmacy Distribution Network. You may reference the complete DSCSA Labeling Guide published on Retail Link.

Retail Link > Academy > Ordering and Replenishment > Shipping, Routing, Packaging, Labeling Guide > Packaging > Secondary Packaging.

Individual Products
Key Focus Points:

- Individual products must meet all U.S. regulatory requirements for prescription products including but not limited to CPSC Child Resistant Packaging requirements, FDA labeling requirements, Tamper Evident Packaging requirements, and U.S. Customs Country of Origin Labeling requirements.

- Additionally, **all prescription pharmaceutical products must meet Drug Supply Chain Security Act Product Identifier and Serialization requirements unless the product is otherwise exempt or grandfathered.**

- While Walmart Health is exempt from receiving or capturing transactional data and investigating or responding to information regarding suspect product, **Walmart Health is required to comply with the DSCSA product identifier requirements and authorized trading partners requirements.**

- Prescription Pharmaceuticals must contain serialized information on each individual bottle in both human and machine readable format following GS1 industry standards.

Homogeneous Carton Label
Key Focus Points

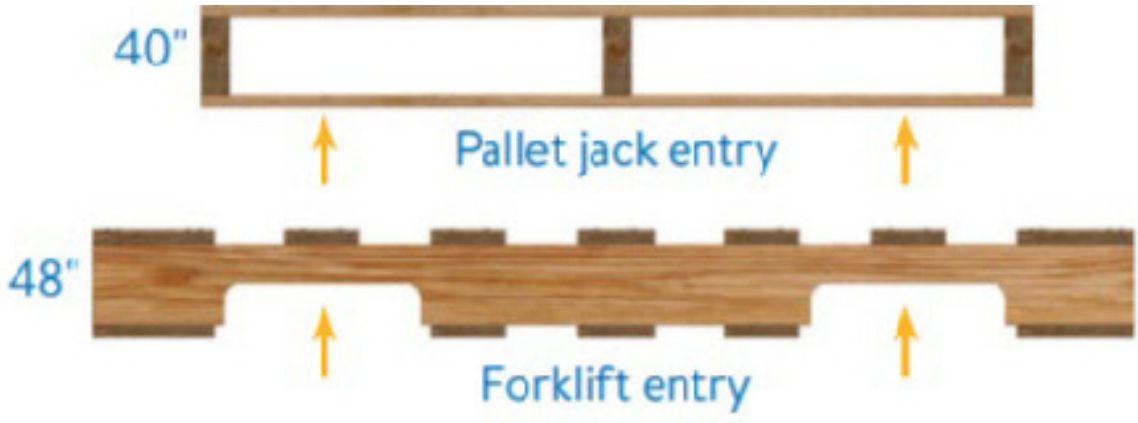
- A combination of both GS1-128 and GS1 Data Matrix should be the symbologies used at the homogeneous shipping case level.

- Product identification labels are required on a minimum of two adjacent sides on each case. A wrap label is acceptable.
- A serialized Shipping Container Code (SSCC) label must be affixed to each individually shipped case, mixed, case, or pallet.

Key Focus Points

The expected method of shipping into a Walmart Pharmacy Distribution facility is on a 48 X 40 grade A pallet.

- Pallets should be designed to accommodate a standard pallet jack and/or power fork-lift with adequate top board spacing so forklift blades will not affect the freight being shipped.
- Pallets must support the weight of the product being shipped.
- Pallets with broken, split wood and/or exposed nails are not allowed.



Direct-to-Center Pharmaceutical Distributors

Walmart Health Centers are serviced by licensed wholesaler distributors that meet both State Board of Pharmacy and FDA wholesale distributor requirements. These wholesalers distributors are called Direct-to-Center Distributors (DSD).

In order for DSD wholesale distributors to supply prescription products to Walmart Health Centers, the distributor must meet or exceed all applicable Federal, State, and local laws and regulatory requirements as well as adhere to any additional requirements stated in an approved supplier agreement.

Additionally, such distributors are responsible for establishing, maintaining, and enforcing policies and procedures that:

- Ensure the integrity, legitimacy, security and authenticity of prescription pharmaceuticals and healthcare product purchases and deliveries;
- Source prescription products from legitimate and verified trading partners;
- Ensure their suppliers are engaged in the lawful distribution of prescription products;
- Ensure verification of vendor and customer licenses/registrations using data from appropriate state and federal agencies, at least annually;
- Ensure all facilities engaged in interstate distribution of prescription products are licensed by the applicable state licensing board as well as hold appropriate DEA registrations; and
- Meet FDA annual prescription pharmaceutical wholesale distributor reporting requirements.
- Only ship product that meets Drug Supply Chain Security Act (DSCSA) product identifier requirements.

Supplier Resources:

Product Recalls: HWRECALLS@walmart.com

Quarantine Product Investigations: HWSCSAFETY@walmart.com

Product Information Sheet:

Retail Link > Docs > Supplier Replenishment Information > Standard Templates > Product Information Sheet

DSCSA ASN DATA Exchange:

DSCSA ASN Guide:
Retail Link > Apps > EDI-B2B > Guides > RX DSCSA ASN

Walmart EDI Support Help-desk at 479-273-8888

DSCSA Labeling Guide:

Retail Link > Academy > Ordering and Replenishment > Shipping, Routing, Packaging, Labeling Guide > Packaging > Secondary Packaging.

Product Removal Requirements for Prescription Product Suppliers

Health & Wellness Product Safety
October 2022

At Walmart, we adhere to strict quality assurance controls and work with our supplier partners to ensure that we provide safe, quality products. However, sometimes product removals may be necessary in the event of a withdrawal or recall.

Product removals are classified under two categories:

- **Recall** - safety-related product removals: Examples of reasons to recall product include but are not limited to product that does not meet product specification, fails to have required warning, or packaging does not meet child safety requirements. These products may pose a potential safety risk if consumed or used.

- **Withdrawal** - non-safety-related product removals: Reasons to withdraw products include but are not limited to product or package appearance. These products are perfectly safe to consume or use, but do not meet a non-safety related regulation or the supplier's desired quality.

Product removals are initiated by a supplier or regulatory agency and upon request and executed by the assigned Walmart Recall team. In some cases however, a recall or withdrawal may be initiated by Walmart due to internal information such as consumer complaints or concerns. If you become aware of a regulatory, safety, or quality issue with any product or ingredient used in any product shipped to Walmart, **immediately contact the Walmart Recall Team at 479-644-9606 or by email at HWRECALLS@email.wal-mart.com.**

If it is determined that a withdrawal or recall notification to any Walmart Pharmacy Distribution Center, Walmart Pharmacy, Sam's Club Pharmacy, Vision Center, or Walmart Health Center is necessary, you will be directed to **complete a Product Removal Form in Retail Link** using your supplier Retail Link access and the following path.

Retail Link – Apps – Product Removal – Create New – Walmart or Sam's

The following information will be necessary when completing the Product Removal Form in Retail Link:

- Reason for the removal;
- Item number/NDC number or UPC number when applicable;
- Lot codes and expiration dates;
- Distribution date for the implicated product;
- Walmart Pharmacy, Sam's Club Pharmacy, Vision Center or Walmart Health Center facility list for product shipped directly to locations by DSD Distributors;
- Walmart Pharmacy Distribution Center list that received the implicated product if shipped to the Walmart Pharmacy Distribution Network;
- Disposition and handling instructions for the product;
- Press Release: Will there be a press release regarding the recall?

The Walmart Recall team will promptly notify all impacted facilities using the information that you have provided. **Do not notify any Walmart Pharmacy, Sam's Club Pharmacy, Vision Center or Walmart Health Center locations directly.** All product removal notifications are handled centrally by Walmart's Corporate Office Recall team.

Resources:

Product Recalls or Withdrawal:

HWRECALLS@walmart.com or 479-644-9606