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DSCSA 2023: A Look Ahead to Enhanced Traceability Requirements

Tuesday, February 14, 2017
3:00 PM–4:00 PM (Eastern)
Welcome

Anita Ducca
Senior Vice President, Regulatory Affairs
Healthcare Distribution Alliance (HDA)
Before we get started...

• Today’s webinar is being recorded.
• All participant lines are muted.
• Presentation and audio-replay will be made available by Tuesday, February 21.
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This webinar is sponsored by:
Panelists

Anita Ducca, Senior Vice President, Regulatory Affairs, HDA

Elizabeth Gallenagh, Esq., Senior Vice President, Government Affairs and General Counsel, HDA

Tish Pahl, Principal, Olsson Frank Weeda Terman Matz PC

Brian Waldman, Partner, Arent Fox LLP
HDA Traceability Website

• The HDA Pharmaceutical Traceability Website
• FDA Drug Supply Chain Security Act (DSCSA) Website
• Finally, we urge you to check with your own trade associations or professional societies for additional DSCSA information
Purpose and What We’ll Cover

• Reach a common understanding of the DSCSA’s 2023 “Enhanced Drug Distribution Security” requirements, focusing on §§ 582(g) and (k)

• Discussion will include:
  – DSCSA requirements in 2023
  – What it means for the supply chain, FDA, and others
  – Legislative negotiations and Congress’ intent
  – And more
Why Look So Far Into the Future?

- 2019 systems development already underway
- Some want to modify 2019 systems to use in 2023
- Critical: understand requirements before designing pilots; pilots must start years before 2023
- FDA also looking at 2023 pilots
“10 years after the date of enactment... interoperable, electronic tracing of product at the package level requirements shall go into effect:”

“(A) The [TI] and the [TS] as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under [FDA guidance]...” The FDA guidance shall:

– Define circumstances when the supply chain may “infer the contents of a case, pallet, tote, or other aggregate...” without opening the container

– Identify methods/processes to enhance secure tracing, verification, inference and aggregation, etc.
2023 - Sections 582(g)(1)(B) and (C)

“(B) The [TI] required under this section shall include the product identifier at the package level for each package...

“(C) Systems and processes for verification... at the package level, including the standardized numerical identifier, shall be required in accordance with [FDA standards]... pursuant to [the DSCSA’s specifications for the guidances]” such as

- Suspect product risk scenarios, a process for identifying/determining suspect products, and a process to terminate notifications,
- Unit level tracing,
- Standards for interoperable data exchange,
- May include the use of aggregation and inference as necessary.
“(D) The systems and processes necessary to promptly respond with the [TI and TS]...” upon the Secretary’s (FDA) or other appropriate official’s request “… in the event of a recall or [to investigate] a suspect product or an illegitimate product...”
“(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the [TI] for each transaction going back to the manufacturer, as applicable, shall be required—”

- In the event of a request by FDA or other official for a recall or investigating a suspect or illegitimate product; or
- In the event of a request by an authorized trading partner to investigate a suspect product or assist FDA or other appropriate official in the event of a recall or suspect or illegitimate product investigation

“(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the [product’s TI and TS]...”
“(k) Sunset- The following requirements shall have no force or effect beginning [in 2023]:

(1) The provision and receipt of [TH] under this section.”
Focus Points

• Verification
• “Facilitate gathering”
• Inference and aggregation
• Preemption
Discussion and Questions
Verification Questions

What does “Verification” mean?
Definition of “Verification” § 581(28)

“The term ‘verification’ or ‘verify’ means 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...by the manufacturer or the repackager...”
Verification, Continued

When is a member of the supply chain required to “verify” the identifier?

Do the verification requirements apply to pharmacies and other dispensers?
Verification, Continued

What was the underlying purpose of having such a requirement in the DSCSA?

Why did Congress set up the verification requirements as it did?
“Facilitate Gathering” Questions

What does it mean where the legislation says that a trading partner must “facilitate gathering” the TI and what is the trading partner required to produce?
“(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the [TI] for each transaction going back to the manufacturer, as applicable, shall be required—”

• In the event of a request by FDA or other official for a recall or investigating a suspect or illegitimate product; or

• In the event of a request by an authorized trading partner to investigate a suspect product or assist FDA or other appropriate official in the event of a recall or suspect or illegitimate product investigation
Why did Congress let the TH sunset after 2023?
“Facilitate Gathering” Continued

Can FDA or a trading partner request the data at any time?

If we do not have to produce the entire TH, is the 2023 model going to be sufficiently protective?
Pathway to 2023 Enhanced Traceability

- **Nov. 27, 2013**
  - DSCSA Enactment

- **2015 (2016)**
  - Manufacturers affix product identifiers
  - Verify returns before resale
  - Additional measures

- **2017**
  - Repackers affix product identifiers
  - Verify returns before resale
  - Additional measures

- **2018**
  - WDs only transact in products with identifiers*
  - Additional measures

- **2019**
  - Dispensers only transact in product with identifiers*
  - Additional measures

- **2020**
  - WD licensure reporting (3PLs in 2014)
  - ATP requirements

- **2023**
  - Unit level traceability

* Unless grandfathered
Inference and Aggregation Questions

What does the DSCSA say about inference and aggregation?

Can FDA require inference or aggregation?
If FDA can’t require aggregation, why did Congress include it in the DSCSA?
Preemption

What does the legal research say about the DSCSA and “Preemption”?
What is actually happening among the states regarding the DSCSA requirements?
Audience Questions
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HDA Distribution Management Conference and Expo
March 5 – 8, 2017 | Palm Desert, Calif.
http://www.hda.org/events
Contact HDA

Anita Ducca
aducca@hda.org
(703) 885-0240

Elizabeth Gallenagh, Esq.
egallenagh@hda.org
(703) 885-0234
Thank you