Q: What is the procedure to return products without EPCIS data?

A: Policies & procedures may vary somewhat once the decision is made to return product without supporting package level TI & TS detailed in an EPCIS file. Typically though, the process starts with the supplier issuing a return call tag to be applied to the logistical containers to get the product returned to the shipper.

Q: How do you destroy a serial number of damaged products?

A: The DSCSA does not specifically call out this as a requirement so it's a business decision. That said, "destroying" a serial number would be accomplished using the de-commission event. If using EPCIS guideline 1.2 see: https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Guideline-Implementation-Guideline-Applying-GS1-Standards-for-DSCSA-and-Traceability-R12.pdf , if using guideline 1.3, use: https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Applying-GS1-System-of-Standards-for-DSCSA-and-Serialized-Interoperable-Traceability-R1-3.pdf

Q: What does the date in the EPCIS file need to be when an event is observed? The date the event happened or the date it was observed?

A: EPCIS Implementation guide v 1.2: https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Guideline-Implementation-Guideline-Applying-GS1-Standards-for-DSCSA-and-Traceability-R12.pdf , section 8.2.1 gives rules for assigning event date & time. Likewise, version 1.3 does the same: https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Applying-GS1-System-of-Standards-for-DSCSA-and-Serialized-Interoperable-Traceability-R1-3.pdf , also, sec. 8.2.1 , also quoting the DSCSA regarding transaction date/versus actual ship date: FD&C Sec. 581, ``(26) Transaction information.--The term `transaction information' means-- ... `(G) the date of the transaction; (H) the date of the shipment, if more than 24 hours after the date of the transaction; having cited all this, it's best to have "observed" the date something happened as close to actual data & time as possible/practical/reason although note EPCIS gives some flexibility so longs as events occur in the correct chronological order as the guide emphasizes to prevent out of sequence file rejection errors.

Q: As a distributor how do I meet DSCSA requirements when shipping into a 340B contract pharmacy which services multiple covered entities?

A: The 340b covered entity is the party taking ownership of the product. As such, the file at a minimum needs to be addressed & sent to them or the DSCSA software service provider they use . If you have written authorization from each covered entity to send to a common contract pharmacy, you need to still send/forward separate files to the contract pharmacy. Specify the contract pharmacy's sGLN in the StandardBusinessDocumentHeader receiver ID when authorized by the covered entity. If you are physically combining both 340b and non-340b product transacted into a single tote, consider some sort of segregation mechanism such as stickers or slip sheets to segregate transacted product. Do not attempt to combine separate 340b transactions into a single file to provide to the covered entity or contract pharmacy.

Q: How will most be handling "Grandfathered" products?

A: It depends on is meant by the term "grandfathered product" in your question. Grandfather product historically referred to product that was packaged before then end of FDA's PI enforcement discretion: https://www.fda.gov/media/109591/download , there are certain very limited products with long shelf lives that might still be considered grandfathered, check with the manufacturer regarding specific product dating/grandfathering. if you are referring to product introduced into commerce by the manufacturer/repackager before the end of FDA stabilization period: https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems , then we refer to this as transitional inventory, NOT Grandfathered Product. See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhanced-drug-distribution-security-requirements-under-section-582g1-federal-food-drug-and-cosmetic

Q: What advice do you have for small businesses to manage the financial and operational challenges posed by the DSCSA while remaining compliant and competitive in a market where larger businesses with more resources can absorb the costs and complexities of DSCSA compliance?

A: One set of tasks you can do is thoroughly review the law and all guidances applicable to the class of trading partner you are(manufacturer/repackager, wholesale distributor, dispenser) issued by FDA. As always, we recommend seeking legal/regulatory counsle help where clarification is needed. Armed with this knowledge, you will be in a better position to know what you will need and what you don't.

Q: Our company is considered as ""MAH - Manufacturer Authorized Holder"". We have shipped few products, one of our customers (Distributor) identified one SGTIN(Child) is not in EPCIS files. Then we re-checked in our repository, This SGTIN is not in our system and asked our CMO about this SGTIN. CMO

Confirmed that this GTIN in De-Commission status, but Quality is good & verified successfully. and CMO mentioned While packaging Child SGTIN to Shipper case, Packed De-commissioned SGTIN instead of Commissioned SGTIN, It's exceptional case and changing process. The issue is customer asking updated EPCIS Files with correct SGTIN. Based on CMO Inquiry, SGTIN is not illegitimate. Please let me know how to handle these exception issues.

A: Any EPCs in a list as part of a packing event must be in a commissioned status. To prevent further exceptions of this type, validate each EPC in a list for that packing event making sure each one is commissioned with disposition: active.

Q: What is the current state of handling Exceptions using GS1's standard for 'Error Declaration'. Are any solution providers supporting this, and has GS1 promoting the usage of this structure for handling exceptions?

A: Companies that offer DSCSA EPCIS based compliance systems or other trade partners that developed in-house systems largely have not built void shipping and error declaration into their systems. This is a case of a standard offered to industry that was not adopted for use. GS1 is publishing an EPCIS exception technical guide that uses widely adopted existing EPCIS coding to address the most common types of exceptions. This guide is expected to be published late Q3 or early Q4 of this year.

Q: When distributor/wholesaler constructs EPCIS xml for downstream partner, Should they need to include the events in that occurred in upstream partner(Manufacturer)? specially case to Pallet aggregation event that occurred in Manufacturer/CMO location? or should Distributor/wholesaler mention the aggregation and disaggregation happened in their custody alone?

A: It would depend on the nature of the transaction you had with a given downstream trade partner. If you are transacting manufacturer sealed homogeneous cases, then yes full commissioning and packing aggregation data as supplied from the manufacturer at the case level would need to be passed onto your downstream trade partner. If you are transacting shrink-wrap sealed pallets received from a manufacturer to a downstream trade partner, it may be convenient to simply leave the package to case, case to pallet aggregation also in place and simply forward onto your trade partner with accompanying master data, SSCCs, biz transaction list, etc. as applicable. If however, you are filling a loose pick order of single packages of a given product into a tote with other products from that and other suppliers then, using epc lists wherever possible, simply list the commission events for those packages, then aggregating all products in the tote to an SSCC-18. Your decision as to whether to perform disaggregation during receiving/putaway is largely a business/technical decision. Obviously, if your implementation requires it, you may need to de-aggregate cases from pallets, and packages form cases, where it requires them during receiving/putaway steps.

Q: The FDA standard is a 5-4-2 format: FDA_NDC_11. However, some of our wholesalers are using the 5-3-2 format. Is there a way for the systems to reconcile the two or do they have to change to the 5-4-2 format?

A: Actually, there are three distinct syntax formats for the 10 digit NDC structure: 4-4-2, 5-3-2, and 5-4-1. While FDA acknowledges the existence of the 5-4-2 format used by other entities, FDA only references the 10 digit length. Since EPCIS implementation guide 1.2 requires the 11 digit NDC, you should be getting an 11 digit NDC in your 1.2 version files though some system implementations might not validate this. If you are getting only the 10 digit and need the 11, I would follow up with your wholesaler.

Q: I work for a wholesale distributor that services mainly small clinics. We opted to use customer numbers versus GLN numbers due to the fact that many have been enumerated multiple times. Since there is no one official GLN, and many aren't public, this was our work around. Has GS1 or anyone else made progress on cleaning those up? How long will we be able to continue using a customer number when the spirit of DSCSA is to use GLN/SGLN?

A: Actually, the DSCSA does not specifically require the use of GLNs. The GLN was determined by GS1, working with industry, as being the ideal standards-based location identifier to use when passing on EPCIS files to subsequent trading partners given the encoding requirements of sGLNs into EPCIS schema 1.2, used in implementation guidelines 1.2 & 1.3. From what you describe, your solution is making package level TI & TS data available to your small clinic customers via a portal, presumably rendered there in some other format besides EPCIS allowing for the use of your internal system account numbers. As such, you are not passing on EPCIS files and can use an alternative location identifier as you see fit. It is not known when the GLN registry will get updated with most duplicates removed though the intent is to get as close as practical to a good clean registry before this November. As with any master system, it will require constant attention to keep current well into the future. We recommend contacting GS1 if you have further questions.

Q: How are 3PLs/ MFGs dealing with mis-shipments involving PROD EPCIS?

A: It depends on what caused the miss-shipment. A carrier induced miss-shipment would either have the carrier re-route the product where intended or if not feasible, returned to the shipper with a return call-tag issued by the supplier/shipper. If miss-shipment went to the correct legal entity but landed in the wrong warehouse, trading partners may make a business/technical decision as to getting ship-to location data corrected if feasible/needed for business/tech reasons, accepting both data and product as is, or returning the product with a supplier issued return call-tag.

Q: All collaboration and testing takes time… What do you think is the drop-dead date for manufacturers to participate in end-to-end testing? September? October?

A: Interoperability testing of the VRS messaging standard has largely been completed for the service providers that offered services as of mid-2023. New entrants into the VRS network should plan to go through the same testing protocols to assure their systems function as required. Ideally, a system should be fully tested and in production a month in advance of the end of the stabilization period, 11/27/24 to allow for any undetected software defects.

Q: When adjusting a GLN what fields can be modified?

A: It's probably best to steer you to this GS1 webpage. It gives you everything you would need to know in managing GLNs. For your specific question, you probably need to scroll down to section 3, GLN management rules but I recommend book marking the entire site: https://www.gs1.org/standards/gs1-gln-allocation-rules-standard/current-standard#1-Introduction

Q: Where does the state license details fall into this picture? I assume that fits into DSCSA requirements as well? What is recommendation on getting these details and tying to GLN?

A: In your account master data, it may be necessary to have two user defined reference fields (assuming your database does not already have place holders the two), one housing GLN, and the other the state license. To my knowledge, state license number is.