

AmerisourceBergen Contribution to the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting

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Accomplishments

To date

- Rx product is moving through the supply chain.
- We are receiving and transmitting the required transactional data with little or no issues.
- We have worked closely with dispensers and pharmacies to ensure understanding of the federal requirements and committed to training on how to access the required transactional data.
- We continue to work closely with industry partners to ensure alignment and avoid confusion on expectations. (FDA, PDSA, HDA, GPhA, NACDS, PhRMA, GS1 Global and GS1 US.



Readiness

AmerisourceBergen's work to date

- Participated in HDA Pilot – Results to be Delivered in November 2016.
- AmerisourceBergen conducted it's own 2015 pilot activity.
 - Pilot Objectives:
 - > Understand serialized processes.
 - > Test technical capabilities.
 - > Measure impact to operations.
 - > Data or shipping errors of products.
 - Scope and Timing:
 - > 4 AmerisourceBergen distribution centers (Specialty and Drug Distribution).
 - > 4 Rx Manufacturers engaged (aggregating) 40 serialized SKUs.
 - > 4 Weeks of “live” operations.
 - > Happy path.

What We Learned

What we are doing

- What Worked?
 - Executed end to end process flow.
 - Coordination and execution with our partners.
 - Captured 750,000 EPCIS Events.
- What Were The Bumps?
 - EPCIS Data Exchange.
 - Some scanning challenges.
- What Did We See?
 - Not all labeling is equal.
 - Operational impacts significant.
 - Exceptions WILL be a challenge.
 - Data exchange... Test. Test. Test.

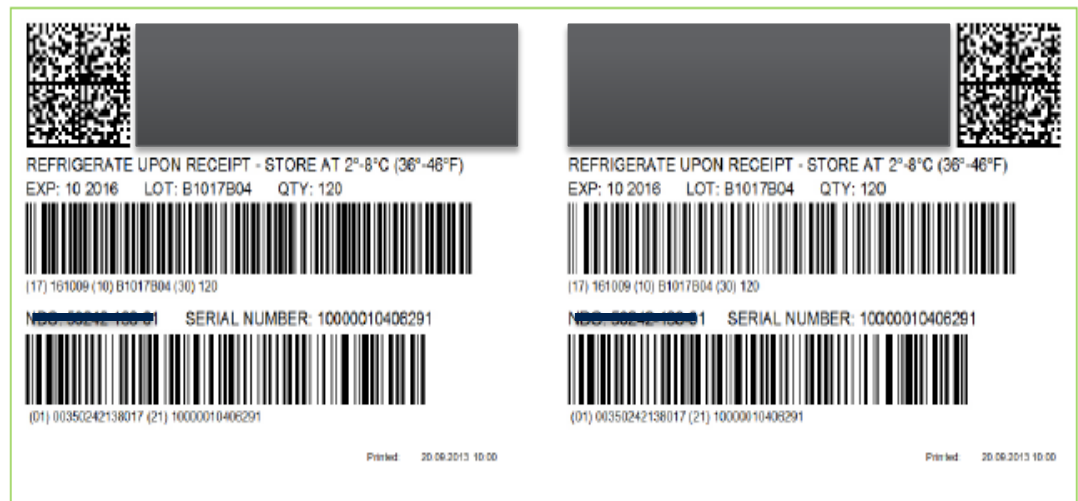
Moving to a Serialized World

Lesson's learned from AmerisourceBergen's 2015 serialization pilot



Serialized data in vulnerable position on packaging

Proposed HDA Label Guidance Revision



AmerisourceBergen 2015 Pilot

Other serialized labeling challenges



What label should we scan?



Unable to scan: Reflective glare.



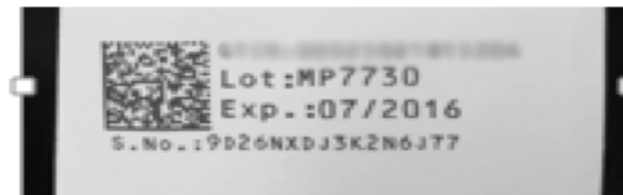
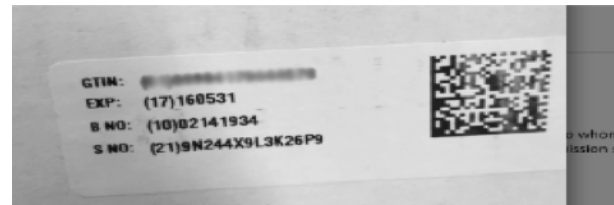
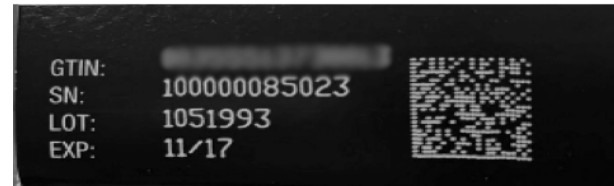
Moving to a Serialized World

Product labeling: Good examples

Encoded to GS1 Standards
Human readable (HR) close to 2D →
Clear identification of HRI

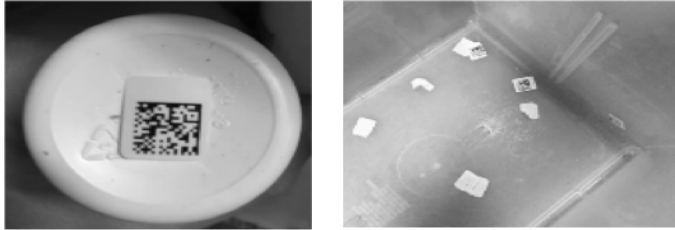


Sealed “Each”
Eliminates potential returns issue

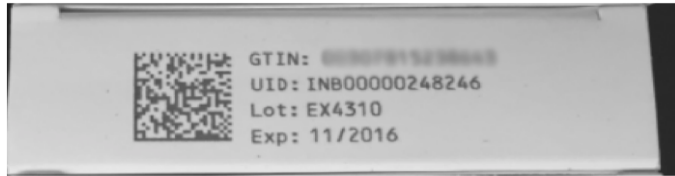


Moving to a Serialized World

What are we seeing on a larger scale?



Incorrectly coded barcodes.
Barcodes falling off.
Missing Human Readable.



What is a UID?
(Yes, it's the serial number.)



Incorrectly coded GS1 barcodes.
Using NDC instead of GTIN.

AmerisourceBergen Serialization Activities

What's next

- AmerisourceBergen Services:
 - Working with the manufacturers on assessing barcode readability.
 - > Ensuring proper grading and quality inspection of 2D barcodes at the point of packaging.
 - Supporting dispensers and pharmacies with daily DSCSA activities.
 - > Fielding approximately 100+ questions.
- AmerisourceBergen 2017 Pilot focused on Serialized Exceptions:
 - 4 Distribution Centers (Specialty and Drug Distribution).
 - 12 Manufacturers engaged, 50-100 serialized SKUs.
 - Focus on measuring and developing a process to resolve exceptions:
 - > Data, no Product.
 - > Product, no Data.
 - > Packaging / Labeling Issues.
 - 8 weeks of execution starting mid-January 2017 through March 2017.

Challenges and Opportunities

Pressing issues

■ United States:

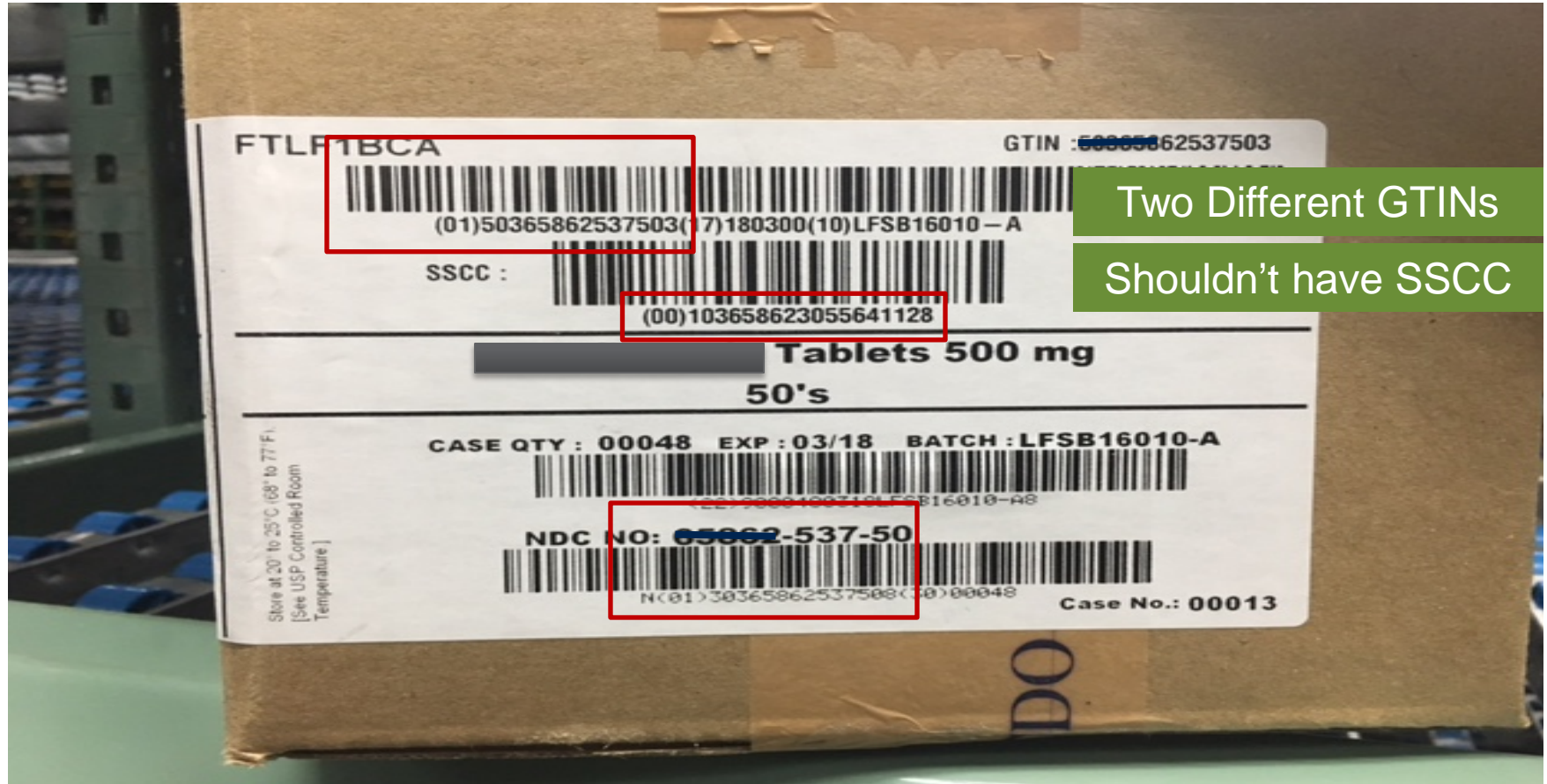
- Handling 340B transactions.
- Borrowing and loaning of Rx products between dispensing entities.
- Aggregation and Inference.
- Preemption concerns continue as States struggle to understand Federal requirements.

■ International:

- India: Export serialization requirements are not consistent with DSCSA requirements.
 - > Product identifiers not represented in the same manner, multiple product identifiers being applied, aggregation at various levels inconsistent between regulations.
 - > Industry meeting tentatively planned for the first quarter 2017 to outline the commerce concerns of the conflicting regulations.

India: Impact on U.S. Supply Chain Management

Tertiary and secondary GTIN on same homogenous case



- Per SNI and GS1 Standards: you can have only one GTIN per current trade item.
- SSCC contained on case that was not a logistic unit.

Thank You

You can contact us at:

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reach and partnership
shape healthcare delivery.