Liz Gallenagh, Esq.
Vice President, Government Affairs
& General Counsel
HDMA
Now is the time for Congress to move one national solution for a safer, more secure pharmaceutical supply chain. #1RxSolution
DQSA/DSCSA History

- Multi-year effort to produce a *balanced* product in an effort to consider stakeholder priorities

  - Factors included California delegation concerns with preemption
  - FDA desire to preserve “pedigree” AND get to a more robust, more transparent track-and -trace, as well as 10\textsuperscript{th} Amendment concerns
  - Industry stakeholders generally united in ultimate goal but various opinions about how to get there
  - Increasing concern & anticipation about California implementation dates
DQSA/DSCSA History

- August bipartisan bicameral negotiations
- Late September House passage of H.R. 3204, *The Drug Quality and Security Act* (includes compounding Title I)
- Senate passage 11/18/15
- President’s signature expected soon
- Effective Immediately upon signature; Title II is the *Drug Supply Chain Security Act*
Big Ticket Issues

- Full pedigree vs. interim provisions
- Licensure floor or ceiling
- Returns
- Dispenser activity
- Exemptions
- Implementation dates
- Phase II
Drug Supply Chain Security Act

Phase I

Preemption of state activity

Pre-serialization pedigree requirements

Serialization & lot level “product tracing”

“Product Identifier” applied by manufacturer includes SNI, lot # & expiration date

“Verification” of suspect and illegitimate product and saleable returns
<table>
<thead>
<tr>
<th>Phase II</th>
<th>Unit level “Traceability”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transaction history sunsets</td>
</tr>
<tr>
<td></td>
<td>Self-effectuating provisions</td>
</tr>
<tr>
<td></td>
<td>New FDA authority and responsibilities</td>
</tr>
<tr>
<td>Licensure</td>
<td>Preservation of role for state agencies</td>
</tr>
<tr>
<td></td>
<td>“Floor” and “ceiling”</td>
</tr>
<tr>
<td></td>
<td>Separate licensure status for 3PLs</td>
</tr>
</tbody>
</table>
FDA Timelines

- 180 Days after enactment – Guidance on suspect and Illegitimate product
- Jan. 1, 2015 – Annual reporting by wholesalers re: licensure information and FDA establishes public database of authorized wholesalers
- One year after enactment:
  - Secretary issues draft standards for TI/TH/TS
  - 3PL licensure reporting
FDA Timelines

- Two years after enactment, the Secretary:
  - Establishes by regulation wholesaler and 3PL licensing standards
  - Issues guidance for waivers and product identifier exceptions
  - Issues guidance for grandfathering
  - Public meetings (no less than 5 meetings, with the first to take place no earlier than 1 year after enactment)
FDA Timelines

- No date specified:
  - Guidance for unit-level traceability (not less than 18 months after conducting a public meeting)
  - Assessment of small dispenser capabilities (not later than 18 months after the Secretary issues final guidance on suspect and illegitimate product and unit-level tracing)
  - Updates to guidance (not later 18 months after conducting a public meeting on interoperable standards, the Secretary shall update and finalize previously issued guidance)
  - Pilot Projects – Secretary shall establish 1 or more pilot projects to inform guidance for unit-level tracing and standards for interoperable data exchange
Implementation Timeline

November 2013
Congress Enacts the Drug Quality and Security Act (H.R. 3204)

DONE
NATIONAL TRACEABILITY SOLUTION

January 1, 2015
Manufacturers Send and Distributors Receive TH/TI/TS + Begin Direct Purchase Pedigree

July 1, 2015
Dispensers Receive TH/TI/TS


Federal Licensure Standards for Distributors Raised

Manufacturers Serialize Product (4 years)

Repackagers Serialize (5 years)

Distributors Lot Level Traceability (6 years)

Pharmacy Lot Level (7 years)

Unit Level Traceability (10 years)
Preemption - Pedigree

- Immediate preemption of all state laws, regulations, and requirements for tracing products through the supply chain, including any recordkeeping and pedigree requirements.

- Federal pedigree requirements under PDMA continue in force until January 1, 2015, as a bridge to the new national framework.
Preemption - Licensure

- Preemption of state activity regarding wholesale distributor and 3PL licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards established by the Act.

- In other words, states cannot alter the standards established by the Act, but they may continue to regulate wholesale distributors and 3PLs in areas that are not covered by and not directly related to the licensing standards in the Act.
Product Tracing vs. Pedigree

- Phase I requires manufacturers, wholesale distributors, dispensers, and repackagers to pass, capture, and maintain certain information with respect to each transaction.
- Emphasis on lot-level information (vs. SNI or unit)
- Now, “pedigree” or “product tracing” requirements are triggered by changes in ownership (or transactions) between trading partners.
- Note also new definition of “affiliate” re: intracompany transfers
Product Tracing – Phase I

Transaction information (TI) - includes the name of the product, strength and dosage form, NDC, container size, number of containers, lot number, transaction date, the *shipment date and the name and address of the businesses previous and subsequent owner.

Transaction history (TH) - paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.
Product Tracing – Phase I

Transaction statement (TS) - paper or electronic attestation by the entity transferring ownership of the product that it:

– Is authorized under the Act;
– Received the product from an authorized party;
– Received TI and TS from the previous seller;
– Did not knowingly ship suspect or illegitimate product;
– Systems and processes...to perform verification...
– Did not knowingly provide false transaction information and did not alter the transaction history.
Product Tracing – Phase I

- Each business must (i) provide the TI, TH, and TS to the subsequent owner for each transaction, and (ii) capture and maintain for six years the TI, TH, and TS for each transaction, whether as the buyer or as the seller.
- This obligation begins on January 1, 2015 for manufacturers, wholesaler distributors, and repackagers; and on July 1, 2015 for dispensers.
- Manufacturers are required to pass this information in electronic format beginning no later than four years after enactment of the Act.
Exemptions

- Blood and blood components intended for transfusion.
- Radioactive drugs and radioactive biologics.
- Intravenous products.
- Medical gas.
- Compounded drugs.
- Dispensing drugs pursuant to a prescription.
- Medical convenience kits and combination products.
- Sterile water and products intended for irrigation.
Product Tracing Deadlines: Manufacturers

- Traceability requirements (TI/TH/TS) beginning Jan. 1, 2015; also verification, including quarantine, investigation, disposition & notification

- Year 4
  - Serialization/product identifiers
  - Accepting and Responding to Requests for Verification
  - Verification of Saleable Returned Product at Package level

- Year 10 - Unit level tracing (phase II)
Deadlines - Wholesalers

“Product Tracing” requirements - Jan. 1, 2015 (1 yr)
- Verification: quarantine, investigation, disposition, notification
- Authorized trading partners only

Year 6
- Receive and maintain transaction information, (including lot number) electronically
- Only engage in transactions with product identifier/SNI
- Enhanced verification of saleable returns at package level

Year 10
- Unit level tracing (and “pedigree” sunsets)
Interim Product Tracing: Wholesalers

- Direct purchases – if the wholesale distributor purchased directly from the mfr, exclusive distributor, or a repackager that purchased direct, provide a “direct purchase statement”

- Transaction history and information in this case shall not include lot #, initial transaction date/shipment date from the mfr.

- If provided to a wholesaler, any combo of paper, data, package information; if provided to a pharmacy, one document.
Interim Product Tracing: Wholesalers

- Non-direct purchasers provide full transaction information, history and statement to subsequent purchasers.
- If provided to a dispenser – one document;
- If provided to a wholesaler – any combo of self generated paper, electronic data, product packaging.
- If a wholesaler purchases from a direct purchasing wholesaler, the TH starts with the direct purchaser information.
Returns

- Returns from dispenser or repackagers in years 1-6, by agreement between the trading partners
  - Dispensers return saleables to entity from which they purchased
  - Subsequent TH starts with accepting wholesaler

- Enhanced returns – years 6-10, a wholesaler can only accept returns from a dispenser or repackager if they can associate/verify the TI and TS for that product;
  - Subsequent TH starts with the accepting wholesaler and dates need not be included if not reasonable.
Repackagers and 3PLs

- Repackagers are generally between manufacturers and wholesalers and treated similarly to manufacturers
  - Serialization at 5 years

- Third Party Logistics providers
  - No ownership of product by definition, therefore not required to adhere to TI/TH/TS provisions
  - Assumption is that role will be determined by the 3PL and its agent (e.g., manufacturer or wholesaler)
Deadlines - Dispensers

- Traceability requirements– July 1, 2015 (year 1)
  - Receive and capture TI/TH/TS;
  - may have a third party perform this function
  - Verification: quarantine, investigation, disposition, notification

- Year 7
  - Only engage in transactions with product identifier/SNI
  - Lot level investigation of suspect product
  - Investigation including 3 packages or 10% at package level
Systems, Notification, Disposition

- Beginning January 1, 2015, trading partners must maintain systems and processes for investigating and quarantining products that are suspect or illegitimate.
- If a product is determined to be illegitimate, the partner must notify the Secretary and its trading partners, take steps to disposition the product, and, if requested by an appropriate government official, retain a sample.
- Manufacturers, wholesale distributors, dispensers, and repackagers must only utilize “authorized trading partners” beginning January 1, 2015.
Suspect Product

- Suspect Product is a product for which there is reason to believe that such product:
  - Is potentially counterfeit, diverted, or stolen;
  - Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
  - Is potentially the subject of a fraudulent transaction; or
  - Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
Illegitimate Product

- Illegitimate product – a product for which credible evidence shows that the product:
  - Is counterfeit, diverted, or stolen;
  - Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
  - Is the subject of a fraudulent transaction; or
  - Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.
Investigations

- As requested by the Secretary (or other appropriate federal or state official), a trading partner must provide the TI, TH, and TS to the official as part of a recall or investigation of a product that is suspect or illegitimate.

- Manufacturers, wholesale distributors, and repackagers must respond to such requests within 1 business day, but not more than 48 hours. Dispensers must respond to requests within 2 business days.

- Some of what an entity is required or able to produce may depend on the current requirements & timelines.
Important Time Limitations

Record keeping – maintain for SIX years

• Responses to requests from the Secretary in cases of a recall or investigation related to suspect or illegitimate product
  – 1 business day or up to 48 hours
  – Dispensers have 2 business days

Notify Secretary – 24 hrs
Product Identifiers

- Beginning four years after enactment, manufacturers must affix a “product identifier” to each individual package and homogenous case of product. Repackagers must affix product identifiers within five years of enactment.

- A product identifier is a standardized graphic (a two-dimensional data matrix) that carries the product’s standardized numerical identifier (SNI), lot number, and expiration date in both human- and machine-readable format.
Case Level
Individual unit
Package & Individual Saleable Unit

- **Package** -
  The smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

- **Individual Saleable Unit** -
  The smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.
Use of Product Identifiers / SNI

- Beginning four years after enactment, manufacturers must, upon request of other sectors, verify the SNI of suspect products.
- Manufacturers, repackagers, and wholesale distributors must verify the SNI of saleable returns beginning four, five, and six years after enactment, respectively.
- Note the use of Product identifiers including SNI, becomes more robust as time progresses.
Verification

- Verification or Verify – determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.
Exceptions

- The Secretary is required to establish a process for granting waivers and exceptions (e.g., economic hardship exemptions) to the above requirements. Additionally, products already in the supply chain will generally be grandfathered for purposes of the traceability and product identifier requirements.
Phase II – Unit level traceability

- Phase II provisions are *self-effectuating*
- Phase II requirements will go into effect 10 years after enactment
  - Supply chain members electronically trace product at the individual package (unit) level (vs. lot).
  - A series of assessments, public meetings, and at least one pilot program will be conducted over the interim period to develop the precise requirements for, and ensure the technological feasibility of, Phase II.
Licensure

- Establishment of uniform national licensing standards for wholesale distributors and 3PLs
- The Secretary is tasked with issuing regulations to further define those standards. States will continue to license wholesale distributors and 3PLs, but they will be required to do so utilizing the federal standards established.
- In the absence of a state licensing program that satisfies the federal requirements, a federal licensing program will be established to license wholesale distributors and 3PLs in those states.
Licensure

- Categories for wholesaler licensure:
  - Storage and handling of Rx drugs, including facility requirements
  - Recordkeeping
  - Surety bond (and waivers)
  - Background checks for facility managers or designated representatives
  - Qualifications for key personnel
  - Mandatory inspections
  - Prohibited persons – i.e., felons, repeat violations, etc.
Impact on States

- Licensure regulations and adoption process
- Enforcement roles & partnership with FDA
- New reporting requirements for wholesalers and database establishment
- Year one – PDMA current federal minimum as a transition from “pedigree” to “product tracing”
Next steps...

- FDA draft guidance within one year
  - Interoperable electronic data exchange standards for TI/TH/TS
- Licensure standards and adoption
- Transaction information/history/statement exchange –
  - ASN / Invoice / Other
  - One document for dispensers
  - Pre- and post- serialization
- Information/investigation and enforcement expectations from FDA
- Pilots / testing for use of serialization and Phase II
2013 HDMA Map of State Pedigree Legislation/Regulations
As of November 25, 2013

Legend:
- 20: No Legislation or Regulations
- 1: Proposed Legislation
- 8: Enacted Legislation
- 3: Enacted Legislation, Rules In Development
- 18: Final Rules Adopted

States are color-coded based on the status of legislation/ regulations as of November 25, 2013.
We applaud Congress for establishing a national solution to ensure a safer and more secure pharmaceutical supply chain. #1RxSolution
Contact Information

Liz Gallenagh, Esq.
Vice President, Government Affairs
& General Counsel
HDMA

E-mail: egallenagh@hdmanet.org
Phone: (703) 885-0234