Stakeholder Requirements: Drug Supply Chain Security Act

(Title II, Drug Quality and Security Act)

The Drug Supply Chain Security Act (Title II, Drug Quality and Security Act, 2013) addresses risks in the pharmaceutical distribution supply chain by establishing a national system that allows stakeholders and regulators to trace each package of product. The serialization and traceability requirements will be phased in over the next 10 years. The law requires sectors in the supply chain—manufacturers, repackagers, wholesale distributors, and dispensers—to comply with statutory requirements under the following categories.

- Product serialization
- Authorized trading partners
- General product tracing
- Product tracing (salable and nonsalable returns)
- Product tracing (request for information)
- Investigation of suspect product
- Removal and notification of illegitimate product
- Verification (request for verification)
- Verification (salable returned product and nonsalable returned product)
- Verification (electronic database)
- Enhanced drug distribution security (unit-level traceability)

Statutory requirement

Product serialization

Manufacturers	**Nov. 27, 2017** Manufacturers must **affix a product identifier** to each drug package and homogenous case. The product identifier will include a standard numerical identifier, or SNI, unique to each package or case. The product identifier data will be included in a 2-dimensional data matrix bar code on each package; and linear or 2-dimensional matrix bar code on each homogenous case. Manufacturers must **maintain product identifier records** for at least 6 years.
Repackagers	**Nov. 27, 2018** Repackagers must **affix a product identifier** to each drug package and homogenous case. The product identifier will include a standard numerical identifier unique to each package or case. Repackagers may **engage in transactions** involving a product only if the product is encoded with a product identifier. Repackagers must **maintain product identifier records** for at least 6 years; records include those that allow the repackager to associate the product identifier with the one assigned by the original product manufacturer.
Wholesale distributors	**Nov. 27, 2019** Wholesale distributors may **engage in transactions** involving a drug product only if the product is encoded with a product identifier.
Dispensers	**Nov. 27, 2020** Dispensers may **engage in transactions** involving a drug product only if the product is encoded with a product identifier.

Statutory requirement

Authorized trading partners

Manufacturers	**Jan. 1, 2015** Manufacturers may only distribute drug to trading partners that are "authorized," i.e., that have a valid registration or license.
Repackagers	**Jan. 1, 2015** Repackagers may only distribute drug to or accept drug from trading partners that are "authorized," i.e., that have a valid registration or license.
Wholesale distributors	**Jan. 1, 2015** Wholesale distributors may only distribute drug to or accept drug from trading partners that are "authorized," i.e., that have a valid registration or license.
Dispensers	**Jan. 1, 2015** Dispensers may only accept drug from trading partners that are "authorized," i.e., that have a valid registration or license. To receive drugs, trading partners must also be authorized.

Statutory requirement

General product tracing

Manufacturers	**Jan. 1, 2015** Prior to or at the time of the transaction, manufacturers must **provide** trading partners with transaction information, transaction history, and a transaction statement in a **single paper or electronic document.** Manufacturers must **capture** transaction information (including lot-level information), transaction history, and transaction statement for each transaction and **maintain** this information for not less than 6 years. **Nov. 27, 2017** Manufacturers must **provide** the transaction information, transaction history, and transaction statement in **electronic form**. Exception: This information may be provided to certain health care practitioners in paper form.
Repackagers	**Jan. 1, 2015** Repackagers must **not accept ownership** of a product unless the previous owner provides transaction information, transaction history, and a transaction statement. Prior to or at the time of the transaction, repackagers must **provide** subsequent owners with transaction information, transaction history, and transaction statements. Repackagers must **capture** the transaction information, transaction history, and transaction statement for each transaction and **maintain** this information for not less than 6 years.

Wholesale distributors

Jan. 1, 2015
Wholesale distributors must **not accept ownership** of a product unless the previous owner provides transaction information, transaction history, and a transaction statement.

Wholesale distributors can provide transaction information, transaction history, and transaction statements in one of two ways.

With **direct purchases** (from a manufacturer, the exclusive distributor of a manufacturer, or a repackager that purchased directly from the manufacturer), the wholesale distributor must provide—prior to or at the time of the transaction—the subsequent purchaser with a **transaction statement** stating the product was purchased directly from the manufacturer, an exclusive distributor, or a repackager that purchased directly from the manufacturer.

With **direct purchases**, the wholesale distributor must also provide a **version** of transaction history and information (that does not need to include the lot number, initial transaction date, or initial ship date); the wholesale distributor must also inform the subsequent purchaser that they received a **direct purchase statement**.

With **direct purchases**, such information must be on a single document in electronic form when provided to dispensers; when provided to other wholesale distributors, it can be any combination of paper, electronic, or manufacturer-provided information on the product package.

In the case of purchases **other than direct purchase** (see above), the wholesale distributor must provide—prior to or at the time of the transaction—transaction information, transaction history, and transaction statement to the subsequent purchaser. Transaction history will begin with the wholesaler that first purchased the product from the manufacturer.

Regardless of whether the purchase is direct or indirect, the wholesale distributor must **capture** the applicable transaction information, transaction history, and transaction statements for each transaction and **maintain** this information for not less than 6 years.

The wholesale distributor must maintain confidentiality of transaction information, transaction history, and transaction statements in a manner that prohibits disclosure to any person other than a Food and Drug Administration or other official, except: (1) to comply with requirements to share transaction information, transaction history, and transaction statements with subsequent purchasers; and (2) starting 6 years post-enactment, pursuant to a written agreement with the subsequent purchaser.

Dispensers

July 1, 2015
Dispensers must **not accept ownership** of a product unless the previous owner provides transaction information, transaction history, and a transaction statement.

Dispensers do not need to provide transaction information, transaction history, and transaction statements when dispensing to a patient, returning a product, or selling a product to a dispenser to fulfill a specific patient need. In all other cases, dispensers must provide subsequent owners with transaction information, transaction history, and transaction statements prior to or at the time of the transaction.

Dispensers must **capture** transaction information (including lot-level information, if provided), transaction history, and transaction statements as necessary to investigate a suspect product and **maintain** this for not less than 6 years.

Dispensers may enter into a **written agreement with a third party**, including an authorized wholesale distributor, to confidentially maintain transaction information, transaction history, and transaction statements on the dispenser's behalf. Dispensers must maintain a copy of the written agreement and are still **responsible** for their statutory obligations.

Statutory requirement

Product tracing (salable and nonsalable returns)

Manufacturers	Manufacturers can **return nonsalable product** without providing transaction information, transaction history, and transaction statements.
Repackagers	Repackagers can **return nonsalable product** without providing transaction information, transaction history, and transaction statements. Repackagers acting on behalf of a hospital or the health care entity that owns the product may **return salable or nonsalable product** without providing transaction information, statements, and history.
Wholesale distributors	**Prior to Nov. 27, 2019** Wholesale distributors can **distribute salable returned product** without providing transaction history. For subsequent sales of that product, the transaction history will begin with the wholesale distributor that accepted and verified the returned product. **Nov. 27, 2019** Wholesale distributors must, in the case of **salable returns**, accept returned product from repackagers and dispensers only if the wholesaler can associate the returned product with the transaction information and transaction statement associated with that product. The transaction history for that returned product must begin with the wholesale distributor that accepted and verified the returned product. Wholesale distributors may **return nonsalable product** without providing transaction information, transaction history, and transaction statements.
Dispensers	Dispensers can **return salable or nonsalable product** without providing transaction information, transaction history, and transaction statements.

Statutory requirement

Product tracing (request for information)

Manufacturers	Manufacturers must **provide** transaction information, transaction history, and transaction statements the earlier of 1 business day or 48 hours after request by appropriate federal or state officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product.
Repackagers	Repackagers must **provide** transaction information, transaction history, and transaction statements the earlier of 1 business day or 48 hours after request by appropriate federal or state officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product

Wholesale distributors

Wholesale distributors must **provide** transaction information, transaction history, and transaction statements the earlier of 1 business day or 48 hours after request by appropriate federal or state officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product.

Dispensers

Dispensers must **provide**, in paper or electronic format, transaction information, transaction history, and transaction statements the earlier of 1 business day or 48 hours after request by appropriate federal or state officials, in the event of recall or investigation of suspect or illegitimate product.

If the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer was not included in the transaction information, transaction history, and transaction statements provided by the manufacturer or wholesale distributor to the dispenser, then the dispenser shall not provide such information when responding to a request for information from an appropriate official.

Prior to Nov. 27, 2019
The secretary of HHS or appropriate federal or state officials shall: grant dispensers **additional time** as necessary to provide lot-level information that was provided to them in paper format; limit requests to the 6 months preceding the request or another relevant date; and, in the event of a recall, request information only if the recall involves serious adverse health consequence or death to humans.

Statutory requirement

Investigation of suspect product

Manufacturers

Jan. 1, 2015
Manufacturers must investigate **suspect product** that the manufacturer or the secretary has identified as being in the manufacturer's possession or control.

The investigation must be coordinated with affected trading partners and must include validating the transaction information and transaction history. Product must be quarantined until it is cleared or it is removed from the supply chain.

Nov. 27, 2017
When conducting an investigation, manufacturers must **verify suspect product at the package level.**

If it is not determined to be illegitimate, the formerly suspect product is "cleared product" and it may be distributed.

Records of the investigation must be retained for 6 years.

Repackagers

Jan. 1, 2015
Repackagers must investigate **suspect product** that the repackager or the secretary has identified as being in the repackager's possession or control.

The investigation must be coordinated with affected trading partners and must include validating the transaction information and transaction history. Product must be quarantined until it is cleared or it is removed from the supply chain.

Nov. 27, 2018
When conducting an investigation, repackagers must **verify suspect product at the package level.**

If it is not determined to be illegitimate, the formerly suspect product is "cleared product" and it may be distributed.

Records of the investigation must be retained for 6 years.

Wholesale distributors

Jan. 1, 2015
Wholesale distributors must investigate suspect product that the wholesale distributor or the secretary has identified as being in the wholesale distributor's possession or control.

The investigation must be coordinated with affected trading partners and must include validating the transaction information and transaction history. Product must be quarantined until it is cleared or it is removed from the supply chain.

Nov. 27, 2019
When conducting an investigation, wholesale distributors must verify suspect product at the package level.

If it is not determined to be illegitimate, the formerly suspect product is "cleared product" and it may be distributed.

Records of the investigation must be retained for 6 years.

Dispensers

Jan. 1, 2015
Dispensers must investigate **suspect product** that the dispenser or the secretary has identified as being in the dispenser's possession or control.

The investigation must be coordinated with affected trading partners and must include validating the transaction information and transaction history. Product must be quarantined until it is cleared or it is removed from the supply chain.

Nov. 27, 2020
When conducting an investigation, dispensers must **verify suspect product lot number, and verify suspect product at the package level** of at least **3 packages or 10 percent of suspect product**, whichever is greater.

If not determined to be illegitimate, the formerly suspect product is "cleared product" and it may be distributed.

Records of the investigation must be retained for 6 years.

Statutory requirement

Removal and notification of illegitimate product

Manufacturers

Jan. 1, 2015
Upon determining that a product is **illegitimate**, manufacturers must **quarantine** the product from distribution and **remove** the illegitimate product from the supply chain. Manufacturers will take reasonable and appropriate steps to assist trading partners in doing the same.

Manufacturers must **retain a sample** of the product for further physical examination or laboratory analysis by the secretary or other appropriate state or federal officials.

Within 24 hours of determining that a product is illegitimate, manufacturers must **notify the secretary and all immediate trading partners** that they may have received the product.

If a manufacturer determines or is notified by the secretary or a trading partner that there is a **high risk of illegitimate product**, they must notify the secretary and trading partners that they believe they may have the product within 24 hours.

If a manufacturer, in consultation with the secretary, determines that a notification is no longer necessary, it must promptly **notify immediate trading partners** that the notification has been terminated.

Manufacturers must **retain records** of the removal of an illegitimate product for not less than 6 years.

Repackagers

Jan. 1, 2015
Upon determining, in coordination with the manufacturer, that a product is **illegitimate**, the repackager must **quarantine** the product from distribution and remove the illegitimate product from the supply chain. Repackagers must take reasonable and appropriate steps to assist trading partners in doing the same.

Repackagers must **retain a sample** of the product for further physical examination or laboratory analysis by the manufacturer, the secretary or other appropriate state or federal officials.

Within 24 hours of determining that a product is illegitimate, repackagers must **notify the secretary and all immediate trading partners** that they may have received the product.

If repackagers receive notification from the secretary or a trading partner that they may have received an illegitimate product, they must identify all illegitimate product in their possession or control, including any product that is subsequently received, and they must conduct an investigation with respect to that product.

If repackagers, in consultation with the secretary, determine that a notification is no longer necessary, they must promptly **notify immediate trading partners** that the notification has been terminated.

Repackagers must **retain records** of the removal of an illegitimate product for not less than 6 years.

Wholesale distributors

Jan. 1, 2015
Upon determining, in coordination with the manufacturer, that a product is **illegitimate**, wholesale distributors must **quarantine** the product from distribution and remove the illegitimate product from the supply chain. Wholesale distributors must take reasonable and appropriate steps to assist trading partners in doing the same.

Wholesale distributors must **retain a sample** of the product for further physical examination or laboratory analysis by the manufacturer, the secretary or other appropriate state or federal officials.

Within 24 hours of determining that a product is illegitimate, wholesale distributors must **notify the secretary and all immediate trading partners** that they may have received the product.

If wholesale distributors receive notification from the secretary or a trading partner that they may have received an illegitimate product, they must identify all illegitimate product in their possession or control, including any product that is subsequently received, and they must conduct an investigation with respect to that product.

If wholesale distributors, in consultation with the secretary, determine that a notification is no longer necessary, they must promptly **notify immediate trading partners** that the notification has been terminated.

Wholesale distributors must **retain records** of the removal of an illegitimate product for not less than 6 years.

Dispensers

Jan. 1, 2015
Upon determining, in coordination with the manufacturer, that a product is **illegitimate**, dispensers must **remove** the illegitimate product from the supply chain. Dispensers must take reasonable and appropriate steps to assist trading partners in doing the same.

Dispensers must **retain a sample** of the product for further physical examination or laboratory analysis by the manufacturer or secretary or other appropriate federal or state officials.

Within 24 hours of determining that a product is illegitimate, dispensers must **notify the secretary and all immediate trading partners** that they may have received the product.

If dispensers receive notification from the secretary or a trading partner that they may have received an illegitimate product, they must identify all illegitimate product in their possession or control, including any product that is subsequently received, and they must conduct an investigation with respect to that product.

Dispensers, in consultation with the secretary, upon determining that a notification is no longer necessary, must promptly **notify immediate trading partners** that the notification has been terminated.

Dispensers must **retain records** of the removal of an illegitimate product for not less than 6 years.

Statutory requirement

Verification (requests for verification)

Manufacturers

Nov. 27, 2017
Within 24 hours of receiving a **request for verification** from an authorized repackager, wholesale distributor, or dispenser, manufacturers must **notify** the person making the request whether the product identifier corresponds to the product identifier affixed or imprinted by the manufacturer.

If a product identifier does not correspond to that affixed or imprinted by the manufacturer, the manufacturer must treat the product as **suspect product** and conduct an investigation.

If the manufacturer has reason to believe the product is **an illegitimate product**, the manufacturer must advise the person making the request when responding to the request for verification.

Repackagers

Nov. 27, 2018
Within 24 hours of receiving a **request for verification** from an authorized repackager, wholesale distributor, or dispenser, repackagers must **notify** the person making the request whether the product identifier corresponds to the product identifier affixed or imprinted by the manufacturer.

If a product identifier does not correspond to that affixed or imprinted by the repackager, the repackager must treat the product as **suspect product** and conduct an investigation.

If the repackager has reason to believe the product is an **illegitimate product**, the repackager must advise the person making the request when responding to the request for verification.

Statutory requirement

Verification (salable returned product and nonsalable returned product)

Manufacturers

Nov. 27, 2017
Upon receipt of a **salable returned product** that the manufacturer intends to distribute further, the manufacturer must **verify the product identifier** for each sealed homogeneous case. If the product is not in a sealed homogeneous case, the manufacturer must verify the product identifier on each package.

Repackagers

Nov. 27, 2018
Upon receipt of a **salable returned product** that the repackager intends to distribute further, the repackager must **verify the product identifier** for each sealed homogeneous case of such product. If the product is not in a sealed homogeneous case, the repackager must verify the product identifier on each package.

Wholesale distributors

Nov. 27, 2019
Upon receipt of a **salable returned product** that the wholesale distributor intends to distribute further, the wholesale distributor shall **verify the product identifier** for each sealed homogeneous case of such product. If the product is not in a sealed homogeneous case, the wholesale distributor must verify the product identifier on each package.

Statutory requirement

Verification (electronic database)

Manufacturers	Manufacturers may develop a secure electronic database (or use one developed or operated by another entity) to satisfy verification requirements, but must still respond to requests for verification not submitted through the database.
Repackagers	Repackagers may develop a secure electronic database (or use one developed or operated by another entity) to satisfy verification requirements, but must still respond to requests for verification not submitted through the database.
Wholesale distributors	Wholesalers may develop a secure electronic database (or use one developed or operated by another entity) to satisfy verification requirements.
Dispensers	Dispensers may develop a secure electronic database (or use one developed or operated by another entity) to satisfy verification requirements.

Statutory requirement

Enhanced drug distribution security (unit-level traceability)

Manufacturers	**Nov. 27, 2023** Manufacturers must exchange transaction information and transaction statements in an interoperable electronic manner. Transaction information must include product identifier at the package level. Manufacturers must have systems and processes to promptly respond with the transaction information and transaction statement for a product, as well as the information for each transaction going back to the manufacturer, upon a request by the secretary (or other federal or state officials) in the **event of a recall** or for the purposes of **investigating a suspect product** or an illegitimate product. Manufacturers must also have systems and processes necessary to provide the aforementioned transaction information upon request by an authorized trading partner that is conducting or assisting with an investigation. Manufacturers must accept salable returned products only if they can associate the appropriate transaction information and transaction statements to that product.

Repackagers	**Nov. 27, 2023** Repackagers must exchange transaction information and transaction statements in an interoperable electronic manner. Transaction information must include product identifier at the package level. Repackagers must have systems and processes to promptly respond with the transaction information and transaction statement for a product, as well as the information for each transaction going back to the manufacturer, upon a request by the secretary (or other federal or state officials) in the **event of a recall** or for the purposes of i**nvestigating a suspect product** or an illegitimate product. Repackagers must also have systems and processes necessary to provide the aforementioned transaction information upon request by an authorized trading partner that is conducting or assisting with an investigation. Repackagers must accept salable returned products only if they can associate the appropriate transaction information and transaction statements to that product.
Wholesale distributors	**Nov. 27, 2023** Wholesale distributors must exchange transaction information and transaction statements in an interoperable electronic manner. Transaction information must include product identifier at the package level. Wholesale distributors must have systems and processes to promptly respond with the transaction information and transaction statement for a product, as well as the information for each transaction going back to the manufacturer, upon a request by the secretary (or other federal or state officials) in the **event of a recall** or for the purposes of **investigating a suspect product** or an illegitimate product. Wholesale distributors must also have systems and processes necessary to provide the aforementioned transaction information upon request by an authorized trading partner that is conducting or assisting with an investigation. Wholesale dispensers must accept salable returned products only if they can associate the appropriate transaction information and transaction statement to that product.
Dispensers	**Nov. 27, 2023** Dispensers must exchange transaction information and transaction statements in an interoperable electronic manner. Transaction information must include product identifier at the package level. Dispensers must have systems and processes to promptly respond with the transaction information and transaction statement for a product, as well as the information for each transaction going back to the manufacturer, upon a request by the secretary (or other federal or state officials) in the **event of a recall** or for the purposes of **investigating a suspect product** or an illegitimate product. Dispensers must have systems and processes necessary to provide the aforementioned transaction information upon request by an authorized trading partner that is conducting or assisting with an investigation. Dispensers must accept salable returned products only if they can associate the appropriate transaction information and transaction statement to that product.

Glossary

- **High risk of illegitimate product:** High risk may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the secretary through guidance.
- **Nonsalable returns:** returned products not suitable for further sale or distribution. Typically includes damaged, expired, or recalled pharmaceutical product.
- **Product identifier:** A product identifier is a standardized graphic that includes the standardized numerical identifier, lot number, and expiration date of the product. It must be presented in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization.

- **Salable returns:** returned products intended for further distribution. Typically includes pharmaceutical product ordered in error or that is no longer needed by a pharmacy due to changes by the patient; salable returned product must include certification that the product has been stored under manufacturer's requirements.
- **Standardized numerical identifier:** The term standardized numerical identifier refers to a set of numbers or characters used to uniquely identify each package or homogenous case. The SNI is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.
- **Transaction history:** The term transaction history refers to a statement in paper or electronic form that includes the transaction information for each prior transaction going back to the manufacturer of the product.
- **Transaction information:** The term transaction information refers to a product's proprietary or established name, strength and dosage form, the National Drug Code number, container size, and lot number; the number of containers involved in the transaction; the date of the transaction; the date of the shipment, if more than 24 hours after the date of the transaction; the business name and address of the person from whom ownership is being transferred; and the business name and address of the person to whom ownership is being transferred.
- **Transaction statement:** A transaction statement refers to a statement, in paper or electronic form, that the entity transferring ownership in a transaction is authorized as required under the Drug Supply Chain Security Act; has received the product from a person that is authorized as required under the Drug Supply Chain Security Act; has received transaction information and a transaction statement from the prior owner of the product; did not knowingly ship a suspect or illegitimate product; has systems and processes in place to comply with verification requirements; did not knowingly provide false transaction information; and did not knowingly alter the transaction history.

For further information, please visit:

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