Drug Supply Chain Security Act

Public Workshop | May 8-9, 2014

Standards for the interoperable exchange of tracing information for finished, human, prescription drugs

Agenda

DAY 1	Thursday, May 8, 2014	Speaker
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Welcome and Opening Remarks	Dr. Janet Woodcock
9:15 – 10:15 am	Goals of the Workshop Stakeholder Responsibilities Concepts and Terminology	CAPT Connie Jung
10:15 – 10:30 am	Break	
10:30 – 10:45 am	Workshop Logistics	Abha Kundi
10:45 – 12:15 pm	Breakout Session 1 – TI TH, TS Discussion	LCDR Raichell Brown
12:15 – 1:30 pm	Lunch (on own)	
1:30 – 3:30 pm	Breakout Session 2 – Discussion of Supply Chain Options	
3:30 – 3:45 pm	Break	
3:45 – 4:45 pm	Group Summaries of Session 2	
4:45 – 5:00 pm	Closing of Day 1	LCDR Eleni Anagnostiadis
5:00 pm	Adjourn	

DAY 2	Friday, May 9, 2014	Speaker
9:00 – 9:15 am	Welcome & Overview of today	TBD
9:15 – 10:30 am	What we heard yesterday and discussion	CAPT Connie Jung
10:30 – 10:45 am	Break	
10:45 – 11:45 am	Breakout Session 3 – Review and Revise Supply Chain Options	
11:45 – 12:15 pm	Group Summaries of Session 3	
12:15 – 1:30 pm	Lunch (on own)	
1:30 – 2:45 pm	Breakout Session 4 – Fully Electronic	Carolyn Becker
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How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov .
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2014-N-0337.
- Public workshop docket will close on June 9, 2014.
- Stakeholder input essential and valued!

  (Early submissions appreciated)

- *Public workshop webpage:*
  http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm

Goals of the Workshop

- To obtain input from workshop participants on how trading partners can best comply with the requirements for the interoperable exchange of transaction information, transaction history, and transaction statements under the DSCSA on January 1, 2015 using currently available standards or practices.

- To utilize this input to help FDA establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements in paper of electronic format that will be issued in the draft guidance required under Sec. 203 (h) of the DSCSA.

Stakeholder Responsibilities

Product Tracing

- Beginning 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/15) must provide TI, TH, TS to the subsequent owner for each transaction (which change of ownership occurs).
- Transaction documentation consists of:
  - Transaction ***information (TI)***
  - Transaction ***history (TH)***
  - Transaction ***statement (TS)***
- TI includes lot number of product
  (*except for certain wholesale distributor transactions; see slide 9)*

Product Tracing

- **Accepting ownership**

Beginning 1/1/15, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/15) **cannot accept ownership** of a product, unless the previous owner, prior to, or at the time of, the transaction provides TI, TH, and TS for the product

- **Record keeping (capturing and maintaining information)**

– Manufacturers and repackagers shall capture TI (including lot level information), TH, TS for each transaction and maintain such information, history and statement for not less than 6 years (record keeping requirement).

– Wholesaler distributors shall capture TI (including lot-level information as described by the law), TH, TS and maintain for not less than 6 years.

– *Dispensers shall capture TI (including lot-level information, if provided), TH, TS as necessary to investigate suspect product for at least 6 years (record keeping requirement).*

Product Tracing

Manufacturer Specific

Manufacturers -

- Shall provide to subsequent owner TI, TH, and TS, prior to, or at the time of each transaction (transfer of product with change of ownership) of a product, in a single document (paper or electronic).
- Beginning 11/27/17, shall provide TI, TH, TS electronic format.
  Exception: may continue to use paper format to licensed health care practitioners authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course or professional practice.

Product Tracing

Wholesale Distributor Specific (1)

- If a **WD purchased directly** from the manufacturer (M), the exclusive distributor (ED), or repackager (R) that purchased directly from M –
  - "direct purchase statement" becomes the transaction statement for this WD
  - TH and TI are not required to include lot number of product, initial transaction date, or the initial shipment date from the manufacturer as defined in section 582(26)
  - TI, TH, and TS provided to a dispenser shall be in a single document in paper or electronic format
  - TI, TH,TS shall be provided to subsequent WDs, but can be in any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.

Product Tracing

Wholesale Distributor Specific (2)

- If the **WD did not purchase a product directly** from the M, ED, or an R that purchased directly from the M, then prior to or at the time of transaction or subsequent transaction, this WD shall provide to the subsequent purchaser a TI, TH, and TS in paper or electronic format that complies with the initial standards guidance FDA publishes.
- For this WD, the TH will begin with the WD that purchased directly from M, ED, or an R that purchased directly from the M, and this WD will inform subsequent purchasers that it received a direct purchase statement from the WD that purchased directly from M, ED, or an R that purchased directly from the M.

- Shall maintain the confidentiality of the transaction information, history and statement in a way that prohibits disclosure to any person, with a few exceptions (for example, when sharing with State or Federal officials).

Product Tracing

Dispenser Specific

Dispensers (Pharmacies) -

- May enter into a written agreement with a third party, who confidentially maintains the TI, TH, TS on behalf of the dispenser (could be an authorized wholesale distributor).
- Shall maintain a copy of the written agreement.
- Are not relieved of obligations of the dispenser.

Product Verification

- No later than 1/1/15, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements
  - Must be able to respond to verification requests from Secretary about suspect product
  - Quarantine and investigate suspect product to determine if illegitimate product (includes validating applicable TI and TH)
  - Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
  - Respond to notifications of illegitimate product
  - Recordkeeping

Request for Information

When responding to **requests for information** from FDA or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect or illegitimate product,

- **Manufacturers, Wholesale Distributors, Repackager:**

  Shall provide applicable TI, TH, and TS, not later than 1 business day, not to exceed 48 hours after receiving request

- **Dispensers:**

  Shall provide applicable TI, TH, TS not later than 2 business days (or another reasonable time as determined by FDA) after receiving request; shall not include lot, initial transaction date or initial shipment date unless such information was provided; may respond in paper or electronic format; certain limitations to information requests apply until November 27, 2017.

Concepts and Terminology

Concepts and Terminology (1)

The following concepts and terminology are presented for discussion purposes only and do not reflect the position of FDA or an interpretation of the law.

Interoperability	**Interoperability is the ability to exchange information accurately, efficiently, and consistently among trading partners.**
Electronic interoperability	**Electronic interoperability is the ability to exchange information accurately, efficiently, and consistently among trading partners solely using electronic means.**

Concepts and Terminology (2)

Advance Ship Notice (ASN)	ASN is an Electronic Data Interchange (EDI) transaction used to provide the receiving company with advance data on shipments.
Drug Pedigree Messaging Standard (DPMS)	DPMS is a GS1 standard that defines an XML (extensible mark-up language) data format designed specifically to satisfy pedigree requirements.
Electronic Data Interchange (EDI)	EDI is the computer-to-computer electronic communication of purchase orders, invoices, shipment notices, other key business to business messages based on defined industry standards.

Concepts and Terminology (3)

Electronic interoperability	Electronic interoperability is the ability to exchange information accurately, efficiently, and consistently among trading partners solely using electronic means.
Electronic Product Code Information Services (EPCIS)	EPCIS is a standard developed by GS1 that defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.
Interoperability	Interoperability is the ability to exchange information accurately, efficiently, and consistently among trading partners.

Concepts and Terminology (4)

Invoice	Invoice is an itemized bill that identifies the seller/payee and purchaser/payor. Invoices may also contain additional information.
Packing slip	Packing slip is a list of products shipped included with the shipment. A packing slip usually includes the names and addresses of the shipping party and the receiving party as well as a control or tracking number.
Web portal	Web portal is a secure single point of internet access utilized by different stakeholders to deposit and retrieve information.

Workshop Logistics

- This 2-day workshop is designed to be collaborative and solution-focused.
- Participants have been assigned to specific tables to ensure representation of different trading partner and stakeholder groups.
- As such, please remain at your assigned table
- We emphasize this because over the next two days, you and your group are going to work together to develop a solution-focused supply chain option that meets the new FD&C requirements for the interoperable exchange of TI, TH, and TS that begin in 2015
- Each table will have FDA representatives as a facilitator and scribe to aid the discussion and capture participant input
- Information captured will be aggregated and not associated with a specific individual or company.
- Press/Media representatives are in attendance to cover the workshop and have a separate assigned table.

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Workshop Logistics

- Today, during Sessions 1 and 2, there will be discussions about TI, TH, and TS and what tools are currently available to exchange this information, and we will end with brief summaries from each table on their supply chain option.
- Tomorrow, before Session 3, we will summarize the options that we heard on Day 1 and allow for questions and discussion.
- Session 3 will allow each table to consider revising their option if desired.
- At the end of tomorrow, we'll have time as a group to discuss any issue or part of the workshop.

Workshop Logistics: Discussion Tips

Think 'outside the box'
Consider different approaches

- **No complaining**
- **Be solution-focused**

Don't disregard an idea

- Initially consider all ideas as good ideas
- Build on someone's idea to make it better

Evaluate ideas *after* brainstorming

- **Be open to others' opinions**
- **Add your thoughts – each perspective is important**
- **Focus on a workable solution**
- **Options should not be product- or service-specific**

Breakout Session 1: TI, TH, and TS Discussion

Goals:

- To identify definition related issues that may require FDA clarification and/or guidance.

- To identify challenges to exchanging transaction information (TI), transaction history (TH), and/or transaction statement (TS) that any category of trading partners faces.

Transaction Information, History, & Statement

Transaction Information (TI):

- Proprietary or established name or names of the product;
- strength and dosage form of the product;
- NDC number of the product;
- container size;
- number of containers;
- lot number of the product;
- date of the transaction;
- date of the shipment, if more than 24 hours after the date of the transaction;
- business name and address of the person from whom and to whom ownership is being transferred.

Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

Transaction Statement (TS): A statement, in paper or electronic form, that the--

- entity transferring ownership in a transaction is authorized as required under DSCSA;
- received the product from a person that is authorized as required under DSCSA;
- received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- did not knowingly ship a suspect or illegitimate product;
- had systems and processes in place to comply with verification requirements under the law;
- did not knowingly provide false transaction information; and
- did not knowingly alter the transaction history.

Breakout Session 1: Thought Starters

1) Are the required data elements of transaction information (TI), transaction history (TH), and transaction statement (TS) adequately described in the statutory definitions? **If not, please:**
   a. Identify each ambiguous term and explain the perceived ambiguity.
   b. Propose an interpretation of the ambiguous term and reasons why you believe your interpretation will best serve the collective goal of all trading partners to exchange TI, TH, and TS through the supply chain.

2) For the trading partner category that you represent, do you perceive any challenges to fulfilling the specific statutory responsibilities to receive (in-bound) or transfer (out-bound) TI, TH, and/or TS? **If yes, please:**
   a. Identify each perceived challenge.
   b. Explain what you believe is needed, consistent with the statute, from other trading partners and/or FDA to overcome this challenge.

(Note: Proposals to change the statute are beyond the scope of this discussion.)

Breakout Session 2: Supply Chain Options

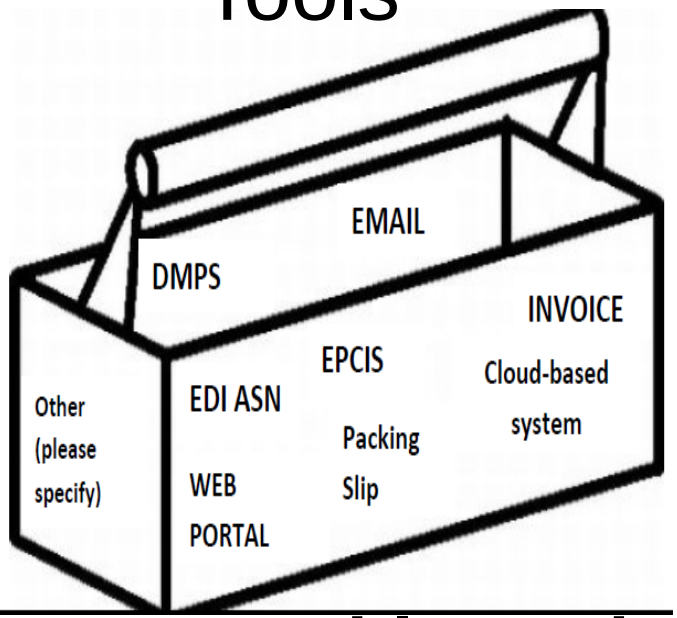
Goals:

- To explore possible options for trading partners to exchange of TI, TH, and TS, as required by the statute beginning on January 1, 2015, using established drug supply-chain "tools."

- To have a workable supply chain option to present to the larger group.

Breakout Session 2: Supply Chain Options

Trading Partners (M, R, WD, D) + Tools =



Options for Interoperable Exchange of TI, TH, and TS

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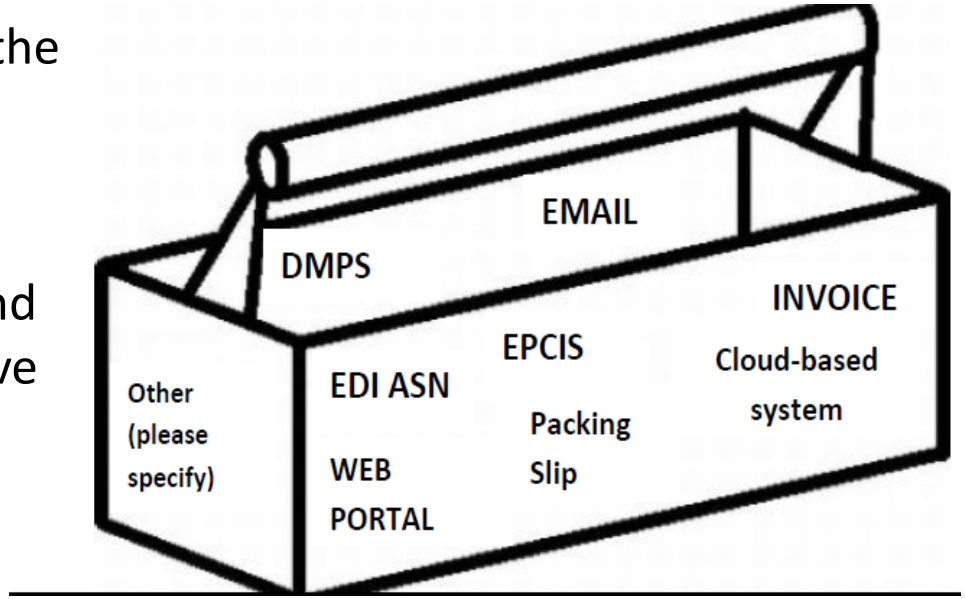
Breakout Session 2: Discussion of Supply Chain Options

Using any combination of tools in the toolbox assembled for you below and the diagram of trading partners within the supply chain located on your tables, develop **HOW** manufacturers, repackagers, wholesale distributors, and dispensers can accomplish the collective goal of exchanging TI, TH, and TS from the first to the last trading partner of a given transaction as required by the statute. Use the diagram to illustrate your option if needed.



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