



California State Board of Pharmacy

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DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

E-Pedigree Committee

Randy Kajioka, PharmD, Chairperson

Shirley Wheat, Public Member

Ryan Brooks, Public Member

Rosalyn Hackworth, Public Member

Amy Gutierrez, PharmD

Deborah Veale, RPh

Report of the E-Pedigree Committee Meeting on June 24, 2013.

a. Next Scheduled Meetings of the E-Pedigree Committee for the Remainder of 2013 Have Been Set

- September 26: Southern California
- December 10: San Francisco

b. Presentation by TechN'Arts

Turkey has implemented a unit serialization e-tracking system for prescription drugs, according to parameters similar to California's requirements. During the June Meeting, Taha Yayci provided an overview of the requirements of Turkey's system, and how the system was implemented and has operated. This presentation was provided via Skype, a new board first, and the board has preserved a recording of the presentation on the board's Web site.

During the July board meeting, Mr. Yayci will provide a similar presentation. At the time this packet is being prepared, it is not certain whether this presentation will be in person or done via Skype. Mr. Yayci has indicated his strong interest in attending a future meeting of the board in person, either at this meeting or the next e-pedigree committee meeting in September.

The minutes of the June meeting provide a summary of the presentation and comments made by Mr. Yayci.

c. Discussion Regarding Comments Submitted by the Board of Pharmacy in Response to Federal Legislation in April 2013

Attachment 1

In April different versions of federal legislation to provide supply chain security were introduced in both the House of Representatives and the Senate. In May, the House passed its version. In the Senate, the Senate HELP Committee has passed its bill but the full Senate has not voted on this

matter yet. If the Senate passes the bill pending there, the matter will go to a conference likely in the fall committee to resolve the differences.

At the request of President Weisser, the board submitted comments to both houses on their legislation. Copies of these letters are provided in **Attachment 1**.

The Senate version of the bill that is still pending a final vote there also contains provisions dealing with pharmacy compounding, and provisions dealing with when a pharmacy's compounding would be subject to FDA regulation. There is nothing in the House bill that was passed that deals with compounding. This is another area that will need to be worked out federally.

d. Update on the Status of Pending CA Regulations on Requirements for the Serialized Numeric Identifier, Reporting the 50 Percent of Products Serialized by January 2015 and the Remaining 50 Percent by January 2016, and "Grandfathering" Parameters for Unserialized Products in the Supply Chain – 16 California Code of Regulations Section 1747. -1747.1

Attachment 2

At the February Board Meeting, the board held a regulation hearing and approved regulation requirements for the following items (the specific language is provided in **Attachment 2**):

1. The serialized numeric identifier (section 1747)
2. The process for advising the board how a manufacturer will reach the 50 percent of its products that will be sold in California after January 1, 2015, and the remaining 50 percent by January 1, 2016 (section 1747.1)
3. How to designate unserialized product that may exist in the supply chain after the staggered implementation dates (section 1747.1).

The rulemaking file was prepared and submitted to the Department of Consumer Affairs in early April. It was approved by the State and Consumer Services Agency mid-July. The board is now waiting for the Department of Finance to complete its review. After this review is completed, the rulemaking file will be submitted to the Office of Administrative Law, which has 30 working days to review the file. We hope to have the review process fully completed by September. The board's staff has been nudging agencies to help speed the review of these important requirements.

In recent months, Executive Officer Herold has been providing webinars on California's e-pedigree requirements and timelines. A number of questions asked during these presentations focus on provisions in these regulations especially those dealing with the 50 percent of product that must be compliant by January 1, 2015.

e. Discussion on GS1 Healthcare US's Implementation Guideline *Applying GS1 Standards to US Pharmaceutical Supply Chain Business Processes, Release 1.0*

Attachment 3

At the board's last e-pedigree meeting, GS1 presented their new implementation guideline. This guideline was agendaized for discussion at the June meeting to ensure interested parties were aware of and able to access this information. Although it takes about 100 pages to lay out the standards,

the material is valuable in providing considerable background about tracking and tracing in the pharmaceutical supply chain.

During the June meeting, Bob Celeste of GS1 provided a presentation on how the EPCIS can be used to support California pedigree requirements. The presentation has been attached at the back of the June meeting minutes.

Following the presentation, Mr. Celeste responded to questions. He answered that GS1 Global worked with Turkey on the successful implementation of their track and trace system. He added that it is important to work towards a standardized way of tracking products through the supply chain on a global scale.

A number of implementation issues were discussed in a question and answer period by Mr. Celeste and the committee members. A description of this discussion is provided in the meeting minutes. Many of the questions dealt with closing out a pedigree at the end of life of the product and detection of counterfeit products in a serialized tracking system.

Chair Kajioka asked that board staff identify end of life scenarios and proposals for the committee to vet-out as a precursor to a future rulemaking on closing out a pedigree, which is recognized as being a key component to effective tracking and tracing systems aimed at detecting adulterated or counterfeited drugs.

f. Update on Proposed Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163

Attachment 4

At the June meeting, the committee discussed work on the proposed regulation language for inference.

Background:

Since July 2012, the board has several times released written requests for specific comments needed to develop possible regulations to authorize inference. Until the March e-pedigree meeting, the board received only a few comments directly responsive to these requests. The initial comments provided by the supply chain are available in the meeting materials for the December 4, 2012 Meeting Materials of the Enforcement Committee:

<http://www.pharmacy.ca.gov/about/meetings.shtml#enforce>

At the March Enforcement and E-Pedigree Meeting, draft language was released for discussion purposes to develop the regulation language for inference. A copy of this proposal is provided as **Attachment 4**.

Following the March meeting, the board received additional comments specific to the draft language released. These comments are also provided in **Attachment 4**.

During the June meeting, the committee considered inference requirements. There was general discussion about the written comments received on the draft requirements that were prepared by staff. These proposed provisions were intended for discussion. Staff recommended that the

committee and board determine the direction for the regulation so that it can be finalized by the October board meeting.

The committee asked that comments be integrated into the text of the regulation for easier committee review. Staff are completing this integration as the board packet is being compiled. These materials will be released as a supplement to the board packet once they are ready, and before the July board meeting.

July Board Meeting:

The committee encourages a discussion by the board on the elements for this first regulation on inference. Especially critical for the immanent January 2015 and 2016 serialization deadlines is the inference that may be used between the manufacturer and the wholesaler.

The regulation proposes that inference may be used on a homogeneous case of product, shipped in a sealed container from the manufacturer to a wholesaler. The manufacturer and wholesaler must have trusted trading partner relationship that ensures a positive track record of the ability of the manufacturer to accurately aggregate the specific serialized items in the case.

Once a wholesaler opens the case, each item in the case must be scanned and pedigree of the item appended. If a sealed case is shipped through the wholesaler without being opened and the seals on the box remain intact, the case can continue to be inferred until it is finally opened by a downstream partner (each item within the case does not need to be independently scanned).

g. Discussion Concerning Possible Regulation Requirements on the Certification Process Needed to Comply with California's E-Pedigree Law

Attachment 5

Just as discussed in item f above, at the March Enforcement and E-Pedigree Meeting, the board distributed possible regulation language for the certification of each sale and purchase into the e-pedigree record.

A copy of the certification proposal is provided in **Attachment 5**. Also included in this section is proposed language for a regulation to specify board access to e-pedigree information during inspections.

Written comments submitted following the March meeting that pertain to these proposals are contained as part of the comments provided in **Attachment 4**.

Again, board staff will integrate the comments received into the proposed regulation. These comments will be available before the July board meeting.

The committee requests comments from the board during the July meeting on the future direction of the proposed regulation elements.

Staff believe that the largest issue that the board needs to resolve with this certification proposal is what the party is actually certifying to. In other words, to what level of information are they verifying or confirming as true or correct for the next recipient of that product.

h. Discussion and Possible Action Concerning Possible Regulation Requirements on the Use of Drop Shipments in an E-Pedigree System

Attachment 6

The committee is also working on the process by which drop shipments will be addressed in the e-pedigree system. The reference in California's Business and Professions Code with respect to drop shipments is provided below.

4163.1. Drop Shipment by Manufacturer

- (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:
 - (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.
 - (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.
 - (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.
- (b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

In February, the board released a request for comments on drop shipments. One comment was received before the March Enforcement Committee Meeting (see **Attachment 6**).

During the March committee meeting, the committee saw a PowerPoint presentation about drop shipments prepared by HDMA. (An excerpt of the minutes of this meeting and the HDMA PowerPoint are provided in **Attachment 6**.)

During the June meeting, the committee continued its discussion about this topic and determine its policy on drop shipments.

Board staff has not drafted a regulation proposal. The proposal submitted as part of the February request for comment from John Valencia is:

"For the purposes of Business and Professions Code Section 4163.1, when a manufacturer utilizes the "drop shipment" means of sale for a dangerous drug product as defined by that section, only those entities involved in the physical handling, distribution, or storage of a dangerous drug product, are required to provide or receive the "pedigree" required by Section 4034. Any entity, including but not limited to a wholesale distributor, that is not involved in the physical handling, distribution, or storage of the dangerous drug product sold by means of "drop shipment," is not required to provide or receive a pedigree for that dangerous drug product, [even if such entity holds legal title to the dangerous drug product]. For purposes of this section, facilitating the distribution of a product by providing various administrative services, including processing of orders and payments, [even if holding title,] shall not, by itself, be construed as being involved in the physical handling, distribution, or storage of a product."

During the meeting the committee discussed various items related to this draft. Supervising Attorney Joshua Room agreed to modify the language and bring the new version to this board meeting. The revised proposal will be added to the supplemental board packet once we receive it.

If the language is acceptable to the board, the board may wish to approve this language for release as a proposed regulation.

i. Minutes of the June 24, 2013 E-Pedigree Committee Meeting

Attachment 7

ATTACHMENT 1



April 26, 2013

Transmitted via email to drugdistributionsecurity@help.senate.gov

Senator Tom Harkin, Chairman, Committee on Health Education Labor & Pensions

Senator Lamar Alexander, Ranking Member, Committee on Health Education Labor & Pensions

Senator Michael F. Bennet, Member, Committee on Health Education Labor & Pensions

Senator Richard Burr, Member, Committee on Health Education Labor & Pensions

RE: FEDERAL EFFORTS TO SECURE DRUG DISTRIBUTION SECURITY
Comments of the California State Board of Pharmacy
*Draft Proposal to Improve Drug Distribution Security – released/posted for stakeholder
comments April 19, 2013; comments due to the above by April 26, 2013; 6:00 p.m.*

Dear Chairman Harkin, Ranking Member Alexander, Senator Bennet, Senator Burr,
members of the Committee and the Drug Distribution Security working group:

I write on behalf of the California State Board of Pharmacy (Board). We thank you for this opportunity to submit written comments on the Draft Proposal to Improve Drug Distribution Security (“DDS Draft”), made available on April 19, 2013. We recognize and appreciate how much effort has gone into developing this bipartisan proposal, which has addressed many of the difficult questions that were raised by the November 2012 draft, and which is improved since the November 2012 draft. We also recognize and appreciate that the DDS Draft was clearly written with California’s interests in mind, and thank the entire working group, particularly the members of the California delegation in both houses, for considering and promoting California’s unique but shared perspective, and for our collaborative relationships. We have been pleased to work closely with the staffs of the committees and the members, and this has been gratifying.

We will reiterate herein some of what has been expressed in our prior comments, but will try to be as brief and direct as possible in addressing the particular legislative proposal now under consideration. Because we refer to some of the points raised in our longer set of comments dated November 7, 2012, a copy of those comments is enclosed and incorporated by reference.¹

¹ We have tried to keep these comments succinct. Given the time constraints, and the number of comments we expect you will receive, we have not attempted to make this document comprehensive. Instead, we look forward to the ongoing opportunity to engage with you on the details. Also, many of the comments submitted in our November 7, 2012 letter remain applicable, so we refer you to that document. To the extent possible, we ask that you not treat these comments as exhaustive, that we be allowed to communicate any later-realized comments to the working group in follow-up communications, and most important, that you not presume that our silence, relative silence, or lack of objection to any concept or provision indicates that we support and/or do not oppose that concept or provision. We do not intend any such silence to indicate assent.

Also, the order in which comments are presented is not necessarily meant to signal their importance.

We are prepared at this time to offer the Board's reserved support for the direction offered in the DDS Draft proposal released April 19, 2013, and believe that with some modifications, this proposal offers the potential for significant public protection. We are by no means satisfied with the current form that the draft proposal takes, and believe it represents a significant step backward from the California model for electronic pedigree/track-and-trace. We are especially dismayed by the additional delay that is built into the various stages of the proposal. We believe regulators and the industry can and must do better than this, and that the public has a right to demand more. It has been over 25 years since the Prescription Drug Marketing Act (PDMA) was signed into law. We should not have to wait another 10 years for full implementation of this latest attempt to secure the supply chain, and/or it should be possible during that period to more closely mimic the California model. In the comments that follow, we will identify a few key areas where we seek improvement.

However, as we have repeatedly stated, we strongly support the principle of a federal law in this subject area, and a nationalized model that increases the security of the entire national supply. We believe that this proposal, particularly Section 3, while it is less than an adequate replacement for California's pedigree law, will make some positive difference in supply chain security, and we are prepared to treat this as an incremental improvement upon which we can still hope to build with continued engagement in this subject area. We also recognize and appreciate the bipartisan nature of this proposal, and the tremendous effort expended to reach a form of consensus. We do not wish to let the perfect be the enemy of the good, or to presume that we hold all of the answers.

Therefore, on balance, while we cannot express enthusiasm for the proposal as drafted, nor do we actively oppose its passage. We recognize that the federal government has a primary role to play in this national security issue, and welcome this expansion in the federal portfolio in this area. We look forward to the continuing opportunity to engage in this shared project.

We should be clear, however, that our support or lack of opposition is entirely conditioned on the continued inclusion of a robust, definite, and self-executing Section 3. We view this as the most important section of the proposal, and we will not support any effort to delete, weaken, delay, or make conditional or dependent on external events, the provisions of Section 3.

General Comments on the DDS Draft

In the interests of time, we will not repeat a lot of what was expressed in our November 7, 2012 comments, and will simply refer you to that document. However, it is worth repeating very briefly a few of the general points made in those prior comments, including:

- It is not only the people of California that stand to benefit from implementation of California's electronic pedigree requirements, as we believe the entire supply chain will be strengthened by compliance with the California requirements; certainly, the pharmaceutical supply chain is in need of additional security features;
- California's law has been in place since 2004, and is scheduled to go into effect on a rolling timetable between 2015 and 2017, so there has been plenty of notice and opportunity for members of the supply chain to come into compliance;
- Many members of the pharmaceutical supply chain are already on track to meet the 2015-2017 timeline for compliance with California's law, and we believe that those "early adopters" should get the benefit of their voluntary compliance;

- We must assess this federal proposal as a substitute for California’s law; and
- As the FDA has repeatedly expressed, we believe that any federal track-and-trace solution should include at least: participation by *all* industry partners; in passing and receiving electronic drug “pedigree”/chain-of-custody data as to *all* prescription drugs; to which data all the shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level at each stage of distribution.

By these latter two standards, the DDS Draft falls short, in both timing and substance. Of greatest concern, not only does the DDS Draft push the timeframe for Section 3, the only part of the proposal that even approximates the California model, out for 10 years, even at that point there is significant underutilization of the serialization technology that is required by the proposal. We know from our experience in California that legislation in 2008 which pushed the (previous) implementation date back from 2011 to 2015-2017 resulted in the suspension of the momentum, effort and commitment to compliance by supply chain members for several years, so setting the key federal implementation phase out 10 years following enactment is very problematic.

Additionally, the proposal does not adequately specify or require that each shipment (at the unit level) be *automatically validated* to transaction data from trading partners. Nor does the draft seem to ensure full chain-of-custody visibility for downstream trading partners. We also believe that the proposal does not adequately ensure full participation by all members of the supply chain. For instance, we understand the reasoning behind the allowance for some supply chain participants (particularly small dispensers) to seek waivers from the requirements of the proposal. However, we do not believe that supply chain security can be adequately assured without full participation. We are dismayed that dispensers, who are on the front lines of patient care and are therefore closest to the potentially devastating effects of counterfeit, adulterated, or otherwise unfit drugs, might not take advantage of the additional security promised by the proposed system. More to the point, we are concerned that any such loophole(s) in the closed system can and will be exploited.

Specific Comments on the DDS Draft²

Again, we will keep these comments short, and refer you to our November 7, 2012 letter, as many of the specific comments contained in that document remain applicable. We will limit these comments to just a few of the more significant and noticeable changes we would suggest, in the general order of the DDS Draft (rather than in their order of perceived importance):

SECTION 2

We should first reiterate a point made at some length in our November 7, 2012 letter: that what is labeled Section 2 (previously denominated Phase I), does not offer the improvement(s) in supply chain security that are promised by California’s pedigree law, and/or by the kind of national end-to-end track-and-trace/pedigree infrastructure in an interoperable format envisioned by the FDA in public comments it has made about its standards development under FDAAA. Although the DDS Draft studiously avoids use of the term “pedigree,” what it contemplates in Section 2 is lot-level tracking of product through association of such product at the lot level with paper or electronic “pedigree” materials (“transaction history” and “transaction statement” documents). This is only a very small advance in security.

² Again, these comments are not intended to be exhaustive or comprehensive, and the failure to make a comment on any of the concepts and provisions in the DDS Draft is not intended to signal the Board’s assent or lack of objection

While it includes a requirement of product (package) serialization, Section 2 does not require or provide opportunity for trading partners to do real-time, contemporaneous product validation (at the unit level, or even the lot level). Therefore, it does not provide substantial additional security, and does not materially advance us toward the universal track-and-trace infrastructure that is the endpoint. Moreover, these requirements seem to assume there will be identifications/interdictions of “suspect” / “illegitimate” drug products. However, it is not clear how, under this proposal, it would be *any more likely* that such products would be identified *before* an unfortunate patient-harm incident or other proof of illegitimacy. Given this unlikelihood, the notification/verification terms may be merely window dressing.

Section 581. Definitions

“Disposition” (§ 581(3)): We believe this concept needs further refinement, either in its definition or in its operational deployment throughout the draft. Specifically, we are concerned that the instructions throughout the draft for trading partners to “disposition” suspect/illegitimate product may be (or may be interpreted to be) an instruction to the investigating party to destroy/send for destruction suspect/illegitimate product without retaining a sample, *hampering the ability of investigatory agencies to study the suspect/illegitimate product, collect samples thereof, etc.* We believe some work may be required to specify that regulatory agencies must be offered (a sample of) suspect/illegitimate product for analysis and investigation before the product is shipped away or destroyed. We are also unsure whether the draft defines specifically enough who may make a “disposition” decision.

“Illegitimate Product” (§ 581(5)): Especially given how much hinges on these definitions (both this one and that for “Suspect Product,” see below), we believe this term is (still) defined too narrowly. There are numerous additional types of illegitimacy that are not mentioned here, and that may not fit within the categories that are mentioned here, including subpotent/superpotent drugs, mislabeled or misbranded drugs, new drugs without appropriate approval(s), among others. We believe this should be given as broad a definition as possible. For this reason, we would also not limit it to “intentionally” adulterated product, as intention should be irrelevant if a drug is adulterated. Likewise, we would not make the definition of “illegitimate product” dependent on proof of either actual or potential patient harm, so we would remove the phrases starting with “such that . . .” from both (B) and (D). If this is not possible, we would at least change the “would” in sub-part (B) to match the “could” in sub-part (D).

“Suspect Product” (§ 581(17)): See comments for “Illegitimate Product,” except that the definition for “suspect” product should be even more broad and inclusive, since this is merely the threshold for commencing an investigation (and potentially “clearing” the product). At a minimum, the “would” that appears in sub-parts (B) and (D) should in both instances be replaced with “could.” But we believe that this definition should be significantly expanded, to include the numerous other possibilities that exist with regard to product interference, mislabeling, other otherwise illegitimate practices.

“Third-Party Logistics Provider” (§ 581(18)): We are not aware that 3PLs perform these services for (other) wholesalers, dispensers, or providers, and can think of no circumstances under which they might legitimately do so. We suggest this definition be further refined.

“Transaction” (§ 581(20)): Based on our experience with implementation of our law, we ask the working group to consider not limiting the transaction history to transactions in which a change of ownership occurs. In other words, we suggest you at least consider tracking every change of location and/or possession, since that will provide a more complete record and will be tracked (internally) by the trading partners, anyway. We are also concerned that this definition may introduce an inconsistency or ambiguity into the legislation, because the law also applies requirements to “transactions” not involving a change of ownership (e.g., transfers of possession to a third-party logistics provider).

We are also concerned about the exemption (in (B)(vii)) for distribution of a “minimal” quantity of products from a pharmacy to a practitioner for office use. This strikes us as an exemption that is ripe for widespread abuse, especially given our recent experiences with pharmacy re-sales and compounding.

“Transaction History” (§ 581(20)): We are perplexed by the continued allowance for a “paper” transaction history, as such paper documents can be easily forged or created post-hoc. Moreover, we ought to be developing the electronic infrastructure for real-time validation.

“Transaction Statement” (§ 581(23)): Similarly, we cannot understand why this would be a paper document. We would suggest that this (hopefully electronic) data have to be signed, and that it include an attestation by a party able to bind the entity (with an electronic or digital signature). What is not clear from this definition is whether this “transaction statement” will include *any* reference to quantity, lot number, number of containers, NDC numbers, SNIs, or any other identifying information for the particular drugs (packages, cases, lots, etc.) that are shipped and received. It does not appear there will be any requirement that the shipper or receiver make any attestation about the actual product. We think this is a mistake, and would substantially increase the requirements for this statement.

Section 582. Requirements⁴

Subdivision (a)(2)(A) (page 18): We believe that the word “draft” should be deleted.

Subdivision (a)(7) (page 22): We are confused by this provision, which appears to deem third-party logistics providers licensed without benefit of either State or Federal licensure proceedings. We believe that states should continue to license these entities, exercising their usual discretion.

Subdivision (b)(4)(B)(i)(II) (page 27): We believe that there needs to be a specification that, as part of the “disposition” of illegitimate product, each entity in possession or control of same (so this is a comment that will apply to succeeding sections of the draft, but will not be repeated) must offer the drug or a sample thereof to the FDA and/or state authorities, to retain for future investigation. Because there is no explicit requirement that a “disposition” include retaining the drug or a sample thereof, we are very concerned that we will lose the ability to conduct forensic analysis on these drugs for origin, etc.

Subdivision (b)(4)(B)(ii) (page 28): We do not believe that the requirement to notify regulatory bodies and trading partners of the existence of an illegitimate product should be contingent on an entity (here, manufacturer, but this comment also applies to the other supply chain partners) having possession or control of the product. Any trading partner having knowledge (or reason to know) of an illegitimate product should be obligated to share that knowledge (or suspicion) with the FDA and its partners.

Subdivision (c)(1)(A)(ii)(II) (page 34): We are confused and concerned by the exemption of the lot number, transaction date, and initial shipment date from the transaction history/information.

Subdivision (c)(1)(B)(i)(I) (page 37): Here and elsewhere in the draft, we are confused and concerned by the exemption from the requirement of provision and receipt of a transaction history for saleable returns. We believe that this exemption will simply invite waste and abuse.

Subdivision (d)(4)(C) (page 52): We believe that dispensers should have the same continuing obligation to respond to verification requests, notwithstanding maintenance of an electronic database, as do all other supply chain partners. Indeed, we believe that dispensers are of primary importance in the effort to ensure supply chain security, and we would like to see their role expanded, not diminished.

Subdivision (g) (page 65): We find this definition or deployment of drop shipments confusing and concerning, as under the heading of “drop shipment” this provision seems to exempt from all of the transaction statement/history, verification, and other requirements, any entity that does not physically handle a product. This is a significant broadening of the “drop shipment” concept with potentially real consequences that are as yet unknown, because this does not limit “drop shipment” to manufacturer-to-dispenser/administerer direct shipments. Moreover, as we know, many such entities take ownership of drug products, and so would (normally) be included in the “transaction” history of such products. This broad and general exemption will have an uncertain impact on the operation of the requirements.

SECTION 3

We would like to first express our appreciation for the increased level of certainty that is now inherent in Section 3, and the self-executing nature of its requirements. It is solely on this basis that we are able to offer our reserved support or lack of opposition to the DDS Draft.

However, we believe that Section 3 should be made effective far more quickly than 10 years from enactment. We would suggest a maximum period to effectiveness of 5-7 years. We know that a great deal of work has already been done to achieve compliance with California’s pedigree law; we believe that work should not be rendered stale, and that momentum should not be lost, by this delay.

We also believe that Section 3 can and should be made still more certain, definite, and detailed, and should capitalize on the work that has already been done by the FDA to identify and define some or all of the requirements for an interoperable unit-level track-and-trace system. We do not believe further development or implementation of such requirements should be delayed or left to the future.

Finally, we believe that any such system should incorporate automatic verification (at unit level) by each supply chain trading partner, i.e., validation of shipped and received product against “pedigree” (transaction) data that is received and transmitted by supply chain trading partners. It is not clear to our eyes whether Section 3 requires this kind of routine verification (and associated attestation), and we do not believe any system that does not make that sort of automatic verification explicit is adequate. It is *not* sufficient for each trading partner to simply share the data pertaining to each single transaction with that trading partner, as this does not enable the kind of supply-chain visibility that is necessary for the (particularly downstream) trading partners to be assured of the legitimacy of the drug product(s).

Subdivision (a)(4) (page 71): We do not believe that the statute contemplates or requires the promulgation of regulations (at least with regard to system requirements), so do not understand this provision’s reference to promulgation of such regulations. Should this read “guidance”?

Subdivision (l) (pages 83-84): We are confused and concerned by these sunset provisions, particularly that in subdivision (l)(1) calling for the sunset of exchanges of transaction histories.

SECTION 4

We are pleased to see that our concerns and recommendations regarding national licensure standards for wholesalers (and third-party logistics providers) were heard and considered, and that the result is what we understand to be legislation setting a floor but not a ceiling for license requirements. If we are in any respect mistaken about that understanding, we hope that can be clarified. But assuming we are not, we fully support the notion and execution of minimum national licensure standards. We would appreciate an explicit acknowledgment that states may enact additional/further requirements.

Subdivision (b) (page 88): We are, however, concerned by the inclusion of a list of exemptions from the definition of “wholesale distribution” that seems in many respects to mimic the similar list of exemptions from the definition transactions to be recorded on a transaction history. We do not see the utility of inclusion of this list. Some of the transactions in this list would not, in any event, constitute wholesale distributions, but some might, and there seems to be no reason to exclude those. More to the point, it seems to be better policy to adequately define “wholesale distribution,” rather than burden this definition with a long list of excluded transactions that seems to be imported from elsewhere.

We also have particular concerns about some of the exclusions listed here, including sub-parts (E), (K), and (M) through (S). There seems no good reason to exempt these from the definition.

Section 583. National Licensure Standards for Wholesale Distributors

As referenced above, we would be more reassured if, somewhere in these provisions (on or about page 96 would seem to be the appropriate place), there were an explicit acknowledgment/allowance of states’ continuing ability to enact and enforce requirements additional to the minimum federal standards.

SECTION 5

We continue to believe that third-party logistics providers can continue to be licensed/regulate as wholesale distributors, but recognize that reasonable minds can differ on this point and are willing to accede to your considered wisdom that they should be a separate license category. Our understanding of the federal statutory scheme is that this will require additional legislation in California and other states to create (and define) this separate license category. Again, we would hope that the federal legislation will retract its apparent intention to “deem” third-party logistics providers licensed, and make that dependent (as the draft elsewhere seems to do) on state and/or federal license approval.

Otherwise, we repeat our comment made above about wholesale distributor licensure, and ask for an explicit acknowledgment/allowance for enactment of state standards above the federal minimum.

SECTION 7

Subdivision (b) (page 105): This may be another, or the best, place to specify that states retain their present ability to enact licensing and enforcement requirements for wholesalers and third-party logistics providers that are above and/or additional to the federal minimum standards.

Conclusion

For all of these reasons, we offer our reserved support or lack of opposition to the proposal’s direction, although we believe and reiterate that it can be made far stronger, and definitely should be implemented far more quickly. We believe the security of the drug supply and the public’s trust in that drug supply are threatened, and any further delay simply adds to the scope of these threats.

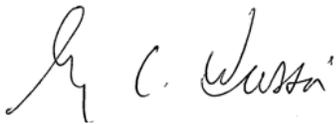
We also believe that the endpoint should be a national end-to-end track-and-trace system that is worthy of any additional delay, and adequate to replace the California model. We believe the necessary components of any such system include: participation by *all* industry partners; in passing and receiving electronic drug “pedigree”/chain-of-custody data as to *all* prescription drugs; to which data all shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level at each stage of distribution. We believe this proposal fails to fully articulate the system first envisioned by the FDA.

We again commend you for your leadership on these vital issues of national security. Thank you also for your willingness to hear our input. We look forward to our continuing work together to secure the nation's drug supply. Please feel free to contact the Board any time if we can be of assistance.

The best ways to reach me are on my cell phone, (909) 633-2574, or by email to stanweisser@aol.com. You may also communicate with the Board's Executive Officer, Virginia Herold, by telephone at (916) 574-7911, or by email to virginia.herold@dca.ca.gov.

Thank you again for your efforts. We are grateful to all of you, and hopeful that we are nearing a strong federal system for regaining a strong pharmaceutical supply.

Sincerely,

A handwritten signature in cursive script that reads "Stanley C. Weisser".

STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy

Enclosure: November 7, 2012 Board comment letter



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
EDMUND G. BROWN, JR., GOVERNOR

May 28, 2013

Transmitted via email to

Representative Henry Waxman, Ranking Member, Energy & Commerce Committee

Representative Frank Pallone, Jr., Ranking Member, Health Subcommittee,
Energy & Commerce Committee

RE: FEDERAL EFFORTS TO SECURE DRUG DISTRIBUTION SECURITY
Comments of the California State Board of Pharmacy on
H.R. 1919, "Safeguarding America's Pharmaceuticals Act of 2013"

Dear Mr. Waxman and Mr. Pallone:

I write on behalf of the California State Board of Pharmacy (Board). We appreciate this opportunity to submit our written comments on H.R. 1919, titled the "Safeguarding America's Pharmaceuticals Act of 2013." Our comments pertain to H.R. 1919 as it was reported out of the Energy & Commerce Committee on or about May 15, 2013. We write to express our concern that this bill, as currently drafted, does not do enough to promise an increase in the security of the drug distribution supply chain, while at the same time preempting the California pedigree law and tying the hands of states like California to regulate wholesalers.

We want to first thank you and the bill's authors and co-sponsors for acknowledging and taking on the challenge of increasing drug supply chain security. We understand that it is not an easy task to balance the need for increased security against a desire to avoid adding unnecessary costs and possible interruptions to the supply chain. We also recognize and appreciate just how much effort has gone into the bipartisan and bicameral effort to reach agreement on legislation necessary to achieve needed improvements in drug supply chain security. Finally, we agree that it would be ideal for the subject of supply chain security to have a federal legislative solution, as this is a subject that would be more ideally regulated at the federal level than by the states.

However, we believe H.R. 1919 does not promise the kind of robust supply chain security that is necessary to ensure adequate patient protection, and is not an adequate replacement for the California pedigree law that, absent this bill, will go into effect beginning in 2015. Our reasons for this are various; many of these have been covered in our comments on prior legislative drafts. In the interest of brevity, and because we want to get these comments to you in time for them to be considered along with any action that might be taken on H.R. 1919, we will keep this iteration of our comments relatively succinct. Please find enclosed our letters dated April 26, 2013, on the draft of the bipartisan Senate bill released for comment at that time (since introduced in much the same form as S. 957, and combined with S. 959), and November 7, 2012, on the bicameral DDS Draft that was at that time sent out for comment, which we hereby incorporate by reference.

In brief, our primary though by no means only objection to this draft is that it promises no certainty that we will ever see the end-to-end, full participation, electronic track-and-trace system monitoring drug distribution security at the unit (package) level, with trading partner verification and validation and the resulting protections against counterfeit and adulterated products, that has been the recommendation of the FDA since its Counterfeit Drug Task Force convened in 2004. This bill leaves the development of any such system to some future rulemaking, to be published no sooner than 2027, effective 2 years later, and even then this legislation requires no particular outcome of such rulemaking. We have no confidence, given the history of the Prescription Drug Marketing Act of 1987 (PDMA), that this deferral will result in any increase in security. While we have also expressed concern (see April 26, 2013 comments) that Section 3 of the Senate draft should be improved and strengthened, and that it should not take an additional 10 years to get to the system outlined in that section, we far prefer the relative certainty of the Senate model to this draft. There has already been substantial agreement that a uniform track-and-trace infrastructure is needed to ensure supply chain security, and many participants in the supply chain are already well on their way to implementing that infrastructure to comply with the California timeline. We believe that without placing a definite outcome and a date certain into the legislation, all of that momentum will be lost and all of that industry investment will be wasted. We believe the public deserves a robust supply chain security system, and we further believe that the industry needs the certainty of firm deadlines and objectives in order to adequately plan their capital investments.

Of nearly co-equal importance, we also object, for many of the same reasons stated in our November 7, 2012 letter, to the language in Section 585, subdivision (b) (and/or elsewhere), that has the effect of making the proposed national wholesaler licensure standards *both* a “floor” and a “ceiling” on the independent authority of states to regulate wholesalers. We support national minimum standards for wholesalers, and also support federal licensure of distributors in states that do not provide such licensure. But we strongly believe that states should remain able to enact and enforce state-specific provisions that go above and beyond national minimums, to respond to more local issues and also to later developments requiring more immediate action. We are happy to work with you further on this topic, and to share examples of why we believe it is so crucial for states to retain flexibility and additional authority with regard to regulating wholesalers.

One such example would be the difficulty experienced in California and other states over the last few years with “gray market” purchase and re-sale practices by (secondary) wholesalers. California has seen a dramatic uptick in re-sales of drugs that are in short supply, as wholesalers and their trading partners evade typical drug shortage allocations by purchasing from pharmacies who become de facto “purchasing agents” for the secondary wholesalers, acquiring drugs from a primary wholesaler for the purposes of re-sale to the secondary wholesaler, which in turn re-sells the drugs to another secondary wholesaler or to an end user. These practices can result in further increases in the already-increased prices of shortage drugs, in further distortions in supply, and in supply chain vulnerabilities from the multiple purchases/re-sales. Some of these problems have been documented in a bicameral investigation report by Senators Rockefeller and Harkin, and by Representative Cummings, which addressed the problem and possible solutions. A copy of this report is available at <http://cummings.house.gov/cummings-releases-joint-report-gray-market-drug-companies>. This kind of unexpected and unprecedented conduct by wholesalers presents a new challenge, that has not been anticipated by previous licensing schemes (or the framework in the present draft). California and other states will have to devise new regulatory language that is able to better handle these kinds of market innovations. We must retain the flexibility to do so, and to add to the federal minimums when these kinds of situations come up. Under the language of H.R. 1919, we will not have the necessary flexibility and authority to do so.

Conclusion

For these reasons, as well as those spelled out in more detail in the enclosed letters, we cannot support the current draft of H.R. 1919, although we believe and reiterate that a federal model is ideal. We do not believe that additional drug security can await the possible development of future standards some 14 or more years after enactment. We believe the security of the drug supply and the public's trust in that drug supply are threatened, and any further delay simply adds to the scope of these threats.

We also believe that the endpoint should be a national end-to-end track-and-trace system that is worthy of any additional delay, and adequate to replace the California model. We believe the necessary components of any such system include: participation by *all* industry partners; in passing and receiving electronic drug "pedigree"/chain-of-custody data as to *all* prescription drugs; to which data all shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level at each stage of distribution. We believe this proposal fails to fully articulate the system first envisioned by the FDA.

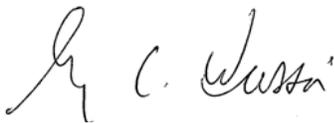
Finally, we remain concerned that the hands of California and other states with robust programs to license and regulate wholesale distributors will be tied by the national licensure standards section(s) of the bill. We would encourage you to adopt a model wherein the federal legislation sets a floor for wholesaler licensure standards (and provides for federal licensure where states do not offer same), but not a ceiling.

We again commend you for your leadership on these vital issues of national security. Thank you also for your willingness to hear our input. We look forward to our continuing work together to secure the nation's drug supply. Please feel free to contact the Board any time if we can be of assistance.

The best ways to reach me are on my cell phone, (909) 633-2574, or by email to stanweisser@aol.com. You may also communicate with the Board's Executive Officer, Virginia Herold, by telephone at (916) 574-7911, or by email to virginia.herold@dca.ca.gov.

Thank you again for your efforts. We are grateful to all of you, and hopeful that we are nearing a strong federal system for regaining a strong pharmaceutical supply.

Sincerely,



STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy

Enclosures: April 26, 2013 Board comment letter
November 7, 2012 Board comment letter



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
EDMUND G. BROWN, JR., GOVERNOR

November 7, 2012

Senator Tom Harkin, Chairman, Committee on Health, Education, Labor & Pensions
c/o Kathleen Laird (Kathleen.Laird@help.senate.gov)

Senator Michael B. Enzi, Ranking Member, Committee on Health, Education, Labor & Pensions
c/o Grace Stuntz (Grace.Stuntz@help.senate.gov)

Representative Fred Upton, Chairman, Energy and Commerce Committee
c/o Carly McWilliams (Carly.McWilliams@mail.house.gov)

Representative Henry A. Waxman, Ranking Member, Energy and Commerce Committee
c/o Allison Corr (Allison.Corr@mail.house.gov)

RE: FEDERAL EFFORTS TO SECURE DRUG DISTRIBUTION SECURITY
Comments of the California State Board of Pharmacy
*Draft Proposal to Improve Drug Distribution Security – released/posted for stakeholder
comments October 24, 2012; comments due to the above by November 7, 2012; 6:00 p.m.*

Dear Chairman Harkin and the members of the Drug Distribution Security working group:

I write on behalf of the California State Board of Pharmacy (Board). We thank you for this opportunity to submit written comments on the Draft Proposal to Improve Drug Distribution Security (“DDS Draft”), released/made available on October 24, 2012. We also recognize and appreciate that the DDS Draft was clearly written with California’s interests in mind, and thank the entire working group, particularly the members of the California delegation in both houses, for considering and promoting California’s perspective, and for our collaborative relationships. We have been pleased to work closely with the staffs of the committees and the members. We will reiterate herein some of what has been expressed in our prior comments, but will try to be as brief and direct as possible in addressing the particular proposal now under consideration.¹

In general, our response to the DDS Draft is cautious and very guarded optimism that this document may represent a framework for moving forward to a robust federal solution. As you know, we have repeatedly stated our preference for a federal legislative solution to supply chain security that would implement a solution as robust as California’s pedigree law(s) at the federal level. This draft has that potential. However, because so much of the DDS Draft is conditional and dependent on decisions yet to be made, not only on the bracketed items but in a subsequent federal rulemaking, we cannot yet offer a broad endorsement of this approach. Moreover, we do have significant concerns both about the general structure of this legislation and about many of the particulars, which will be discussed in more detail below. We do not believe these concerns are irreconcilable with the current draft, so remain optimistic this framework could be modified to become a more acceptable solution. We look forward to working with you toward that end.

¹ As a representative sample of longer comments on this topic that we have submitted in the past, that give some of the history of California’s pedigree legislation, please find enclosed a comment letter dated May 9, 2012, addressed to Chairman Harkin. Similar letters were sent to other members of the working group and the California delegation.

California's Interest in Supply Chain Security

As you know, this Board, and Californians more generally, have a significant interest in this subject area. California already has in statute a robust pharmaceutical electronic pedigree requirement, on track to be fully implemented over the next five (5) years, a system that we believe represents a significant step forward in supply chain security. California is also the marketplace for some 10-12% of the total prescription drugs distributed and dispensed in the United States, so has the most to gain from a secure distribution system, and the most risk in the event of breaches in drug distribution security that threaten patient safety or health. As has been reported elsewhere, Californians and other U.S. patients have already been victimized over the years by gaps in the supply chain, and we believe it is now past time to act decisively to reduce the chances of similar incidents. We are extremely pleased to be joined in that view by the members of this working group, and are excited about the federal interest in this subject. We would like to thank all the members of this working group for their leadership on this topic.

We also know that we are joined in our focus on supply chain security and patient safety by the members of the supply chain. We have been repeatedly impressed over the several years that we have worked on these supply chain security issues (e.g., the first legislation establishing California's pedigree requirement(s) was enacted in 2004) with the good faith and earnest effort that participants in the supply chain have put forth. We have valuable working relationships with supply chain participants from all sectors, and have worked collaboratively both in passage of the legislation that created California's requirements, and to find answers to particular issues and questions relating to implementation of those requirements. Even though we have not always agreed on the particulars of any given proposal, we have managed to find much common ground regarding underlying goals and principles. We have never doubted that those in the supply chain with whom we have worked closely share our deep and abiding concern for patient/public health and safety. We know that this is not just because they would have much to lose in the event of a negative outcome relating to the drugs they manufacture, distribute, or dispense, but also because their motives for being in this business at all are almost always at least partially altruistic. As we have repeatedly stated, we also know that what California's law requires of them is not easy, and we very much appreciate the effort and dollars that have already been expended to comply.

In that vein, we feel some obligation to speak here for the many "early adopters" in the supply chain who are already well along the road to compliance with California's law. Many are ready or soon will be ready for full implementation of a secure, interoperable, electronic pedigree system that tracks (and traces) drug packages at unit level throughout the supply chain. All these companies deserve credit for their innovation, not only in deploying their own system(s) but also in providing leadership to working groups and other members of the industry on implementation strategies. Their substantial investments in compliance ought not to have been in vain.

More to the point, we believe the California electronic pedigree law is the best model for a national supply chain security augmentation. But we know we do not have all the answers, and we do not want the perfect to be the enemy of the good. So we are flexible as to routes to a final solution. However, as was recommended by the FDA Counterfeit Drug Task Force in its reports between 2004 and 2006, and as California law requires, we think any such final solution should include at least: participation by *all* industry partners; in passing and receiving electronic drug "pedigree"/chain-of-custody data as to *all* prescription drugs; to which data all the shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level. We are not aware of any alternative proposal that would promise the same robust level of security.

Comments on the DDS Draft²

We must assess the DDS Draft as a proposed *substitute* for California’s pedigree law(s) (and, potentially, other California law(s) relating to wholesaler licensure, *see infra*), because not only does the DDS Draft contain an explicit preemption provision (§ 7), but even if it did not, it would potentially invalidate California’s pedigree law under the “self-preemption” provision in California law (Cal. Bus. & Prof. Code, § 4034.1) that invalidates the pedigree law(s) “[u]pon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs.” Accordingly, consistent with our mandate to make protection of the public our highest priority (Cal. Bus. & Prof. Code, § 4001.1), we must first be satisfied that the federal legislation provides as much or greater protection to Californians as the California law(s) that it would replace, before we could offer our unqualified support. For all of the reasons that are given below, beginning with the general and moving to the specific, we are not yet so satisfied, and must withhold our support. We are, however, optimistic that it may be possible to improve this draft consistent with the following comments to meet this standard. We certainly agree with the working group that these are serious issues commanding our attention.

General Comments

At this point, we must reluctantly conclude that the DDS Draft is not (yet) an adequate substitute for California law, either as to electronic pedigree/track-and-trace requirements, or on the subject of wholesaler licensure and standards, on which the DDS Draft also (likely) preempts state law. As currently drafted, it would replace the certainty of a California pedigree law which requires universal participation in an interoperable electronic pedigree infrastructure that requires tracking and tracing of all except specifically exempted drug products at the unit level (unless the Board approves aggregate tracking based on inference), that is entering rolling implementation in just over two years and will be fully implemented within five years, with the *possibility* of such a system being implemented at the federal level, if at all, and only if all goes right with the federal rulemaking and implementation, some fifteen years from enactment of the Act. It also has a very real potential to undermine California’s ability to regulate resident and non-resident wholesalers.

We recognize that even getting Section 3 (“Enhanced Drug Distribution Security,” which begins at page 66 of the draft) into a piece of federal legislation is a substantial step forward, and we applaud the working group for taking this initial, though somewhat tentative, step. Any hope that we express that the DDS Draft may eventually be an acceptable substitute for California law is entirely dependent on this section, as we do not believe that the Phase I concepts or provisions are either an adequate substitute or even more than a very marginal improvement in supply chain security. Our hopes for this legislation are entirely pinned on Section 3, subdivision (c).

² We have done our best in these comments to fully respond to the various concepts and provisions included in the DDS Draft. However, in the rush under a compressed schedule to read and comprehend the lengthy proposal, and to formulate our written comments, we have undoubtedly neglected to make comments we might have made with more time to understand the proposal (and discuss it with the authors), omitted comments we intended to make, and/or not included comments that we did not realize were necessary because of our general unfamiliarity with federal law. To the extent possible, we ask that you not treat these comments as exhaustive or comprehensive, that we be allowed to communicate any later-realized comments to the working group in follow-up communications, and most important, that you not presume that our silence, relative silence, or lack of objection to any concept or provision indicates that we support and/or do not oppose that concept or provision. We do not intend any such silence to indicate assent.

Also, the order in which our comments appear is mostly happenstance (or, for the Specific Comments, led by the order of the DDS Draft). The order in which comments are presented is not meant to signal their importance.

As to that section, we are troubled to see that it appears the entire Section 3, and/or all of its subparts (including subdivision (c)), is/are bracketed, suggesting it is still undecided whether this section will even make it into the bill(s) as proposed (or enacted). Let us be clear: without Section 3, which offers at least the *possibility* of a robust federal track-and-trace solution, though in language that we find far less than ideal (*see infra*), we do not support the DDS Draft.

We are also perplexed that Section 3, and particularly subdivision (c), received so little of the focus of the DDS Draft. This section, which we believe is the only part of the legislation that offers a potential for an adequate substitute for California's pedigree law, is roughly sketched out in just over seven pages of the 117-page draft, and only about three pages of that are dedicated to the all-important subdivision (c). Obviously, the importance and effectiveness of legislation is not necessarily determined by its length and/or complexity, but in this case we would rather have seen the kind of detail and statutory specification of scheme that is employed in Section 2 (Phase I) employed instead in Section 3/Phase II. Indeed, we fear that the overwhelming focus on Phase I indicates a likelihood we may never get to Phase II, either because Section 3 is not included in the final legislation, or because even if it is the effort deployed to implement Phase I will soon be seen as "good enough," and the rulemaking and implementation for Phase II will be delayed or eliminated entirely. We say this not to doubt the energy or good faith of the federal agencies that would be involved (primarily the FDA), but because we learned from the prior example of the Prescription Drug Marketing Act (PDMA) that it may be nearly impossible for the FDA (or other federal agencies) to impose true and lasting change by way of regulations. We are now in our 25th year since enactment of the PDMA, and yet the regulations that were supposed to make fully effective the pedigree requirements of that legislation are not yet enforceable.

In general, we are not persuaded that Section 2 (Phase I) would be any sort of substantial improvement in supply chain security over what we have now, and certainly would not be a fully adequate substitute for California's electronic pedigree requirements. In fact, we would happily sacrifice all of Phase I and go directly and expeditiously to Phase II (though we would obviously have to incorporate some of the Section 2 requirements, such as product serialization using SNI, and some of the definitional provisions). We are concerned that Phase I requires investment in technologies and infrastructure necessary to those specific requirements that do not actually help with preparation for Phase II, and that Phase I might actually function as an impediment to a full and expeditious development of an end-to-end national track-and-trace system.

There are some good concepts in Section 2 of the DDS Draft (including development of an alert system, and standards for quarantine and investigation of suspect/illegitimate product), which we might utilize in a more robust version of Section 3 (once the language has been refined as suggested below). But on its own, the non-interoperable lot-level tracking system it envisions, its allowance for paper pedigrees, and its limited requirement(s) of participation by certain of the trading partners in the supply chain (particularly pharmacies [dispensers]), do not guarantee a material advancement of supply chain security and might even impede supply chain innovation toward an eventual end-to-end national track-and-trace infrastructure as envisioned in Section 3.

We would recommend instead that the focus of this legislation be shifted toward a more immediate and expeditious implementation of Phase II, and a Phase II in which *all* participants in the supply chain are required to authenticate drugs at the unit level, using proactive and real-time authentication technologies that have already been developed in response to or to aid compliance with California's pedigree law(s). We would also recommend that more of the burden of setting the requirements for Phase II be accomplished by statute, and less be relegated to the FDA.

On the question of timelines, it seems unfathomable to us that we would be talking about further delaying the implementation of an end-to-end track-and-trace system for another eight to fifteen years, if not longer (depending as the DDS Draft does on the oft-delayed issuance and full implementation of regulations). As mentioned above, it has already been approximately 25 years since passage of the PDMA, which was the first effort to require a nationalized pedigree system. It has been more than eight years since the FDA Counterfeit Drug Task Force was assured by the industry that it would be able to implement a full track-and-trace infrastructure (using RFID) by no later than 2007. It has likewise been eight years since California enacted its pedigree law(s), which originally envisioned implementation (based on that estimate given to the FDA) in 2007. California has already pushed back its implementation date repeatedly, at the request of industry, first to 2009, then to 2011, and then, in the most recent legislation enacted in 2008, to the current rolling implementation schedule of 2015 to 2017. During the legislative negotiations in 2008, a long list of representatives of the industry, from all sectors and from all sizes of companies, gave assurances to California legislators that they would be ready by 2015-2017, and no further delays would be sought. Yet the DDS Draft contemplates a further delay of (at least) up to 15 years.

Perhaps more to the point, we see no reason that there could not instead or in addition be relatively immediate progress, at the federal level, on at least the definitional stage(s) of work to explicate the standards for a full, national, end-to-end track-and-trace infrastructure. We know that, for instance, in compliance with its obligation(s) under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the FDA has already done much of the work required for publication of standards for such a track-and-trace infrastructure. It is puzzling to us that those standards, whether in draft or final form, have not taken a more prominent role in development of this legislation. We would encourage the release of those standards, at least to the members of the working group, and reliance on those standards to write a more robust statutory definition of Phase II to be implemented in the next two to five years, consistent with the California timeline.

Finally, on the subject of wholesaler licensure (Section 4 of the DDS Draft), while we are not averse to the concept of imposing more rigorous national standards for wholesale distributor licensure/registration, and we are certainly flattered to see provisions of California law dropped into federal legislation, we have some significant concerns about the language of the DDS Draft in this section, as well (*see infra*). We support national minimum standards for wholesalers, and also support federal licensure of distributors in states that do not provide such licensure. But we strongly believe that states should remain able to enact and enforce state-specific provisions that go above and beyond those national minimums, to respond to more local issues and also to later developments requiring more immediate action. We are very willing to work with the committee on further development of this section, especially given its reliance on California provisions (the language of which will obviously need to be changed to accommodate the new context), and we can bring to that discussion our substantial experience in regulating wholesalers at the state level.

On a related note, we understand the utility of separately *defining* a third party logistics provider (3PL) and/or what distinguishes it from a wholesaler (or a common carrier). California law has done the same. However, we fail to perceive the need for or advantage of setting forth a distinct (and impliedly less restrictive or demanding) license requirement for 3PLs, separate from that for wholesalers. In our view, both wholesalers and 3PLs (as well as other entities including reverse distributors and drug brokers) are in the business of possessing and/or distributing drugs, and have the same risks attendant to that practice whether or not they take ownership. We would strongly prefer to see one license category that would include all of these business entities. If it is too confusing to license them all as “wholesalers,” we suggest a general “distributor” license.

We reiterate that we are extremely grateful to the members of the working group for their leadership and hard work in this very important area. We recognize the difficulty of the task that this group has set for itself, and we applaud your willingness to take on this challenge. We know that we are all working toward the same primary goal, which is ensuring the health and safety of patients and the public. We will never disagree about the importance of that goal.

Specific Comments³

Turning to the specifics of the text, we provide hereafter a representative, non-exhaustive series of comments on particular concepts and provisions, in the general order of the DDS Draft.

SECTION 2 (PHASE I)

Again, as a general matter, while we recognize that Phase I might provide some marginal or incremental improvements in supply chain security, we believe it is nowhere close to offering the kinds of improvements in that security that are promised by California's pedigree law, or by a national end-to-end track-and-trace/pedigree infrastructure in an interoperable format, such as that envisioned by the FDA in the public comments it has made about its standards development under FDAAA. Although the DDS Draft studiously avoids use of the term "pedigree," what it contemplates is lot-level tracking of product through association of such product at the lot level with paper or electronic "pedigree" materials ("transaction history" and "transaction statement" documents). While it includes a requirement of product (package) serialization, that serialization is not integrated into any sort of interoperable electronic track-and-trace infrastructure. Phase I does not require or provide the opportunity for trading partners to do real-time, contemporaneous product validation (at the unit level). Thus, it does not provide substantial security, and does not materially advance us toward the universal track-and-trace infrastructure that is the agreed goal.

Lot-level tracking is possible in the supply chain right now, as manufacturers already use lot numbers on all of their products. Lot-level tracking is not, however, presently done except in recalls, at least in part because it does not significantly increase security, and any marginal effect it might have on security does not justify the costs it would entail. Likewise, some form of paper "pedigree" requirement has been in place since the 1987 passage of the PDMA, and/or since the 2003 enactment of Florida's pedigree law, but such requirements have not adequately met the challenges of our current distribution system. While we understand that this legislation is a more universal pedigree requirement (as it does not incorporate the "authorized distributor of record" [or similar] concept), we do not believe using these "transaction history" documents would get us meaningfully closer to our end goal. And the allowance for the statements to be given in paper form does not encourage rapid development of an interoperable electronic infrastructure.

There is also a more fundamental issue with the Section 2/Phase I requirements. These requirements seem to assume that there will be identifications/interdictions of "suspect" and/or "illegitimate" drug products. However, it is not clear how, under this statutory scheme, it would be *any more likely* that such suspicious products would be identified (at the front end), before an unfortunate patient-harm incident or other basis for suspicion. Given the unlikelihood there will be any such detections, provisions about alerts and quarantines seem like mere window dressing.

³ Again, these comments are not intended to be exhaustive or comprehensive, and the failure to make a comment on any of the concepts and provisions in the DDS Draft is not intended to signal the Board's assent or lack of objection.

Section 581. Definitions

“Alert” (§ 581(1)): Either here or elsewhere in the draft, we believe additional detail is required as to what constitutes an “alert.” Could it be accomplished manually, by telephone or mail? Is it an electronic message of some sort? Does it need to be secure, acknowledged, signed by a responsible party? Is either the transmitter or the recipient required to retain the “alert”?

“Authorized” (§ 581(2)): As mentioned above and discussed further below, we prefer to retain state licensure over distributors, and to put both wholesalers and 3PLs in this category.

“Dispenser” (§ 581(3)): This may be consistent with other sections of federal law, but it strikes us as curious to define the premises/entity as a “dispenser,” since it is the pharmacist (or other person authorized to dispense) who actually does the dispensing. Would it be more clear or more accurate to call this category the “Dispensing Premises,” or something similar?

Separately, we would not recommend including the bracketed language to include within the definition of “dispenser” the pharmacy’s affiliated warehouse(s) or distribution center(s). It will only confuse matters for both the pharmacy and its warehouse to be called a “dispenser.” If the intention is to exempt transactions between a pharmacy and its warehouse from having to be included on chain-of-custody documentation, that can be accomplished more directly. In fact, in most cases these transactions would probably not in any case be changes of ownership.

We also separately license pharmacy warehouses as wholesalers/distributors, due to the nature of their operations, and this provision would threaten our ability to do so.

“Disposition” (§ 581(4)): We believe this concept needs further refinement, either in its definition or in its operational deployment throughout the draft. Specifically, we are concerned that the instructions throughout the draft for trading partners to “disposition” suspect/illegitimate product may be (or be interpreted to be) an instruction to the investigating party to destroy/send for destruction suspect/illegitimate product, *hampering the ability of investigatory agencies to study the suspect/illegitimate product, collect samples thereof, etc.* We believe some work may be required to specify that regulatory agencies must be offered suspect/illegitimate product for analysis and investigation before the product is shipped away or destroyed. We are also unsure whether the draft defines specifically enough who may make a “disposition” decision.

“Distribute” or “Distribution” (§ 581(5)): We note only that, consistent with our previous comments, this definition of “distribute” is broad enough to encompass the activities of 3PLs as well as traditional wholesalers (and reverse distributors and brokers), so we repeat our call for a single license category (perhaps titled “distributor”) to be applied to all these entities.

“Illegitimate Product” (§ 581(6)): We believe this term is defined far too narrowly; there are numerous additional types of illegitimacy that are not mentioned here, and that may not fit within the categories that are mentioned here, including subpotent/superpotent drugs, mislabeled or misbranded drugs, new drugs without appropriate approval(s), among others. We believe this should be given as broad a definition as possible. For this reason, we would prefer to retain the bracketed term “potentially” wherever it appears in the definition. And we would not limit it to “intentionally” adulterated product, as intention should be irrelevant if a drug is adulterated.

We would *not* make the definition of “illegitimate product” dependent on proof of either actual or potential patient harm, so we would remove the second bracketed clause from (B) and the second bracketed clause from (C). We would also remove “appears” from the first bracketed clause in (C), since very few instances of illegitimacy will be visually “apparent.”

“Licensed” (§ 581(7)): Again, we prefer to retain state licensure over distributors, and to put both wholesalers and 3PLs in this category. We are also confused about why it is necessary to use both the similarly-defined terminology “authorized,” and the terminology “licensed.”

“Manufacturer” (§ 581(9)): We are not familiar enough with federal law to fully grasp the significance of subparts (B) and (C), but we are concerned about defining a manufacturer to include co-licensed parties, if for instance that would include contract manufacturers within this definition, or perhaps even authorized/exclusive distributors. If any of these entities could be a co-licensed partner or person, we would find it troubling to fit them within the general definition of manufacturer, because of the impact that would have on the “manufacturer” obligations with regard to placement of serialized numerical identifiers, and initiation of pedigree/track-and-trace data. We believe those obligations must remain with the entity with the financial investment in the drug, to ensure proper alignment of incentives and accurate completion of those tasks.

“Package” (§ 581(10)): We would not make this definition dependent on placement into “interstate” commerce, as placement into any form of commerce should be sufficient. This will mean deleting “interstate” not only from the first sentence, but also from the second.

This definition is a bit unclear and could use some work. For instance, it is not clear why it is necessary to use two largely redundant sentences to define a relatively simple concept.

“Product” (§ 581(12)): We do not understand why “product” is defined separately from “prescription drug” and/or “package,” and we believe this introduces ambiguity into subsequent sections of the law when “product” is used to refer to an undifferentiated quantity of drug(s). It appears the intent is to require tracking only at the lot level, but this is not actually specified.

“Product Identifier” (§ 581(13)): We also do not understand why “product identifier” is defined separately from “Standardized Numerical Identifier or SNI.” We are uncertain what is meant by “standardized graphic that includes, in both human-readable form and on a machine-readable data carrier . . . the standardized numerical identifier.” Is the intention of this definition to permit only use of “graphic” representations (e.g., 2D barcodes) and to preclude use of other data carriers (e.g., RFID)? If so, we oppose such preclusion. If that is not the intention, it is not clear what purpose this serves. And why require the “product identifier” to be human-readable?

“Return” and “Returns Processor” (§581(15) and (16)): Is there an inherent conflict in or between these two definitions, in that the former is limited to transfers back to the trading partner from whom a product was received, in exchange for compensation, while the latter is apparently not so limited? As to returns, why limit the definition to transfers for compensation?

“Standardized Numerical Identifier or SNI” (§ 581(18)): Is there some reason not to refer to or incorporate by reference the FDA guidance on this topic issued in March 2010? Does this language track correctly with the language utilized in that guidance?

“Suspect Product” (§ 581(19)): See comments for “Illegitimate Product,” except that the definition for “suspect” product should be even more broad and inclusive, since this is merely the threshold for commencing an investigation (and potentially “clearing” the product).

“Third-Party Logistics Provider” (§ 581(20)): We are not aware that 3PLs perform these services for other wholesalers, dispensers, or providers, and can think of no circumstances under which they might legitimately do so. We suggest this definition be further refined.

“Transaction” (§ 581(22)): Though we know the standard on this has been largely set by this requirement in California law, based on our experience with implementation of our law, we ask the working group to consider not limiting the transaction history to transactions in which a change of ownership occurs. In other words, we suggest that you at least consider tracking every change of location and/or possession, since that will provide a more complete record and may be tracked (internally) by the trading partners, anyway. We are also concerned about the exemption (in (B)(vii)) for distribution of an undefined “minimal” quantity of products from a pharmacy to a practitioner for office use. This strikes us as an exemption that is ripe for widespread abuse, especially given our recent experiences with pharmacy re-sales and pharmacy compounding.

“Transaction History” (§ 581(23)): We are perplexed by the continued allowance for a “paper” transaction history, as such paper documents can be easily forged or created post-hoc. Moreover, we ought to be developing the electronic infrastructure for real-time validation.

“Transaction Statement” (§ 581(25)): Similarly, we cannot understand why this would be a paper document. We would suggest that this (hopefully electronic) data have to be signed, and that it include the attestation set forth in subpart (D). What is not clear from this definition is whether this “transaction statement” will include *any* reference to quantity, lot number, number of containers, NDC numbers, SNIs, or any other identifying information for the particular drugs (packages, cases, lots, etc.) that are shipped and received. It does not appear there will be any requirement that the shipper or receiver make any attestation about the actual product. We think this is a mistake, and would substantially increase the requirements for this statement.

“Wholesale Distributor” (§ 581(27)): Again, this definition is already broad enough to encompass 3PL activities, and we would suggest inclusion of 3PLs (and reverse distributors and brokers) under a more general “distributor” license category.

With regard to the “Exemptions” listed in subpart (B): We are not clear why these need to be repeated, here, as part of the definition of “wholesale distributor.” That seems a mistake, as these seem definitionally to be included within wholesaling/distribution. If the purpose is simply to exempt these transactions from chain-of-custody requirements, that can be done directly. We would also (separately) recommend elimination of Exemptions (B)(v) and (B)(ix).

Section 582. Requirements⁴

Subdivision (a)(2) (page 23): It is not clear why this standards-development section is included in Section 2/Section 582 (Phase I), rather than in Phase II. We are also unsure how the standards are supposed to compare/relate to standards that have been developed or are now being developed by the FDA in compliance with its obligations under FDAAA. We would also place a far shorter timeline on the development of these standards, which should be available now.

Subdivision (a)(5)(A) (page 25): We would expedite production of this guidance.

Subdivision (a)(5)(B) & (C) (page 25): We prefer to retain state licensure over (all types) of distributors, and to put both wholesalers and 3PLs into this (state) licensure category.

Subdivision (b) (page 26 et seq.): We encourage the shortest timeline in all instances.

⁴ The Requirements section (Section 582) includes (some) duplicative requirements as to the supply chain partners. In some cases, we do not repeat a comment made on an earlier version of the requirement (as to another entity type).

Subdivision (b) (page 26 et seq.): We believe that the transaction history, transaction information, and transaction statement should be received before the drugs are accepted, and before the drugs are shipped, and should be maintained/retained for at least three years.

Subdivision (b)(5) (page 32): As noted above, we believe specifications for disposition of product need to be further refined, to be sure that evidence necessary to investigations (by the appropriate regulatory/enforcement body) are not impaired by destruction of evidence.

Subdivision (c) (page 35 et seq.): Repeat all comments applicable to subdivision (b).

Subdivision (c)(1)(B)(i): We are *not* comfortable with the exception for saleable returns, and believe these returns should be accompanied by transaction history/information/statement documentation. Otherwise, “returns” will become the exception that swallows the rule. As is further specified below, this is a major issue for us, and a point of real contention with the draft.

Subdivision (c)(1)(B)(ii): We are also not comfortable with this language, especially because it does not adequately define what makes something a “nonsaleable return,” or how that type of return is to be distinguished (by a regulator) from a return intended to be saleable.

Subdivision (d) (page 44 et seq.): Repeat all comments applicable to subdivision (c).

Subdivision (d)(1)(A)(ii) (page 45): It is not clear why dispenser-to-dispenser transfers to fulfill a specific patient need should be exempt from chain-of-custody requirements. We have a substantial amount of experience in California with seemingly innocent exemptions of this type being manipulated to avoid prohibitions and requirements, and are uncomfortable with this one.

Subdivision (d)(1)(C) (page 46): Again, we are uncomfortable with returns exception(s).

Subdivision (d)(3) (page 47): Why limit the verification requirements for dispensers?

Subdivision (d)(6) (page 52): Dispensers should also have full alert responsibilities.

Subdivision (e) (page 52 et seq.): See comments for subdivisions (a), (b), (c), and (d).

Subdivision (f) (page 61 et seq.): See comments on prior subdivisions.

One final general comment on Section 2: We need to ensure that returns, already a very vulnerable risk area for insertion of illegitimate product into the supply chain, do not become an even greater vulnerability in what is intended to be a more secure supply chain. We reiterate our concern that exempting (saleable or nonsaleable) returns from even the limited chain-of-custody documentation requirements in Phase I will prove to undermine even its incremental value. For both preventive and investigative purposes, we need a full chain of custody, including returns.

SECTION 3 (PHASE II)

We cannot state strongly enough how important Section 3 is to the overall draft, and how much our cautious support for the proposal is contingent on its continued inclusion. We believe it is absolutely crucial to supply chain security to establish an interoperable electronic track-and-trace infrastructure that enables real-time unit-level product validation by *all* trading partners.

We believe Section 3 (Phase II) provides a tentative roadmap to this outcome, and we are encouraged by its inclusion. However, we also believe that Section 3 can and must be made far more definitive, declarative, and comprehensive. We also believe that the outcome it envisions can and must be accomplished on a much tighter timeline than the 8-15 years that are proposed.

In terms of methodology to accomplish the increased vitality of the language in Section 3 that we contemplate, our suggestion would be that the working group make real and specific use of the standards for a universal, interoperable, unit-level electronic track-and-trace infrastructure that have already been developed by the FDA pursuant to its obligations under the FDAAA. At least portions of those standards have been shared at public meetings (including Board meetings in California), so we know that they are fairly developed. Rather than having further standards-development *follow* the enactment of this proposal, we would suggest instead that the legislation make use of the standards that have already been developed, at least in draft form. We feel that it would provide the predictability craved by the industry, as well as the certainty that we crave, if as much as possible those standards could become the requirements of the legislation itself. In other words, we suggest that the legislation define as many as possible of the required elements of the universal, interoperable, unit-level electronic track-and-trace infrastructure, and that FDA rulemaking be limited to fleshing out those requirements as necessary for clarity of purpose. We do not believe it is necessary to delay the process of defining the elements further by delegating it to a future rulemaking, which might also be delayed or entirely prevented from occurring.

Having said that, we do have some specific comments on the text as proposed, though we hope that these comments will prove unnecessary if, as we suggest, Section 3 is expanded.

Subdivision (a) (page 66): We do not see the need for or the clear advantage of requiring agency initiation and/or supervision of pilot projects at this stage of development. Several pilots have already been run, and/or are ongoing, and those have already provided proof of concept. It is no longer necessary to use pilots as preliminary learning devices, as the time for that is past. After eight years of waiting (under California law), the time for actual implementation is here. Too many companies have already invested in technologies and are well on their way to full and actual compliance. We do not want further requirements of pilots to derail that progress.

Of course we do not object to voluntary continuation of existing pilots, or even initiation of voluntary additional pilots. But we do not want the development of standards or regulations to have to wait for the completion of pilots, and the structure of the proposed draft suggests this is the intention (or at least the effect, given the timelines). We are also concerned about setting the Secretary up for failure, since there is no apparent ability to *compel* participation by trading partners in the pilots, such that the industry could simply refuse to take part. If completion of the pilot(s) is taken to be a prerequisite to progress on standards or regulations, that is unacceptable.

Subdivision (b) (page 67): Similarly, while we do not object to the general idea of public meetings convened by the Secretary, we do not see the need for or advantage of *requiring* such meetings (or the attendant reporting/guidance documents that are supposed to result from same), as an implied precondition to promulgation of standards/regulations. As it has already done, the FDA is perfectly capable of convening public meetings without being required to do so, and also of reporting the outcome(s) and learning(s) from such meetings. We do not see that legislating a requirement of such meetings would significantly advance the process. We fear, instead, that it would function solely or primarily as a delay tactic. Moreover, the regulatory process itself will provide more than adequate opportunity for public comment and discussion with the agency. A requirement that meetings be conducted/reported *in advance* of such rulemaking is surplusage.

Subdivision (c) (page 69): The three-plus pages that authorize and (potentially) mandate the promulgation of regulations requiring a universal, interoperable, unit-level electronic track-and-trace infrastructure are obviously, for us, the heart of the matter, and the primary reason we can offer our tentative support for the proposal. We would like to see this section significantly expanded and strengthened, and see it incorporate the standards already developed by the FDA.

With regard to the particulars of this section, as we have already stated we do not believe any sort of significant delay in promulgation of these regulations and/or implementation of the system that will be defined (by the regulations or by a more robust version of the statute(s)) is either necessary or justified. We would suggest a time window of no more than two years for completion of the statutory and regulatory framework, and no more than five years to at least begin if not fully complete implementation. We have already been waiting at least eight years.

We would also obviously require, if the need for this is not obviated by inclusion of the particular elements in the statute itself, that the rulemaking to define the system attributes *must* be mandatory, and that the statutory “trigger” (or “cliff”) be real, enforceable, and immediate. In other words, we would at minimum choose the word “shall” in the bracket at the top of page 70.

In terms of the other particulars in subparts (A) through (D) on page 70, we would choose to include all of the bracketed options (though we are confused by subpart (B), since we hope or assume that dispensers will also be required to participate in the full system under subpart (A)).

We would *not* recommend the inclusion of subdivision (c)(2) (page 71) (“Restrictions”). We are not comfortable with either of these exemptions/exclusions. Subpart (A) would seem to undermine the entire purpose of the statute, since it might prevent requiring adoption of some or all of the technologies requisite to a universal, interoperable, unit-level electronic track-and-trace infrastructure. Subpart (B) is inimical to successful implementation of the proposal, since it must require full participation by all trading partners to create the “closed loop” that is envisioned.

Again, we would also significantly strengthen the “Default Provisions” language that is included in subdivision (c)(4) (page 71). If it is not possible to achieve consensus on including at the “front end” of the legislation the particulars of the required elements (as suggested above), an alternative suggestion would be that the “default” outcome that is defined by this subdivision be where those particular elements are spelled out in the greatest possible detail. This will provide an incentive for appropriate participation in the rulemaking, and a real and meaningful trigger.

Again, we reiterate that while we find Section 3 to be an encouraging sign of willingness to actually and directly confront these issues in a meaningful way at the federal level, we are not yet satisfied with its current shape or vitality. We believe it needs to be greatly strengthened.

SECTION 4 (WHOLESALE STANDARDS)

We hope that Section 4 is intended more as a placeholder than a complete statement of proposed law, because as drafted we find both the purpose and particular provisions of Section 4 very confusing and its real impact difficult to assess. It *appears* that the intention of this draft is to propose replacement of some or all of the states’ licensure authority and/or ability to enforce license restrictions, with regard to wholesalers (distributors), with federal requirements and/or federal enforcement authority. Or at least to create uniform licensing requirements for all states that cannot be supplemented by the individual states. That is the explicit intention of at least the subsection titled “[Part II-Option II]” on page 81 of the draft. If so, we do not support this idea.⁵

⁵ We do not object to a requirement that wholesalers/distributors seek an *additional* “listing” with the Secretary, that is maintained separate and apart from state licensure (and is presumably dependent on prior state licensure). If that is the intention of subdivision (b), on page 76 of the DDS Draft, we would have no objection to that innovation.

As mentioned above, while we fully support (stronger) national minimum standards for wholesalers, and also support federal licensure of distributors in states that do not provide such licensure, we are not comfortable entirely ceding control of either our standards for licensure to these entities or the licenses that we issues to these entities, or our ability to enforce our laws and standards against our wholesaler/distributor licensees. We strongly believe states should remain able to enact and enforce state-specific provisions that go above and beyond national minimums to respond to more local issues and also to later developments requiring more immediate action.

Regulators, and the standards enforced by regulators, largely exist for the percentage of licensed entities that cannot or will not operate safely, ethically, without harm to the public, and within the confines of the law – especially in high-stakes enterprises such as those involving the distribution and dispensing of prescription drugs. The regulatory scheme envisioned for much of Section 4 seems to focus solely on licensing provisions, and not as much on enforcement of the standards against the operations and inevitable bad acts of certain licensees. Without stronger provisions for enforcement, there is no real additional benefit of state or federal licensure.

We will not otherwise meaningfully comment on the specifics of Section 4, other than to say that the text seems to us incomplete, potentially overlapping, and confusing. We assume the contents make sense to the members of the working group because of an ongoing conversation to which the particular provisions relate, but the overall intention and effect is unclear. We will just point out a very few specific textual oddities or uncertainties, as follows:⁶

Subdivision (a)(2)(A)(ii) (page 74): We do not understand this provision at all.

Subdivision (b)(4)(A) (page 76): We believe the listing should be required to be updated with the Secretary more often than once per year. We would suggest that any changes in the data be reported to the Secretary within 10 days of occurrence. Otherwise, the list of wholesalers will never be effectively current or useful (either to the Secretary, or to any other reviewing party).

Subdivision (b)(4)(C) (page 77): What would be the impact of a revocation/suspension of listing by the Secretary? Would that have an impact on the underlying licensure (presuming an underlying state licensure is still required in this version of the proposed licensing scheme)? Would a state licensing authority be able to recommend de-listing based on state discipline?

Also, would revocation of suspension of the license be the only remedy available (to the Secretary, or to any other enforcement authority)? What about authorization to assess or collect fines, fees or costs linked to enforcement, administrative penalties, and the like?

Subdivision (e) (page 78): Again, we see no need to separately license 3PLs.

Section 583, Part I (page 80): Again, we do not think this language is intended as a full and complete elucidation of the concept(s) it identifies, so it is difficult to meaningfully comment on the language. However, we do note that the regulatory authority given to the Secretary seems to be unnecessarily restricted to certain subject areas (the items listed in (b)(1)-(6)). We do not believe this list is complete, and more generally we would not restrict the Secretary's ability to devise standards as appropriate, exercising his or her discretion to formulate complete standards.

⁶ Again, we are picking and choosing particular provisions on which to comment here, and our failure to comment on any particular provision should not be construed as support for or lack of objection to that provision.

Also, we are concerned that this Option I would place unnecessary limits on recourse to and use of the bond (which in California is not simply a prerequisite to licensure, but which can also be accessed for recovery of unpaid fines, fees, and costs, owed to the regulatory agency).

Section 583, Part II, subdivision (c) (page 82): We strongly caution against requiring just one license for any number of locations operated by the same owner within a state. We believe that each site/premises needs to be individually licensed. California currently has a number of wholesalers operating within the state at more than one location, each of which is the subject of a separate license. We feel strongly that this multiplicity of licensure should be maintained, for a host of reasons, including that: a single license for multiple sites would obscure transparency, both to the regulatory agency and to downstream partners, about the location from which drugs are being shipped, possibly masking and/or encouraging unlicensed activity; single licensure will make it more difficult to ensure proper inspection of all sites for security, temperature, sanitation and other important safety factors; single licensure would encourage use of “hidden locations” to mask dishonest wholesaling activities; and single licensure would limit our flexibility in license discipline/enforcement cases, since we would be more often faced with the choice of deploying the “nuclear option” of revoking a wholesaler’s entire (single) license to operate in the state for a problem at one facility, putting that wholesaler entirely out of business in California.

Subdivision (d) (page 82): We also advise against a requirement that changes be reported only after the fact, and without requiring approval by the licensing entity. We suggest that these changes have to be submitted in advance for approval by the regulator.

Subdivision (e) (page 82): We do not feel this list of bases for denial is complete. There are a number of other bases for denial that we would suggest be added.

Subdivision (g)(7)(A) (page 90): We do not understand the reason to establish “first in, first out” (oldest stock to be distributed first) as a requirement, rather than a business decision.

Subdivision (g)(7)(D) (page 92): Why is the retention period for this documentation only set at two years, rather than the three years that is set forth in subdivision (g)(6)(B) (page 89)?

Section 583, Part III, subdivision (b)(3) (page 93): If a bond in one state is proposed to make it unnecessary to secure a bond in another state, will the second (unbonded) state have the ability to access the bond in the first state in the event of discipline, fine, fee, costs, etc.?

Subdivision (d)(1) (page 95): Why limit actionable convictions to felonies? We find that misdemeanor convictions can also be very relevant to fitness to practice. Also, there may be acts that are initially charged (or even convicted) as felonies that are later converted to misdemeanors for purposes of sentencing or completion of probation. Would these convictions be sufficient?

Subdivision (e) (page 95): We find the “Effective Date” provision confusing.

Section 583, Part IV (page 96): We are obviously gratified and flattered to see several of the sections of California law pertaining to wholesalers imported into the DDS Draft. Again, we assume these are intended more as placeholders than final proposals. We reiterate our eagerness to work together with you to best define the national minimum standards using these examples.

SECTION 5 (3PL STANDARDS)

As previously stated, we would prefer to continue licensing 3PLs as wholesalers (or in a more general license category of “distributors”), inasmuch as what they do, including receipt, storage, possession, manipulation, and re-distribution of drugs, places them in the same category of risk and necessity for licensure as traditional wholesalers. We do not see the fact that they do not take ownership of the drugs in their possession as meaningful to licensure requirements.

With regard to the specific provisions, we repeat and incorporate by reference our prior comments on similar provisions in Section 4 of the DDS Draft, except that we also note:

Subdivision (f) (page 114): We believe a three-year renewal period is too long. There is simply too much change that can occur over that period of time (e.g., changes in officers and/or owners, new compliance officer(s), even new location(s)). We suggest annual renewal.

Subdivision (g) (page 114): We are unclear about the purpose or intent of this provision, and are uncomfortable with the limitation that it seems to be placing on use of the bond. Under California law, the bond is not simply a guarantee for licensure, but may also be accessed to pay administrative fines, fees, costs, and other amounts owed to the Board.

SECTION 6 (PENALTIES)

We are not familiar enough with the general statutory scheme to meaningfully comment on this section. However, we do believe that some additional enforcement mechanisms may be required to specifically ensure compliance with the track-and-trace infrastructure requirements. This may entail the specification of milestones, incentives and administrative penalties, or other tools that could be deployed by the FDA (or other appropriate agency) to encourage compliance.

SECTION 7 (UNIFORM NATIONAL POLICY)

Finally, as we stated above, we are concerned that Section 7 would not only preempt the California law(s) pertaining to electronic pedigree/track-and-trace, but would also impair and/or prevent our ability to adequately license and enforce licensure standards against wholesalers (as well as 3PLs, reverse distributors, and brokers). This is fairly broad preemption language.

We acknowledge that subdivision (b)(3) seems to provide states with some ability to still seek suspension or revocation of licenses issued by the state (assuming the state still issues the license), but this would be at least complicated, if not impossible, if what we are talking about is the state having to enforce federal standards through state law. This would seem to require that states (including but not limited to California) re-write their licensing acts to acknowledge that the ability to license and seek license discipline is now derived from federal authority. Also, it is not adequate to merely carve out state licensing authorities’ ability to suspend or revoke licenses, since this would not seemingly preserve states’ ability to cite and fine (federal or state) licensees, or take other administrative action against licensees not amounting to suspension/revocation. At a minimum, we find the possible impact of this preemption clause on our continuing jurisdiction over, and ability to enforce licensing requirements against, wholesalers (and 3PLs) to be unclear.

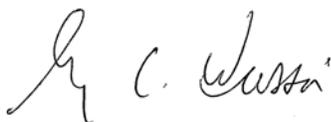
We also do not believe the “Exception” written into subdivision (c) is adequate to fully preserve other laws relating to wholesalers, including the prohibition against selling excessive amounts of controlled substances. To investigate and prove such a violation, the Board must rely on existing methods of tracing product sales – using acquisition and disposition records. If these entities are no longer licensed by the states, or their licensure does not depend on the states, or if the Board loses its direct connection to licensure of these entities, it will also lose access to these investigative tools that are necessary to prove its cases not only against wholesalers/distributors themselves, but also against the pharmacies and other dispensers to whom they distribute.

Conclusion

For all of these reasons, we are concerned about the impacts that the DDS Draft is likely to have on supply chain security in California, and by extension in the rest of the country, when it immediately replaces California’s pedigree law with a less robust infrastructure. We agree in principle that a uniform national standard is ideal. However, we would like to move directly and quickly to the kind of end-to-end national track-and-trace infrastructure outlined in Section 3 of the draft (Phase II). We would like to see that infrastructure spelled out more specifically in the statutory language (perhaps in reliance on the standards developed by the FDA under FDAAA), to provide both certainty of requirements and certainty of timeline in the Act itself. We do not believe California or the nation can wait an additional eight to fifteen years (or more) to have the guarantee of security that is already promised by California’s law, so we urge prompt action.

We once again commend you for your leadership on these vital issues of national drug security. Thank you also for your persistent willingness to hear our input. We look forward to continuing to work together to secure the nation’s drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best ways to reach me are on my cell phone, (909) 633-2574, or by email to stanweisser@aol.com. If you prefer, you may also communicate with the Board’s Executive Officer, Virginia Herold, who may be reached by telephone at (916) 574-7911, or by email to virginia.herold@dca.ca.gov. Thank you again for your efforts.

Sincerely,



STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy

Enclosure: May 9, 2012 Board letter to Senator Tom Harkin re: RxTEC proposal

ATTACHMENT 2

Order of Adoption
Board of Pharmacy
California Code of Regulations

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

ATTACHMENT 3

Future Versions

This document is a preliminary version of the implementation guideline. It is anticipated that it will undergo changes as the industry engages in pilots and implementations of product serialization, track and trace, and pedigree applications. Comments to this document should be sent to GS1 Healthcare US via rceleste@gs1us.org. The document may be updated, replaced or made obsolete by other documents at any time. Please check the GS1 Healthcare US website frequently for the latest version of the document. <http://www.gs1us.org/healthcare>

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About GS1®

GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

About GS1 US®

GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

About GS1 Healthcare US®

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of sixty-six local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.



Part 1: Preface

1. Introduction

California state drug pedigree requirements become mandatory in 2015, marking the beginning of product serialization and visibility in the healthcare supply chain. In response, members of the United States pharmaceutical industry have been preparing their systems and business processes to meet those requirements. During this journey, the healthcare industry has rallied around the use of Electronic Product Code™ Information Services (EPCIS) for pedigree and track and trace. The EPCIS is a GS1 Standard that enables supply chain partners to capture event information about supply chain events (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time.

The EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. There are numerous options for how the standards can be implemented in order to accommodate different applications and environments. Nonetheless, there still needs to be a certain level of consistency in terms of how the standards are implemented by individual trading partners in order to support collaborative supply chain solutions like pedigree and track and trace.

Therefore, members of the U.S. pharmaceutical industry joined forces to determine how the standards can best be applied to support pedigree and track and trace. Over fifty organizations from across the U.S. pharmaceutical supply chain participated. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations all worked together to analyze business processes and post-2015 business requirements, consider the various options, and decide how the standards should be applied.

To support testing and analysis, they created a computerized model of the U.S. pharmaceutical supply chain that simulates forward logistics and reverse logistics processes using GS1 Standards for product serialization and visibility. All of their decisions about how the standards might be applied are embedded in that model, which is known as the Industry Reference Model for the U.S. Pharmaceutical Industry. The reference model provides an example of an implementation, reflecting the current wisdom in industry for how the standards can best be applied to support the needs of the U.S. pharmaceutical supply chain.

This document records all of the decisions points for how the standards are applied. By so doing, this document serves an implementation guideline that shows industry members how to apply the standards to their own business processes to support pedigree and track and trace.

2. Document Information

This implementation guideline was prepared by GS1 US and the Secure Supply Chain Task Force of the Traceability Adoption Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 Standards to support pedigree and track and trace. It is based on the *GS1 General Specification*, the *EPC Tag Data Standard*, the *Tag Data Translation Standard*, and the *EPCIS Standard*. It was developed using information obtained from all members of the U.S. pharmaceutical supply chain from manufacturers to providers.

2.1. Purpose

This document identifies the GS1 Standards used and provides details about how they can be applied toward the purposes of product serialization, track and trace and pedigree. Included are all of the EPCIS *Business Step* and *Product Disposition* combinations used for each supply chain event. By so doing, this document serves an implementation guideline that directs industry members about how to apply the standards to their own business processes to support product serialization, pedigree and track and trace within the U.S. pharmaceutical supply chain.

2.2. Content Condition

This document is a working draft that reflects the current level of thought within industry. As such, it will undergo changes as the Traceability Adoption Workgroup deems necessary to reflect feedback from industry pilots, architecture work being conducted by GS1, and other industry efforts which advance the level of thought. The content may be of assistance as a resource for understanding current thinking or as an aid for pilot preparation. The reader should be aware that changes will be made frequently and should not expect any particular section of content to remain unchanged in the first release.

2.3. Version Updates

Version	Date	Update Notes	Reviewed by Team	Approved for Draft by Team
Release 1.0	02/01/2012	Initial release.		

Table A: Document Version History

2.4. Scope

This guideline presents the current wisdom in industry for how GS1 Standards can best be applied to U.S. pharmaceutical supply chain business processes to support pedigree and track and trace. It does not provide any guidance or advice regarding regulatory compliance.

- The content of a valid ePedigree is specified in pedigree regulations, and companies should consult those regulations for information, guidance and/or advice regarding regulatory compliance.
- The Drug Pedigree Messaging Standard (DPMS) defines an XML data format designed specifically to satisfy pedigree requirements.
- The DPMS complies with all known U.S. pedigree laws, and is currently the only pedigree format approved by regulators.
- The use of EPCIS events along with specific product and location master data provides a means for trading partners to accumulate the information that would be found in the *Drug Pedigree Messaging Standard (DPMS)*.

2.5. Normative References

This application guideline is based on the *GS1 General Specification*, the EPC Tag Data Standard, the Tag Data Translation Standard, and the EPCIS Standard. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 General Specification* – Available in the Knowledge Center through the GS1 website at www.gs1us.org/solutionscenter
- EPC Tag Data Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/qsmp/kc/epcglobal>
- Tag Data Translation Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/qsmp/kc/epcglobal>
- EPCIS Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/qsmp/kc/epcglobal>
- Core Business Vocabulary Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/qsmp/kc/epcglobal>
- GTIN Allocation Rules
- GTIN Allocation Rules for Healthcare
- GLN Allocation Rules

2.6. Non-normative References

Material in this application guideline is based on a number of non-normative guidelines and references available from GS1 and GS1 US. The specific guidelines and documents referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 RFID Bar Code Interoperability Guideline* - Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmp/kc/barcodes>
- *Healthcare Provider GTIN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier GTIN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Provider GLN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier GLN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Provider GDSN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier GDSN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain* - Available on the GS1 US website at www.gs1us.org/hctools

2.7. Additional Considerations & Resources

- GS1 DataMatrix requires camera-based scanners. Traditional laser barcode scanners cannot read the GS1 DataMatrix. As a result, it is important for supply chain partners to communicate prior to implementing GS1 DataMatrix to ensure that the appropriate scanners are in place.
- Prior to purchasing barcode scanning equipment, it is recommended that you consult the *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* (see the Resources page in the Appendix for the link). This document was prepared by GS1 US to assist members of the U.S. healthcare supply chain in evaluating the various barcode scanning equipment options on the market, and selecting the equipment that best fits their needs.
- There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled *Procedure for Responding to Troublesome Barcodes* (see the Resources page in the Appendix for the link) to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

3. Overview of the GS1 Standards Used

This chapter provides a brief definition of each GS1 Standard used in the industry reference model. (Refer to the [Appendix](#) of this document for more information about GS1 Standards that support pedigree and track and trace.)

3.1. Global Location Number (GLN)

The Global Location Number (GLN) is the globally unique GS1 Identification Number for locations and supply chain partners. The GLN can be used to identify a *functional entity* (like a hospital pharmacy or accounting department), a *physical entity* (like a warehouse or hospital wing or even a nursing station), or a *legal entity* (like a health system corporation). The attributes defined for each GLN [e.g., name, address, location type (e.g., ship to, bill to, deliver to, etc.)] help users to ensure that each GLN is specific to one unique location within the world.

3.2. Global Trade Item Number® (GTIN®)

The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number used to identify “trade items” (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a bottle of 100 aspirin tablets; a case of 200 bottles of aspirin tablets, etc.).

3.3. Serial Shipping Container Code (SSCC)

The Serial Shipping Container Code (SSCC) is the globally unique GS1 Identification Number used to identify individual logistic units (i.e., an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain). The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. SSCCs serve as “license plates” from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

3.4. GS1 Data Carriers

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)].

3.5. GS1 Application Identifiers

GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode’s encoded data.) Each data element in a barcode is preceded by its AI. For example, the AI for GTIN is 01. Thus, when “01” appears in the encoded content of a barcode, it means the next 14 digits comprise a GTIN. There are approximately 100 AIs. There is an AI for each GS1 Identification Number. In addition, there are AIs for various types of secondary information to enable supply

chain partners to communicate item-specific information wherever the barcode is scanned (e.g., expiration date; lot number; batch number). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number.

3.6. EPC Information Service (EPCIS)

The EPC Information Service (EPCIS) standard 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. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. In addition, the EPCIS standard also incorporates data standards for how to populate EPCIS data elements. (See Core Business Vocabulary below.)

3.7. Core Business Vocabulary (CBV)

The Core Business Vocabulary (CBV) provides data standards for populating EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies, and element values (with definitions).

3.8. GLN Registry

The GLN Registry is the single source of truth for healthcare location information, offering a comprehensive list of healthcare and healthcare-related facilities in the United States with corresponding Global Location Numbers (GLNs). The GLN is the globally recognized identification number used in the GS1 System to uniquely identify legal entities, trading partners, and locations in electronic commerce transactions. The GLN Registry enables subscribers to access up-to-date, reliable location information, validated by the U.S. Postal Service, for manufacturers, distributors, retailers, hospitals, clinics, as well as retail and mail-order pharmacies in order to improve the accuracy of their supply chain activities.

3.9. Global Data Synchronization Network™ (GDSN®)

The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

4. Background Concepts

4.1. Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a supply chain identifier used to identify *products* for supply chain purposes. The SGTIN is a supply chain identifier used to identify *individual instances of a product* for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in Figure 1, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.

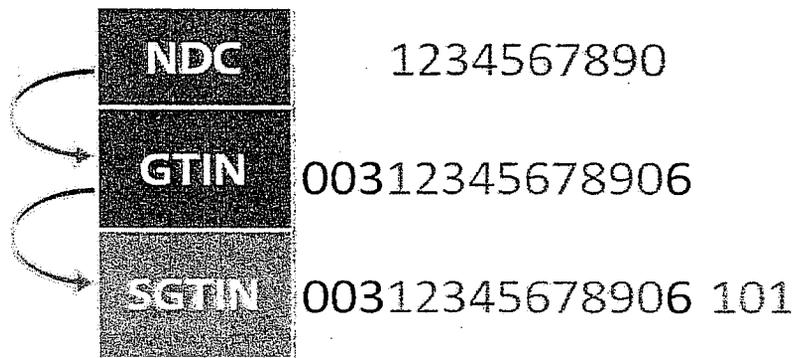


Figure 1: Relationship of the NDC, GTIN and SGTIN

4.2. NDC Labeler Code & GS1 Company Prefix

The NDC is a 10-digit identifier comprising two segments: a *Labeler Code* assigned by the FDA and a *Product/Package Code* assigned by the manufacturer. The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify a company that manufactures a drug (including repackers or relabelers) or distributes a drug (under its own name).

GS1 US has reserved a placeholder in the GS1 Company Prefix numbering system that enables the NDC *Labeler Code* to be integrated into the GS1 Company Prefix for pharmaceutical companies. The placeholder (named the "GS1 Prefix") is **03**, and the GS1 Company Prefix for a pharmaceutical company is simply its *Labeler Code* with "03" appended in front. For example:

GS1 Prefix	03
FDA-assigned <i>Labeler Code</i>	61414
GS1 Company Prefix	0361414

ⓘ In order to use a *Labeler Code* as a GS1 Company Prefix, manufacturers must first contact GS1 US to have a GS1 Company Prefix that embeds their *Labeler Code* assigned to the company.

Pharmaceutical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NDC *Labeler Code*, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their *Labeler Code* when assigning GTINs that embed NDCs (discussed below). However, they may use whichever GS1 Company Prefix they prefer to generate SSCCs and GLNs.

4.3. Integrating NDCs into GTINs

As noted above, NDCs can be integrated into GTINs. Figure 2 illustrates how the two NDC segments (i.e., *Labeler Code* and *Product/Package Code*) are integrated into the segments of a GTIN-14. The NDC *Labeler Code* is integrated into a GS1 Company Prefix (as described above). The NDC *Product/Package Code* is used to populate the Item Reference segment of the GTIN.

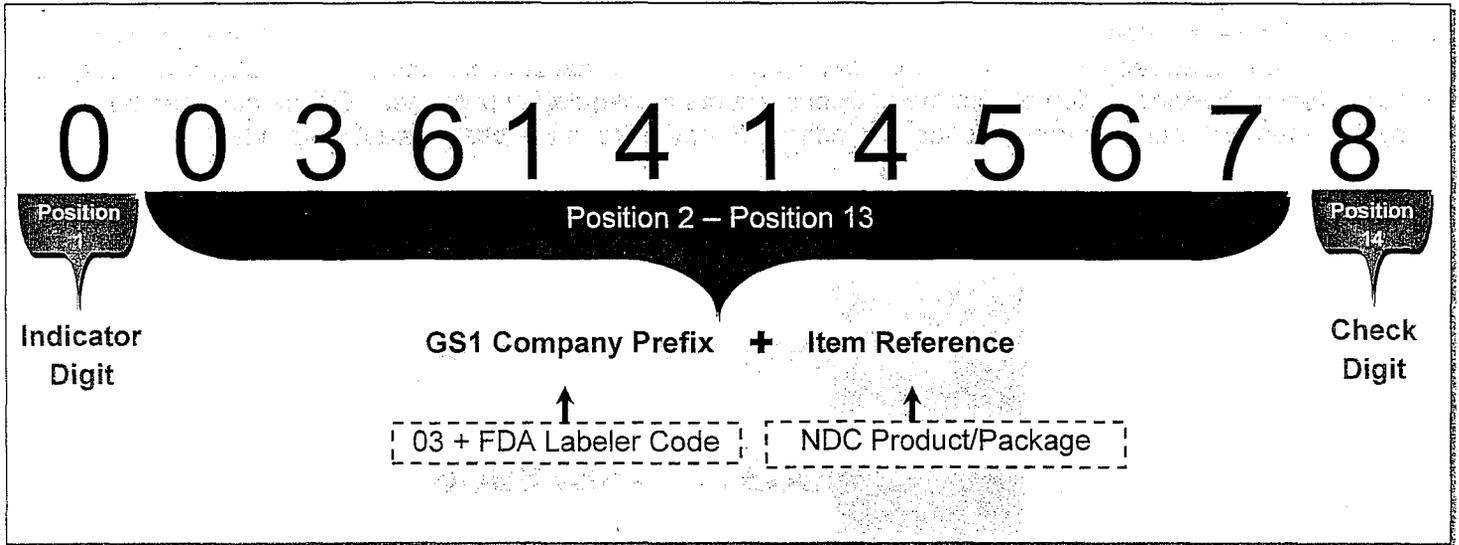


Figure 2: Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN “00361414567894”)

4.4. Assigning vs. Storing vs. Encoding GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Within the U.S. pharmaceutical supply chain, the 12-digit GTIN (“GTIN-12”) and the 14-digit GTIN (“GTIN-14”) are predominantly used. Regardless of how they are assigned, it is important to understand that GTINs are always encoded in barcodes^① and stored in databases in 14-digit format.

Assigning GTINs	Storing GTINs	Encoding GTINs
GTIN-12 or GTIN-14	14-digit format (i.e. GTIN-14 or GTIN-12 in 14-digit format using leading zeros)	14-digit format^① (i.e. GTIN-14 or GTIN-12 in 14-digit format using leading zeros)

Table B: Key to Assigning, Storing and Encoding GTINs

① The exception is the UPC-A, which is the only barcode in which GTINs are encoded as 12 digits.



4.5. Marking Products with Both UPC-A and GS1 DataMatrix

As of this writing, FDA regulations require pharmaceutical products to be marked with a linear barcode that carries their NDC. Serialization requirements and pedigree regulations typically require pharmaceutical products to be marked with a barcode that carries their NDC, a serial number, and possibly other secondary information such as lot/batch or expiration date. To satisfy these requirements, many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A (to satisfy the FDA linear barcode requirement) and a GS1 DataMatrix (to satisfy serialization/pedigree requirements). (See the note in Section 8.1.1 for more information.) The UPC-A holds a maximum of 12 digits, but the GS1 DataMatrix requires the GTIN to be in a format that is 14 digits long. In order to ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations below for all products that will be marked with both a UPC-A and a GS1 DataMatrix:

- assign a GTIN-12 to identify the product at the lowest saleable level (i.e., the bottle or pack)
- create the UPC-A linear barcode using the GTIN-12
- pad the GTIN-12 with two leading zeros to create a "GTIN-12 in 14-digit format" ⓘ

GTIN-12	31414 199999 5
GTIN-12 in 14-digit format	0 031414 199999 5

- when storing GTIN-12s in databases, store them in the 14-digit format
- use the "GTIN-12 in 14-digit format" when encoding the GS1 DataMatrix (along with Expiration Date, Lot Number and Serial Number for serialization purposes)

ⓘ **THIS SHOULD NOT BE DONE IN THE OPPOSITE DIRECTION** (i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a GTIN-14 in a 12-digit format). A true GTIN-14 (one with digits other than "00" in the 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, the check digit (which is calculated using the value and position of each digit) would not match.

A GTIN-12 remains a GTIN-12 whether it is in its original 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a "GTIN-12 in a 14-digit format." It is not a GTIN-14. Therefore, when a product needs to be marked with a UPC-A, it should be assigned a GTIN-12 (not a GTIN-14) in order to preserve the manufacturer's ability to represent the GTIN in a 12-digit U.P.C. as well as any barcode that requires a 14-digit format.

4.6. Case Identification

Cases can be identified using GTIN + serial number or using SSCC, depending on how the case is being used:

- **Use GTIN + serial number** if the case is orderable and if your customer is expecting to identify the contents from the case barcode or EPC/RFID tag
- **Use SSCC** if the case is to be treated as a logistics unit

4.7. Location Identification: Data Capture vs. Data Reporting

The reference model includes a table that provides a reference between a business location (i.e., a building with an address) and internal locations (e.g., loading dock; doorway; etc.). The model captures EPCIS events at the internal location level, and produces EPCIS events for trading partners at the business location level. For example, a manufacturer may capture the location of a palletizer as cases are aggregated or packed onto a pallet. The EPCIS event that is generated for trading partners will include the location of the manufacturing site, not the palletizer itself. The manufacturer may decide to store the lower level location (palletizer) for their own purposes and report a higher level location (the production plant) for the purposes of external track and trace.

4.8. EPCIS & the URI

EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in URI format. "URI" stands for Uniform Resource Identifier, which is used in many Internet-based software systems to refer to any resource on the network. There are two types of URIs: Uniform Resource Names (URNs) and Uniform Resource Locator (URLs). The EPCIS data format standard is a URN which takes the following form:

`urn:epc:id:scheme:component1.component2....`

Scheme names an EPC scheme, and the content and format of the remainder of the URI string (i.e., *component1*, *component2*, etc.) depends on which EPC scheme is being used. Each EPC scheme provides a namespace of identifiers that can be used to identify physical objects of a particular type. There are seven EPC schemes that correspond to GS1 keys. For example, the EPC scheme for SGTIN is provided below:

General syntax: `urn:epc:id:sgtin:CompanyPrefix.ItemReference.SerialNumber`

Example: `urn:epc:id:sgtin:0614141.112345.400806`

The URI scheme to be used for GTIN + serial number, SSCC and GLN are provided in the relevant sections of this manual.

4.9. Determining the Length of GS1 Company Prefixes for URIs

When translating data from URI formats, it is necessary to indicate the length of the GS1 Company Prefix (i.e., how many digits within the GS1 Key belong to the GS1 Company Prefix). Because GS1 Company Prefixes are issued in varying lengths, you will need to obtain the length of each GS1 Company Prefix you expect to encounter in your EPCIS events. To facilitate this, GS1 US has published a list of U.S. GS1 Company Prefixes that you can download and use (www.gs1us.org/gcplist). Alternatively, you can ask your trading partners for the length of their GS1 Company Prefixes and create your own table. (You can even make this part of your on-boarding process for vendors.)

4.10. Inference

Inference is the process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. Inference applies in instances where a collection is moved through the supply chain in an outer container (e.g., pallets; cases; totes; etc.), and less than 100% of data carriers in that collection are read by recipients. In such circumstances, inference enables the recipient of the collection to leave the outer container intact (un-opened) so as not to undermine tamper-evident security features. To gain a more complete understanding of what is contained in the entire collection, the recipient reads the serialized identifiers for the visible items, cross-checks them with the shipping documents for the collection and outer container bundle, and verifies the integrity of the outer container bundle and its security features. If all three conditions are confirmed, the rest of the items in the collection can be inferred to be present.

Inference is a mechanism that enables supply chain partners to leverage strong supply chain practices to meet the potential challenges associated with the receiving/shipping of serialized items. For more information, see the GS1 US white paper entitled *The Practice of Inference in the U.S. Pharmaceutical Supply Chain* (see References above for link).

Use of Inference in examples:

For internal levels of packaging where either barcodes are used or EPC/RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

4.11. Use of Inference

For internal levels of packaging where either barcodes are used or RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

4.12. Drug Pedigree Messaging Standard (DPMS)

The content of a valid ePedigree is specified in pedigree regulations. At the time of publication, the DPMS complied with all known U.S. pedigree laws. The present guideline makes use of GS1 Visibility standards including Global Data Synchronization Network (GDSN), EPCIS, Core Business Vocabulary and the Tag Data Standard to manage, share and assemble pedigree data.

The documented EPCIS events and Master Data Management architecture provides for reporting capabilities that provide all of the information that would be found in the DPMS.

Part 2: Identify

GS1 Identification Numbers globally and uniquely identify supply chain objects (e.g., products, assets, logistic units, etc.), as well as supply chain partners and physical locations. Table 3 lists the GS1 identification standards used in this guideline to support pedigree and track and trace.

Supply Chain Object or Location	Corresponding GS1 Identifier	Instance
Companies and warehouses	GLN	
Specific locations within companies & warehouses	GLN + extension	
Item	GTIN	GTIN + serial number
Kit	GTIN	GTIN + serial number
Homogeneous Case	GTIN	GTIN + serial number, SSCC
Mixed / Partial Case		SSCC
Pallet		SSCC
Tote		SSCC

Table C: GS1 Identifiers¹

¹ There may be other layers of packaging that are not specified here.

5. Identifying Trade Units (Products, Cases and Kits): GTIN

In the GS1 System, products, cases and kits² are identified with the Global Trade Item Number (GTIN). GTIN is a globally unique, standards-based, identification number for trade items. When a manufacturer assigns ("allocates") a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 Standards specify the list of attributes that must be defined for each GTIN, as well as the permissible values. Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. (The section of this guideline entitled "Master Data Management" explains how this information can be combined with EPCIS event information to obtain supply chain visibility.)

(NOTE: GS1 US provides an online tool, known as *Data Driver*®, to support users in allocating GTINs and defining the associated attributes. Visit <http://www.gs1us.org/resources/tools/data-driver> for more information.)

5.1. Assigning GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). However, within the U.S. pharmaceutical supply chain, the GTIN-12 and the GTIN-14 are predominantly used. The choice of format is related to point of sale:

- **Assign a GTIN-12 to pharmaceuticals products that will be scanned at point of sale** (see [Section 4.5](#) for more information)
- **Assign a GTIN-14 to pharmaceuticals that will not be scanned at point of sale**

5.1.1. Creating a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The three segments within a GTIN-12 are:

- **U.P.C. Company Prefix:** A specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-12 identifiers. U.P.C. Company Prefixes vary in length depending on the company/organization's needs. In a GTIN-12 that embeds an NDC, the U.P.C. Company Prefix segment is populated with the NDC Labeler Code with a "3" appended in front.
- **Item Reference:** A number assigned by the holder of the U.P.C. Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the U.P.C. Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-12 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.
- **Check Digit:** A one-digit number calculated from the first 11 digits of the GTIN-12 used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at <http://www.gs1us.org/resources/tools-and-services/check-digit-calculator>.

² Consult the FDA UDI (Unique Device Identification) Rule for Kits that include a medical device.

Although the length of the U.P.C. Company Prefix and the length of the *Item Reference* vary, they will always be a combined total of 11 digits in a GTIN-12. The addition of the *Check Digit* completes the 12 digits of the GTIN-12. Figure 3 provides a color-coded example of a hypothetical GTIN-12 that embeds an NDC, and a key explaining how each digit is populated. (Figure 3 uses hypothetical GTIN 312345678906.)

Example of a GTIN-12 with an NDC embedded												
GTIN-12	3	1	2	3	4	5	6	7	8	9	0	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12

How to Populate Each Digit (*color-coded to coordinate with the GTIN-12 shown above*)

Position 1	GS1 Prefix "3"
Position 2 through 11	NDC <i>Labeler Code</i> as assigned by FDA <u>plus</u> NDC <i>Product/Package Code</i> created by the manufacturer (Although the length of the <i>Labeler Code</i> and the <i>Product/Package Code</i> vary, they will always be a combined total of 10 digits.)
Position 12	Check Digit

Figure 3: Populating the 12 digits of a GTIN-12 with an NDC embedded

5.1.2. Creating a GTIN-14

Each GTIN-14 is a numerical string comprising four distinct segments. The four segments in a GTIN-14 are:

- **GS1 Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8. (The number "0" is used in this position as a fill character when a GTIN-12 or GTIN-13 is written in 14-digit format.)
 - ① *Packaging specialists must review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product. This ensures that there is a unique GTIN on every packaging level, which is imperative to preserve the uniqueness of each GTIN.*
- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs. In a GTIN-14 that embeds an NDC, the GS1 Company Prefix segment is populated with the NDC Labeler Code with a "03" appended in front.
- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the GS1 Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-14 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.
- **Check Digit:** A one-digit number calculated from the first 13 digits of the GTIN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at <http://www.gs1us.org/resources/tools-and-services/check-digit-calculator>.



Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-14. The *Indicator Digit* and the *Check Digit* comprise the remaining 2 digits of the GTIN-14. Figure 4 provides a color-coded example of a hypothetical GTIN-14 that embeds an NDC, and a key explaining how each digit is populated. (Figure 4 uses hypothetical GTIN **00361414567894**.)

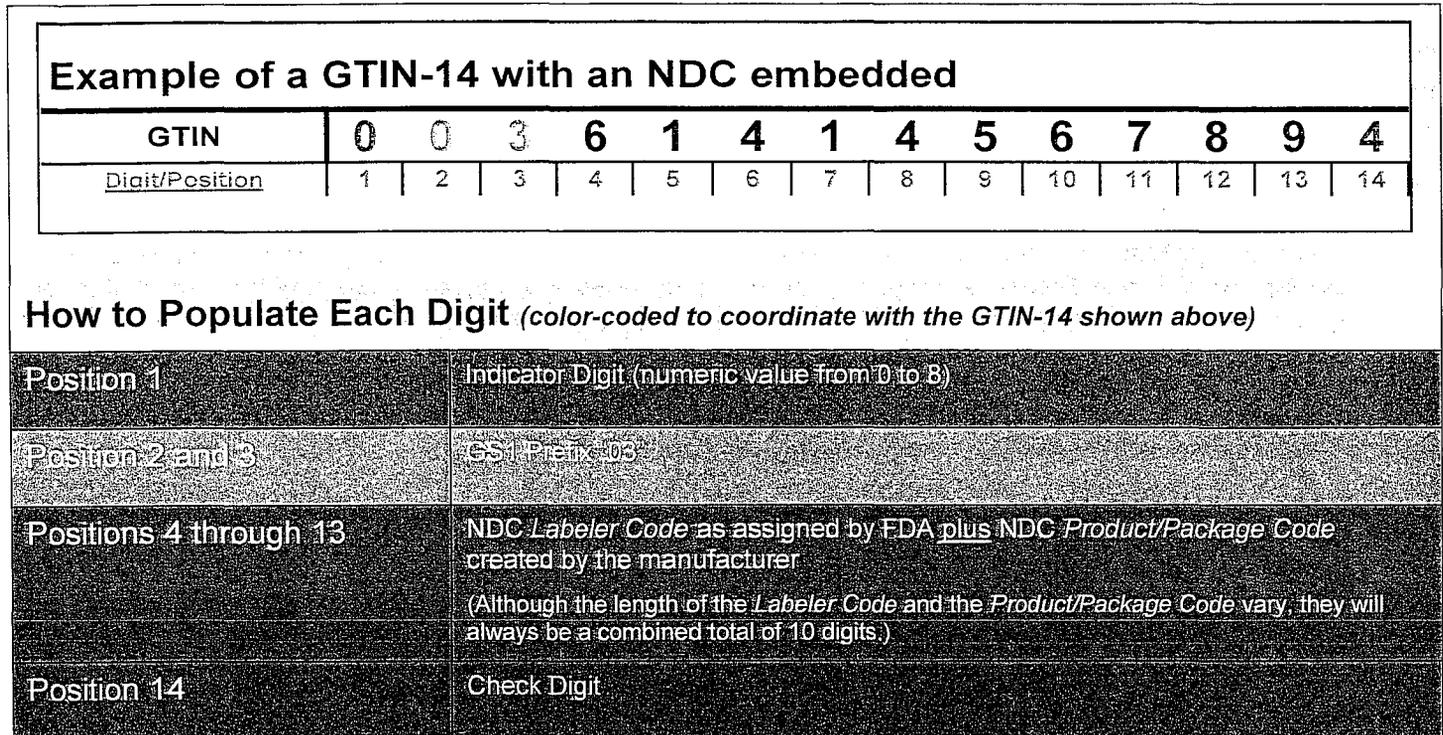


Figure 4: Populating the 14 digits of a GTIN-14 with an NDC embedded

5.2. Assigning/Allocating Serial Numbers

The combination of a GTIN plus a unique serial number is used to identify a specific instance of a trade item. For example, if hypothetical GTIN 00361414567894 is assigned to identify a 100-count bottle of XYZ tablets, then the combination of GTIN 00361414567894 plus a serial number would identify a *specific* 100-count bottle of XYZ tablets. All bottles of XYZ tablets would have the same GTIN, but each bottle would be assigned a unique serial number.

The *GS1 General Specifications* define a serial number for use with a GTIN as an alphanumeric string whose length is variable between one and 20 characters (*the specific characters allowed are defined in the GS1 General Specifications*). Therefore, databases and messages that need to contain a GTIN plus serial number should be designed to accommodate any serial number consisting of 1-20 characters. "Zero" characters in serial numbers are treated as any other alphanumeric character such that serial numbers 7, 07, and 007 are all *different* serial numbers according to the standard. Databases should treat the serial number as a text field so that leading zeros are not inadvertently stripped off.

In GS1 barcodes, serial numbers are represented using AI (21). Any serial number consisting of 1-20 characters may be used in a GS1 barcode per the standard. Although barcodes can accommodate any 1-20 character serial number, the size of the barcode may vary depending on how many characters are used. However, many production systems prefer a consistent barcode size in order to conform to package artwork

constraints and to simplify the quality assurance process. For this reason, manufacturers often adopt a consistent serial number length rather than allow their serial numbers to vary between 1 and 20 characters.

When using EPC/RFID tags, however, certain limitations apply. As with barcodes, EPC/RFID tags having at least 198 bits of EPC memory capacity can accommodate any 1-20 character serial number. However, EPC/RFID tags having 96-197 bits of EPC memory capacity use a 96-bit encoding format (called SGTIN-96) that places limitations on the serial numbers that can be encoded. When using the SGTIN-96 encoding, the serial number must be numeric only (that is, the only characters permitted are the digits '0' through '9'), must not have any leading zeros, and must have a numeric value that is less than or equal to 274877906943.

The following Best Practices have been defined to accommodate all of the considerations described above:

- Business applications, messages, and databases should be designed to accept data from any data carrier. Specifically, this means that applications and databases should be designed to accept the full range of data values defined by GS1 Standards, including a full 14-digit GTIN and a serial number between one and 20 alphanumeric characters. The restrictions on data values that certain data carriers impose (e.g., 96-bit EPC/RFID tags) should not be carried through to this level.
- Applications must not add or remove leading zeros to serial numbers.
- While the standards support serial numbers beginning with "0", applications that assign serial numbers for use with GTIN should avoid serial numbers that begin with a "0" character in order to avoid errors associated with incorrect implementations.
- If 96-bit EPC/RFID tags are to be used, serial numbers must fit within the encoding constraints of the 96-bit SGTIN format as defined by the GS1 EPC Tag Data standard (described above).
- In order to support both barcodes and 96-bit EPC/RFID tags, and to achieve a consistent barcode size, a good policy would be to assign either 11-digit numeric serial numbers within the range 10000000000 – 99999999999, or 12-digit numeric serial numbers within the range 100000000000 – 274877906943.
- The GTIN and serial number identifies a unique instance of a product. Therefore, reuse of serial numbers for a given GTIN is not a best practice at this time. The subject of reuse has been submitted to GS1 for review.

5.3. Data Formats for Databases

5.3.1. GTIN Fields

Although the U.S. pharmaceutical supply chain uses both GTIN-14 and GTIN-12, EPCIS requires GTINs to be in a 14-digit format. Therefore, a GTIN should always be represented in software applications as 14 digits by adding leading zeros as necessary to make 14 digits. In order to preserve any leading zeros that may be present, the GTIN field should be represented in a database as a text field (not numeric). This is especially important for manufacturers who currently have many GTIN-12s in their systems due to the Barcode Rule.

5.3.2. Serial Number Fields

As described above, the industry best practice is for manufacturers to assign all numeric serial numbers of only 11-12 digits in length in order to ensure compatibility of serial numbers across bar codes and 96-bit EPD/EPC/RFID tags. Regardless, serial numbers should always be stored in a text field (not numeric) that is

capable of handling from one to 20 characters. Leading zeros should *never* be added or removed from serial numbers.

5.4. Data Format for EPCIS: URI Format

Within the EPCIS, GTIN + serial number must be stored in EPC URI format. The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

The SGTIN EPC is based on a 14-digit GTIN. Therefore, GTIN-12s will first need to be converted to a 14-digit number by adding two leading zeros. (An example of the conversion is provided below.)

General syntax:

urn:epc:id:sgtin:CompanyPrefix.ItemReference.SerialNumber

Example:

urn:epc:id:sgtin:0614141.112345.400806

Grammar:

SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody

SGTINURIBody ::= 2*(PaddedNumericComponent ".")GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the *GS1 General Specifications*. Figure 5 depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

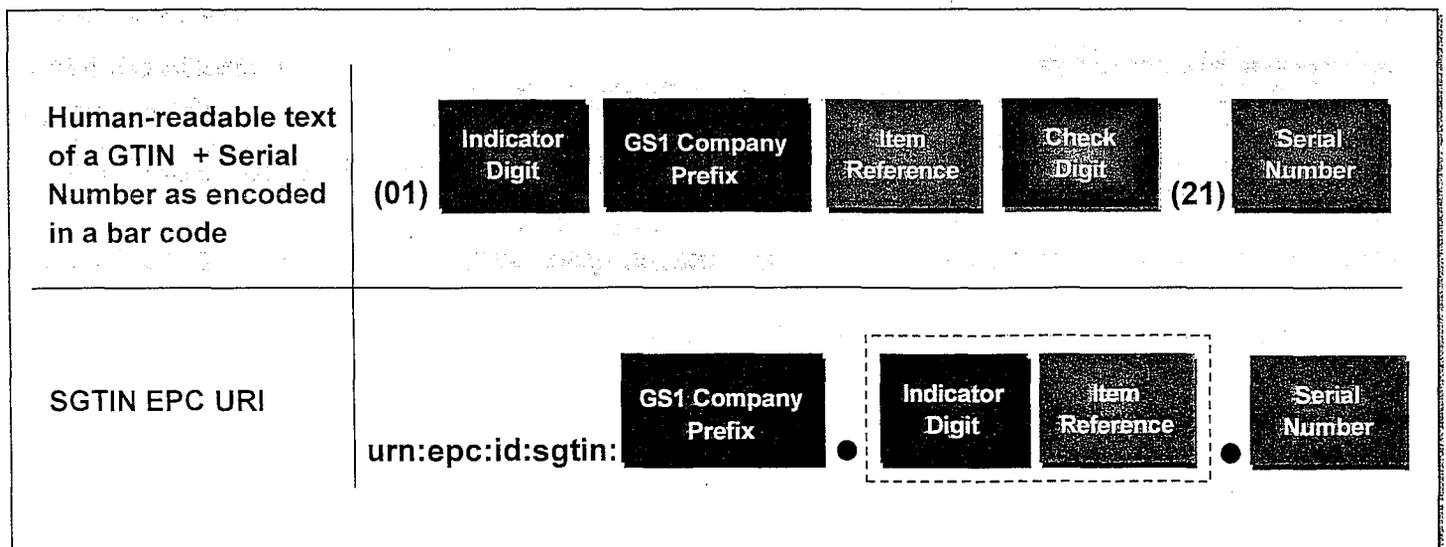


Figure 5: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format



- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI(21).

Example – Converting a GTIN-14 + serial number into EPC URI Format:

GTIN-14	2 030001 123498 7
Serial Number	123456789012
Corresponding Barcode Human Readable Text	(01) 2 030001 123498 7 (21)123456789012
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012

① *The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

Example – Converting a GTIN-12 + serial number into EPC URI Format:

To find the EPC URI corresponding to the combination of a GTIN-12 and a serial number, first convert the GTIN-12 to a 14-digit number by adding two leading zero characters. The first leading zero will serve as the Indicator Digit, and the second leading zero will serve as the first place of the U.P.C. Company Prefix as shown below:

GTIN-12	31234 567890 6
GTIN-12 in 14-digit format	0 031234 567890 6
Serial Number	123456789012
Corresponding Barcode Human Readable Text	(01) 0 031234 567890 6 (21)123456789012
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 031234 . 0 567890 . 123456789012

① *The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

5.5. Data Storage Options

GTIN and serial number are assigned as separate data elements, but are saved together as an SGTIN in EPCIS. Users have several options for how to store GTIN + serial number in databases: (1) GTINs and serial numbers can be saved in their own fields; (2) saved together in the SGTIN EPC URI format (to be parsed by backend systems as needed), or (3) saved as both.



Thus, there are three options for storing GTINs and serial numbers in databases:

- 2 fields = GTIN field and Serial Number field
- 1 field = One field containing serialized GTIN in EPC URI format
- 3 fields = GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 4 below:

Field	Data Format
GTIN	<ul style="list-style-type: none"> ▪ 14 digits ▪ text field (not numeric)
Serial Number	<ul style="list-style-type: none"> ▪ 1-20 characters ▪ text field (not numeric)
Serialized GTIN EPC URI	<ul style="list-style-type: none"> ▪ 33-52 characters <ul style="list-style-type: none"> ▪ 17 characters for "urn:epc:id:sgtin:" ▪ 13 characters for the GTIN (without the Check Digit) ▪ 1-20 characters for the serial number ▪ 2 periods (".") ▪ text field (not numeric)

Table D: Data Formats for GTIN Fields

6. Identifying Logistics Units (Cases, Pallets and Totes): SSCC

In the GS1 System, logistics units such as cases, pallets and totes are identified with the Serial Shipping Container Code (SSCC). The SSCC is an 18-digit, globally unique, standards-based, identification number for logistics units. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

6.1. Assigning SSCCs

Suppliers are responsible for assigning (*allocating*) SSCCs to their logistics units. Each SSCC is a numerical string comprising four distinct segments. The four segments within an SSCC are:

- **Extension Digit:** The Extension Digit has no defined logic. It is available to the company to increase the capacity of the *Serial Reference*. The field consists of a numeric value from 0 to 9.
- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.
- **Serial Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a logistic unit. This segment is the "serial" part of the number assigned one-by-one by the company to create a globally unique SSCC. The *Serial Reference* varies in length as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the first 17 digits of the SSCC used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at http://www.gs1us.org/solutions_services/tools/check_digit_calculator.



Although the length of the GS1 Company Prefix and the length of the Serial Reference vary, they will always be a combined total of 16 digits in an SSCC. Figure 6 provides a color-coded example of a hypothetical SSCC, and a key explaining how each digit is populated. (Figure 6 uses hypothetical SSCC 03345678912345604.)

Example of an SSCC																		
SSCC	0	0	3	3	4	5	6	7	8	9	1	2	3	4	5	6	0	4
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18

How to Populate Each Digit (color-coded to coordinate with the SSCC shown above)	
Position 1	Extension Digit (numeric value from 0 to 9)
Positions 2 through 17	GS1 Company Prefix as assigned by GS1 US plus Serial Reference number as assigned by the owner of the logistics unit
Position 18	Check Digit

Figure 6: Populating the 18 digits of an SSCC

6.2. Data Format for Databases

In databases, SSCC fields should be 18 characters in length. The SSCC should be represented in a database as a text field (not numeric), so that leading zeros are not inadvertently dropped.

6.3. Data Format for EPCIS: URI Format

Within the EPCIS, SSCCs must be stored in EPC URI format. The EPC URI format for an SSCC is the SSCC EPC.

General syntax:

urn:epc:id:sscc:CompanyPrefix.SerialReference

Example:

urn:epc:id:sscc:0614141.1234567890

Grammar:

SSCC-URI ::= "urn:epc:id:sscc:" SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent "."PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields must total 17 (not including any of the dot characters). Figure 7 depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:

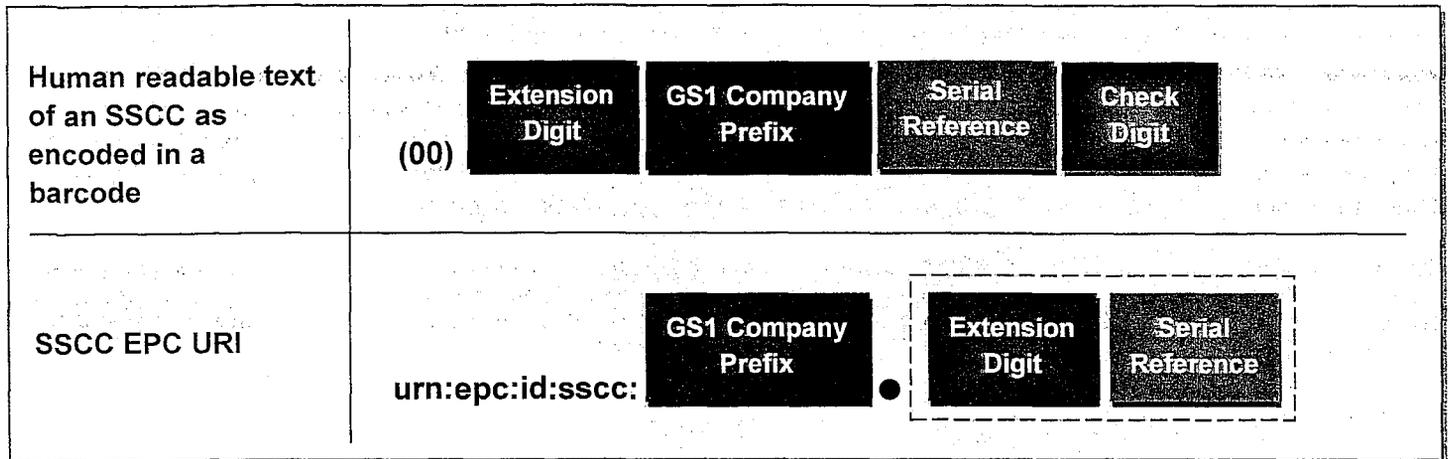


Figure 7: How the segments of an SSCC are represented in the SSCC EPC URI format

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

6.4. Data Storage Options

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

- 1 field = SSCC
- 1 field = SSCC in EPC URI format
- 2 fields = SSCC field and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 5 below:

Field	Data Format
SSCC	<ul style="list-style-type: none"> ▪ 18 digits ▪ text field (not numeric, to avoid dropping leading zeros)
SSCC URI	<ul style="list-style-type: none"> ▪ 34 characters ▪ text field

Table E: Data Formats for SSCC Fields



7. Identifying Parties & Locations: GLN

In the GS1 System, parties and locations are identified with the Global Location Number (GLN). The GLN is a 13-digit, globally unique, standards-based, identification number for legal entities, functional entities, and physical locations. Each company is responsible for assigning (*allocating*) GLNs to its own parties and locations. When a user assigns a GLN, they define a prescribed set of data about the party/location to which that GLN relates (e.g., street address, floor, etc.). These GLN attributes define master data about the party/location (e.g., name, address, class of trade, etc.), which help to ensure that each GLN is specific to one, very precise location within the world. The GLN and its associated attributes are then saved in a database (like the GLN Registry for Healthcare) and shared among supply chain partners.

① GS1 US offers an annual GLN subscription program for companies that are not members of GS1 US and need only one or a few GLNs (e.g., wholesalers, distributors, and retailers without private label products). Subscribers to the GLN Registry for Healthcare have the option of acquiring GLNs using this GS1 US subscription program instead of allocating them as described above. Please call GS1 US Customer Service for more information about this program at +1 937.610.4222.

7.1. Assigning GLNs

Each GLN is a numerical string comprising three distinct segments. The three segments within a GLN are:

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.
- **Location Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a location within the company. The length of the *Location Reference* varies as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the first 12 digits of the GLN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at <http://www.gs1us.org/resources/tools-and-services/check-digit-calculator>. (Check digits can also be calculated manually.)

Although the length of the GS1 Company Prefix and the length of the Location Reference vary, they will always be a combined total of 12 digits in a GLN. The addition of the *Check Digit* completes the 13 digits of the GLN. Figure 8 provides a color-coded example of a hypothetical GLN, and a key explaining how each digit is populated. (Figure 8 uses hypothetical GLN 0321012345676.)

Example of a GLN													
GLN	0	3	2	1	0	1	2	3	4	5	6	7	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13

How to Populate Each Digit (*color-coded to coordinate with the GLN shown above*)

Positions 1 through 12	GS1 Company Prefix as assigned by GS1 US <u>plus</u> Location Reference number as assigned by the owner of the GS1 Company Prefix
Position 13	Check Digit

Figure 8: Populating the 13 digits of a GLN

7.2. Assigning GLN Extensions

GLN Extensions are used to identify internal physical locations within a location that is identified with a GLN. Locations that currently have a GLN may use GLN Extensions to distinguish unique sub-locations within that GLN location (e.g., production line, RFID tunnel, loading dock, etc.) GLN Extensions are represented by AI(254). The GS1 General Specifications define a GLN Extension as an alphanumeric string whose length is variable between one and 20 characters (the specific characters allowed are defined in the GS1 General Specifications). GLN Extensions can be encoded in GS1 DataBar, GS1-128 and EPC/RFID tags. AI(254) may only be used in conjunction with AI(414) [i.e., GLN of a physical location].

Use of GLN Extensions is optional. Sub-locations can be identified by assigning a unique GLN to the sub-location, or by using a GLN Extension with the location's GLN. There is no rule for when to assign a new GLN versus when to use a GLN Extension. However, the GLN Workgroup has identified the following Best Practices to assist companies in making this decision:

- For sub-locations that will never be used as an address (e.g., shelf, door, etc.), use GLN Extensions in order to conserve GLNs.
- For sub-locations where the identifier will be used for purposes other than EPCIS events (e.g., EDI), assign a unique top-level GLN to that sub-location.

(For additional information, consult the GLN Workgroup materials.)

7.3. Data Format for Databases

In databases, GLN fields should be 13 digits in length. The GLN should be represented in a database as a text field (not numeric). The GLN extension should be represented in a database as a text field capable of handling from one to 20 characters.

7.4. Data Format for EPCIS: URI Format

Within the EPCIS, GLNs must be stored in EPC URI format. The EPC URI format for a GLN (with or without Extension) is the Serialized Global Location Number EPC (SGLN EPC).

General syntax:

`urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension`

Example:

`urn:epc:id:sgln:0614141.12345.400`

Grammar:

`SGLN-URI ::= "urn:epc:id:sgln:" SGLNURIBody`

`SGLNURIBody ::= PaddedNumericComponent "."`

`PaddedNumericComponentOrEmpty ::= GS3A3Component`

The number of characters in the two PaddedNumericComponent fields must total 12 (not including any of the dot characters). The Extension field of the SGLN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the AI (254) Extension according to the GS1 General Specifications. Figure 9 depicts how the element string of a GLN corresponds to the element string of an SGLN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 GLN key.
- The *Location Reference* is the same as it appears in the GLN key.
- The *Check Digit* is not used in the EPC URI format.
- The *Extension* is the same as the *GLN Extension* assigned by the managing entity to an individual unique location. If there is no GLN Extension for this location, enter a single zero digit to indicate that the SGLN stands for a GLN without an extension.

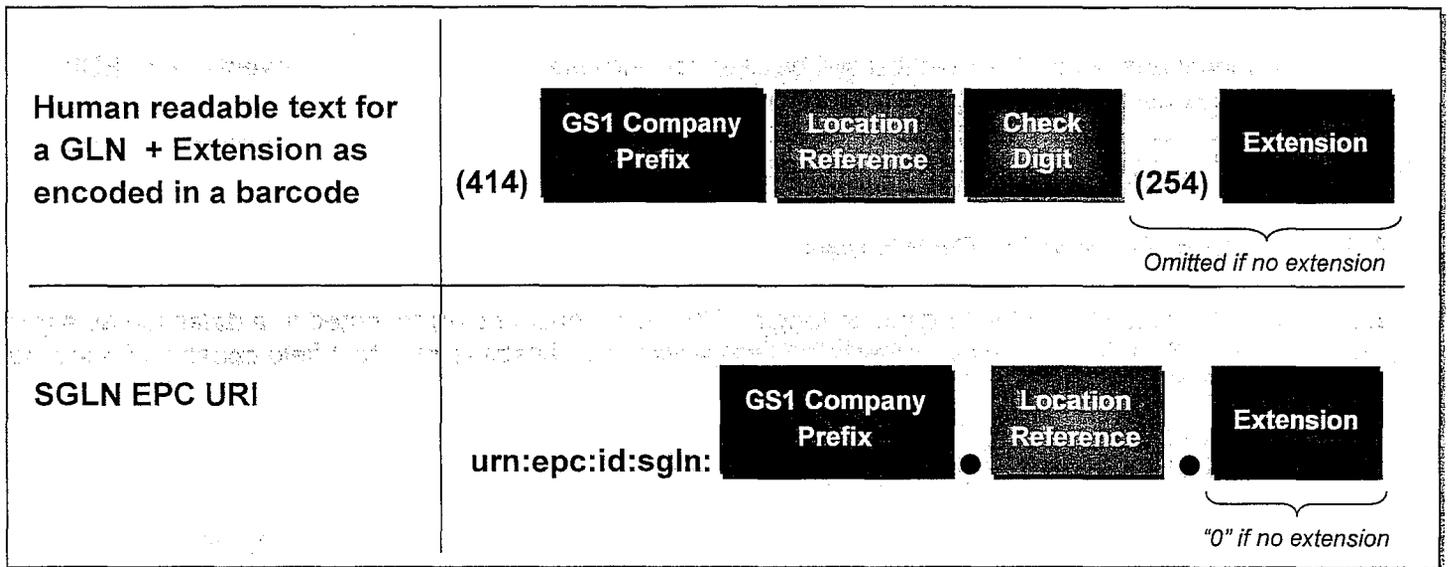


Figure 9: How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format

7.5. Data Storage Options

When storing SGLNs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing a GLN with extension in databases:

- 2 fields = GLN field and GLN Extension field
- 1 field = One field containing GLN + extension in EPC URI format
- 3 fields = GLN field, GLN Extension field, and field containing GLN + extension in EPC URI format



Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 6 below:

Field	Data Format
GLN	<ul style="list-style-type: none">▪ 13 digits▪ text field (not numeric)
GLN Extension	<ul style="list-style-type: none">▪ 1-20 characters▪ text field (not numeric)
SGLN/EPC URI	<ul style="list-style-type: none">▪ 31-50 characters:<ul style="list-style-type: none">▪ 16 characters for "urn:epc:id:sgln:"▪ 12 characters for the GLN (no Check Digit)▪ 1-20 characters for the GLN extension▪ 2 periods ('.')▪ text field (not numeric)

Table F: Data Formats for GLN Fields



Part 3: Capture

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags (i.e., GS1 EPC/RFID Tags).

Table 7 lists the GS1 data carriers used in this guideline to support pedigree and track and trace. Because this guideline documents a specific application of the standards to support serialization and pedigree, only data carriers that can carry serial numbers are shown.

Supply Chain Object	GS1 Data Carrier Options
TRADE ITEMS: Products, Cases & Kits	GS1 DataMatrix GS1-128 EPC/RFID Tag
LOGISTICS UNITS: Cases, Pallets & Totes	GS1-128 GS1 DataMatrix EPC/RFID Tag

Table G: GS1 Data Carriers Used in this Guideline

8. Encoding GS1 Data Carriers

Examples in this guideline use four GS1 Data Carriers: three GS1 barcodes and one EPC/RFID tag. Guidance for encoding those data carriers is provided in this chapter.

8.1. Barcodes

The data elements within a barcode are demarcated through the use of GS1 Application Identifiers (AIs). GS1 AIs are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) Each data element in a barcode is preceded by its AI. There are approximately 100 AIs, including one AI for each GS1 identifier (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for secondary information. The AI's that are relevant to this guideline are:

AI (01)	GTIN	AI (21)	Serial Number
AI (00)	SSCC	AI (10)	Batch/Lot Number
AI (414)	GLN (physical location)	AI (17)	Expiration Date
AI (254)	GLN Extension		

More than one AI can be carried in one barcode. Table 8 presents some high-level concepts and principles that should be followed when encoding barcodes.

Principle	Example/Illustration										
Each barcode data element has a two- to four-digit AI that defines data type and field size.	<table border="0"> <tr> <td>GTIN</td> <td>AI(01)</td> </tr> <tr> <td>Serial Number</td> <td>AI(21)</td> </tr> <tr> <td>Batch/Lot Number</td> <td>AI(10)</td> </tr> <tr> <td>Expiration Date</td> <td>AI(17)</td> </tr> <tr> <td>SSCC</td> <td>AI(00)</td> </tr> </table>	GTIN	AI(01)	Serial Number	AI(21)	Batch/Lot Number	AI(10)	Expiration Date	AI(17)	SSCC	AI(00)
GTIN	AI(01)										
Serial Number	AI(21)										
Batch/Lot Number	AI(10)										
Expiration Date	AI(17)										
SSCC	AI(00)										
When encoding, each data element is preceded by its corresponding AI.	<table border="0"> <tr> <td>GTIN</td> <td>(01)00314141999995</td> </tr> <tr> <td>Expiration Date</td> <td>(17)101231</td> </tr> <tr> <td>Batch/Lot Number</td> <td>(10)987654321GFEDCBA</td> </tr> <tr> <td>Serial Number</td> <td>(21)ABCDEFGH123456789</td> </tr> <tr> <td>SSCC</td> <td>(00)003345678912345604</td> </tr> </table>	GTIN	(01)00314141999995	Expiration Date	(17)101231	Batch/Lot Number	(10)987654321GFEDCBA	Serial Number	(21)ABCDEFGH123456789	SSCC	(00)003345678912345604
GTIN	(01)00314141999995										
Expiration Date	(17)101231										
Batch/Lot Number	(10)987654321GFEDCBA										
Serial Number	(21)ABCDEFGH123456789										
SSCC	(00)003345678912345604										
<p>Encode the GS1 Identifier (GTIN or SSCC) first.</p> <p>Encode any optional data (such as batch/lot number, expiration date, serial number, etc.) following the identifier.</p> <p>NOTE: Although parentheses and spaces appear in the human readable text accompanying the barcode, these characters are not encoded in the barcode itself.</p>	 <p>(01) 00314141999995 (10) 987654321GFEDCBA</p>										
For the most efficient encoding, ensure that fixed-length AIs precede variable-length AIs.	 <table border="0"> <tr> <td>(01) 00314141999995</td> <td>GTIN <i>fixed</i></td> </tr> <tr> <td>(17) 101231</td> <td>Expiration Date <i>fixed</i></td> </tr> <tr> <td>(10) 987654321GFEDCBA</td> <td>Batch/Lot Number <i>variable</i></td> </tr> <tr> <td>(21) 123456789ABCDEFGH</td> <td>Serial Number <i>variable</i></td> </tr> </table>	(01) 00314141999995	GTIN <i>fixed</i>	(17) 101231	Expiration Date <i>fixed</i>	(10) 987654321GFEDCBA	Batch/Lot Number <i>variable</i>	(21) 123456789ABCDEFGH	Serial Number <i>variable</i>		
(01) 00314141999995	GTIN <i>fixed</i>										
(17) 101231	Expiration Date <i>fixed</i>										
(10) 987654321GFEDCBA	Batch/Lot Number <i>variable</i>										
(21) 123456789ABCDEFGH	Serial Number <i>variable</i>										

Table H: Encoding Principles



Human Understandable Text Below A Barcode: Many pharmaceutical companies are including text below the barcode that is more readily understandable by healthcare clinicians and supply chain personnel. Here are some examples:



GTIN 00314141999995
 SN 10000000234
 LOT 987654321GFEDCBA
 EXP 01/2015



GTIN 00314141999995
 SN 10000000234
 EXP JAN 2015
 LOT 987654321GFEDCBA



GTIN 00314141999995
 SN 10000000234
 EXP 25 JAN 2015
 LOT 987654321GFEDCBA

8.1.1. Trade Items: Products, Cases & Kits

As a way of gaining uniformity throughout the supply chain, this guideline includes two best practice barcode options for products, cases and kits: GS1 DataMatrix and GS1-128. There are two required data elements to be encoded: GTIN and Serial Number.

Barcodes for Products, Cases & Kits		
Required Identification Information	Data Element	Corresponding GS1 AI
		GTIN
	Serial Number	AI (21)
GS1 Barcode Options	GS1 DataMatrix GS1-128	

Table I: Barcodes for Products, Cases & Kits

Encoding Principles:

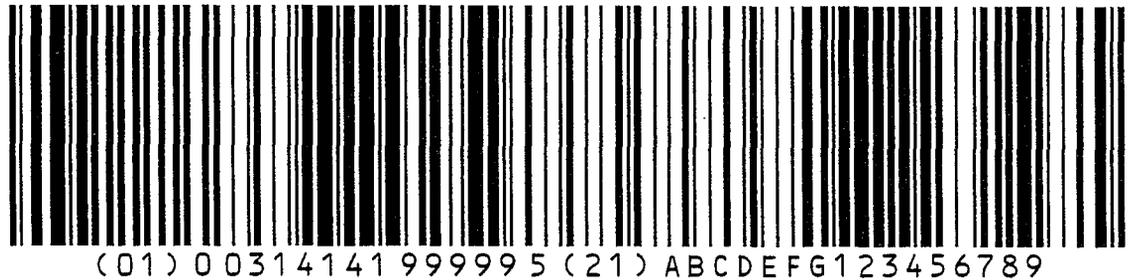
GTIN	<ul style="list-style-type: none"> ▪ Begin with the two-digit AI (01) to indicate GTIN. ▪ A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI. <ul style="list-style-type: none"> ⓘ For GTIN-12: encode in 14-digit format using two leading zeros ▪ The data syntax for the GTIN component is n2 + n14. ▪ EXAMPLE: 0100312345678906
Serial Number	<ul style="list-style-type: none"> ▪ The two-digit AI (21) is used to indicate the <i>Serial Number</i>. ▪ A variable-length field of up to 20 alphanumeric characters of <i>Serial Number</i> data follows the AI. <ul style="list-style-type: none"> ⓘ If using a barcode with a 96-bit EPC/RFID tag: see Section 5.2 for limitations on serial number ▪ The data syntax for the <i>Serial Number</i> component is n2 + a1..20. ▪ EXAMPLE: 21ABCDEFGF123456789

Examples:

Figure 10: GTIN with Serial Number Encoded in a GS1 DataMatrix



Figure 11: GTIN with Serial Number Encoded in a GS1-128

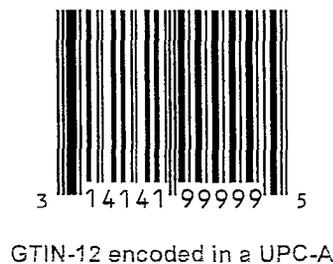


① Marking Products with Both UPC-A and GS1 DataMatrix

Many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A and a GS1 DataMatrix:

- Any item that passes through a POS is typically marked with a UPC-A. The UPC-A is a linear barcode that holds a maximum of 12 digits, which promotes readability by traditional POS systems. The UPC-A can be used to satisfy the FDA's linear barcode requirement. However, because it is limited to 12 digits, the UPC-A cannot carry the information needed to satisfy serialization and/or pedigree requirements.
- The GS1 DataMatrix is a 2D barcode that can carry more data (e.g., GTIN, serial number, expiration date, etc.) in a smaller space. Most manufacturers are choosing to use the GS1 DataMatrix to satisfy serialization and/or pedigree requirements. However, as a 2D barcode, the GS1 DataMatrix does not satisfy the FDA's linear barcode requirement.

Marking pharmaceutical products that cross POS with both barcodes satisfies both types of requirements (i.e., the UPC-A for the FDA linear barcode requirement, and the GS1 DataMatrix for serialization/pedigree requirements). To ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations outlined in [Section 4.5](#) for all products that will be marked with both a UPC-A and a GS1 DataMatrix.



8.1.2. Logistics Units: Pallets, Cases & Totes

This guideline includes two barcode options for pallets, cases and totes: GS1-128 and GS1 DataMatrix. There one required data element to be encoded: SSCC.

Cases Pallets & Totes		
Required Identification Information	Data Element	Corresponding GS1 Standard
	SSCC	AI (00)
GS1 Barcode Options	GS1-128 GS1 DataMatrix	

Table J: Barcodes for Pallets, Cases & Totes

Encoding Principles:

- SSCC
- The two-digit AI (00) is used to indicate SSCC.
 - A fixed-length field comprising the 18 numeric characters of SSCC data follows the AI.
 - The data syntax for the SSCC component is n2 + n18.
 - **EXAMPLE: 00003345678912345604**

Examples:

Figure 12: SSCC Encoded in a GS1-128



Figure 13: SSCC Encoded in a GS1 DataMatrix



8.2. EPC/RFID Tags

EPC/RFID tags use a specialized binary encoding to hold data equivalent to barcode data. Software that reads and writes EPC/RFID tags translates between this binary encoded form and the barcode form (and/or the EPC URI form). See the *EPC Tag Data Standard* for details about how the translations are performed.

9. Translating Captured Data

The EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in EPC URI format, which differs from both the AI-based format used in GS1 barcodes and the binary encoding used in EPC/RFID tags. Therefore, identification information read from either barcodes or EPC/RFID tags must first be translated into EPC URI format in order to be stored in the EPCIS.

Most commercial RFID and/or EPCIS products already have the translation technology integrated into their software so that data read from either barcodes or EPC/RFID tags is automatically translated into EPC URI format when an EPCIS event is created. However, if a company is implementing their own software, they can either write their own translation module or license one of the commercially-available software libraries on the market.

In order to translate barcode data into EPC URI format, it is necessary to know the length of the GS1 Company Prefix (i.e., what is the length of the GS1 Company Prefix in this barcoded GTIN?). To facilitate this, GS1 US has published a table of U.S. GS1 Company Prefixes (www.gs1us.org/gcplist) that you can download and link to your translator/EPCIS to enable your system to access GS1 Company Prefix lengths automatically instead of prompting the user for the information. Alternatively, you can ask your trading partners for the length of their GS1 Company Prefixes and create your own table. (NOTE: EPC/RFID tags already include the length of the GS1 Company Prefix in the encoded binary form. Therefore, no additional lookup is needed to translate binary data from EPC/RFID tags into EPC URI format.)

9.1. EPC URI Format for GTIN + serial number

The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

General syntax:

urn:epc:id:sgtin:*CompanyPrefix.ItemReference.SerialNumber*

Example:

urn:epc:id:sgtin:0614141.112345.400806

Grammar:

SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody

SGTINURIBody ::= 2*(PaddedNumericComponent ".") GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the GS1 General Specifications. Figure 14 depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits, and treating the result as a single numeric string.

- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI(21).

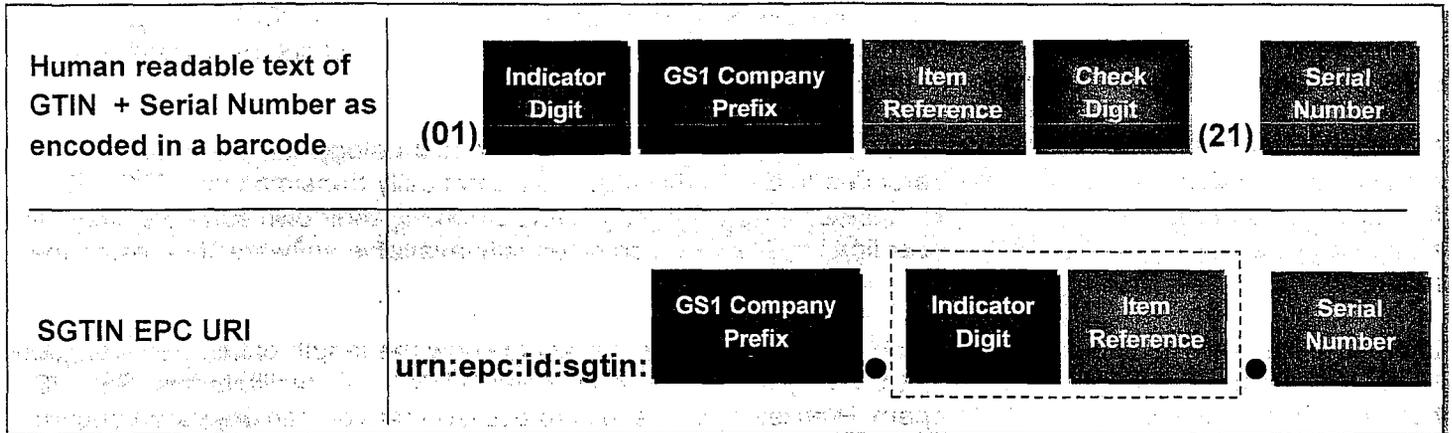


Figure 14: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format

Example – Converting a GTIN-14 + Serial Number into EPC URI Format:

GTIN-14	2 030001 123498 7
Serial Number	123456789012
Corresponding Barcode human readable text	(01) 2 030001 123498 7 (21)123456789012
Corresponding SGTIN EPC URI	urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012

ⓘ The spaces in the examples above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.

9.2. EPC URI Format for SSCC

General syntax:

urn:epc:id:sscc:CompanyPrefix.SerialReference

Example:

urn:epc:id:sscc:0614141.1234567890

Grammar:

SSCC-URI ::= "urn:epc:id:sscc:" SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent "."PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields must total 17 (not including any of the dot characters).

Figure 15 depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

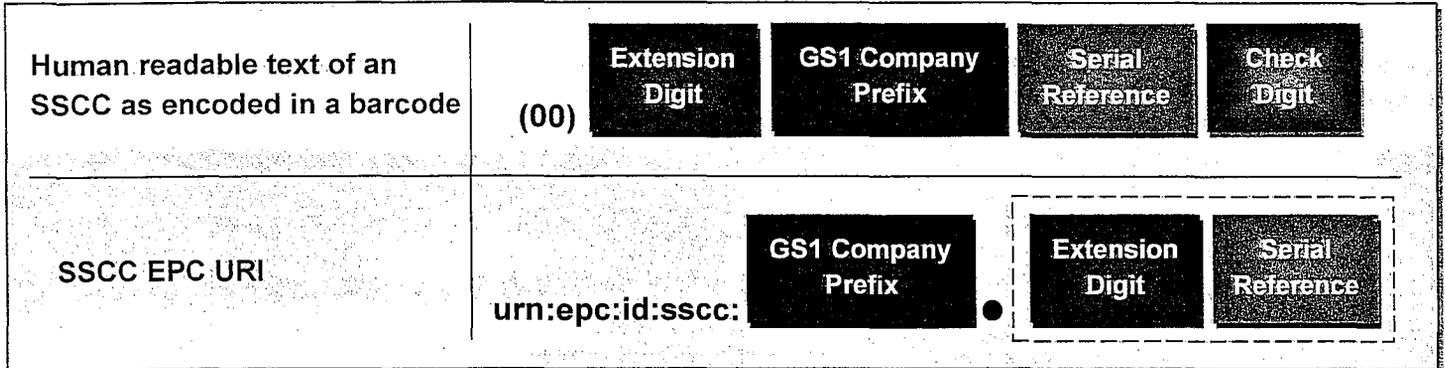


Figure 15: How the segments of an SSCC are represented in the SSCC EPC URI format

9.3. Data Storage Options

When storing GTIN + serial number in databases, GTINs and serial numbers can be saved in their own fields, saved together in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing GTINs and serial numbers in databases:

- 2 fields = GTIN field and Serial Number field
- 1 field = One field containing serialized GTIN in EPC URI format
- 3 fields = GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 11 below:

Field	Data Format
GTIN	<ul style="list-style-type: none"> ▪ 14 digits ▪ text field (not numeric)
Serial Number	<ul style="list-style-type: none"> ▪ 1-20 characters ▪ text field (not numeric)
Serialized GTIN EPC URI	<ul style="list-style-type: none"> ▪ 33-52 characters: <ul style="list-style-type: none"> ▪ 17 characters for "urn:epc:id:sgtin:" ▪ 13 characters for the GTIN (without the Check Digit) ▪ 1-20 characters for the serial number ▪ 2 periods (".") ▪ text field (not numeric)

Table K: GTIN+ serial number Data Formats



When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

- 1 field = SSCC
- 1 field = SSCC in EPC URI format
- 2 fields = SSCC and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 12 below:

Field	Data Format
SSCC	<ul style="list-style-type: none">▪ 18 digits▪ text field (not numeric, to avoid dropping leading zeros)
SSCC EPC URI	<ul style="list-style-type: none">▪ 34 characters▪ text field (not numeric)

Table L: SSCC Data Formats



Part 4: Share Concepts

10. Master Data

When users assign a GS1 Identification Number, they define a set of standardized information (known as *attributes*) about the object to which that identifier relates. The GS1 System specifies the list of attributes that must be defined for each GS1 Identifier, and provides a precise definition as well as acceptable values and data formats for each attribute. This set of attributes constitutes the “master data” about the object. For example:

- The GTIN is the globally unique GS1 Identification Number used to identify products. Standardized GTIN attributes about products include selling unit, item dimensions, and product classification. Once defined by the user, those attributes are then stored in a GDSN-certified Data Pool and shared with supply chain partners using the Global Data Synchronization Network (GDSN).
- The GLN is the globally unique GS1 Identification Number for locations and supply chain partners. Standardized GLN data about locations include name, street address, location type, etc. Once defined by the user, those attributes are then stored in a database and shared with supply chain partners using the GLN Registry.

From there, GS1 Identification Numbers can be encoded into GS1 Data Carriers for identification and automatic data capture, and used in supply chain transactions. Because of this, master data, transaction data, and event data related to supply chain objects are all connected by their GS1 Identification Number.

GS1 Identification Numbers provide a link to information, and GS1 Standards for data sharing enable supply chain partners to share data and link it up in their systems to avoid re-entering it for every application that needs the data:

Sharing Master Data

Products = GDSN, RxNorm, Prime Vendor Database
Locations = GLN Registry for Healthcare

Sharing Event & Disposition

EPCIS

Item Event Locator

Discovery Services

This is especially important for EPCIS applications like pedigree where trading partners capture and share information about numerous supply chain events for each product. Use of GS1 Identifiers minimizes the data collected for each event, and maximizes the data that can be linked to the event. This enables trading partners to avoid massive duplication of data in their systems by managing master data separately from pedigree data. For example, a distributor records a Pedigree Event. The *Object ID* (i.e., GTIN) provides the link to finding master data about the product:

Name: Product X, 50 Tabs

The *BizLocation* (i.e., GLN) provides the link to master data about the location using the GLN Registry:

LocationName: Smithfield Distribution Center

Address: 123 Main Street

City: Lawrenceville

State: NJ

Zip Code: 08648

Best Practices:

- Because master data is managed separately from event/pedigree data, it is essential to archive the original/previous version of master data whenever master data about products or locations is updated or changed. This will ensure that the historic master data is still available if ever needed after the update.
 - Need to validate and establish the source and governance of your master data.
-

① The following documents provide an in depth discussion of Master Data Management concepts (see [Section 2.6](#) for links):

- *Healthcare Provider GTIN Tool Kit*
- *Healthcare Supplier GTIN Tool Kit*
- *Healthcare Provider GLN Tool Kit*
- *Healthcare Supplier GLN Tool Kit*
- *Healthcare Provider GDSN Tool Kit*
- *Healthcare Supplier GDSN Tool Kit*

11. Event Data

Electronic Product Code Information Services (EPCIS) is a GS1 Standard for capturing and communicating data about the movement and status of objects in the supply chain (e.g., products; logistics units; returnable assets; etc.). It enables supply chain partners to capture event information about objects as they move through the supply chain (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time. EPCIS defines technical standards for a data-sharing interface between applications that capture EPC-related data and those that need access to it. EPCIS also provides data standards for how to express what business process was operating on the object and the status of the object upon exiting the process. For the data standards, EPCIS makes use of a second standard named the Core Business Vocabulary (CBV), which offers a pre-defined vocabulary for a large set of business events and scenarios.

The data elements captured and recorded for each EPCIS event are grouped into four dimensions: *what*, *when*, *where*, and *why*. The GS1 General Specifications and the GS1 EPC Tag Data Standard define identifiers for physical objects used in the “*what*” dimension, and identifiers for locations used in the “*where*” dimension. The GS1 EPC Core Business Vocabulary provides lists of acceptable values for *Business Step*, *Disposition*, and *Business Transaction Type* used in the *why* dimension, as well as the format for the business transaction identifiers used in the *why* dimension. Beyond the four dimensions of *what*, *where*, *when*, and *why* defined in the EPCIS standard, this guideline defines extension fields used to provide additional business data for ePedigree in certain EPCIS events.



The data elements captured and recorded for each EPCIS are presented in Table 13 below.

Dimension	Data	Definition	Examples
	Event Type Action	the event type and the action together define the type of EPCIS event; e.g., object creation, object observation, aggregation, disaggregation, etc	Object Event with Action = ADD Aggregation Event with Action = DELETE etc.
What	EPC List	the item's GS1 Identification Key, expressed as an EPC Pure Identity URI. Depending on the event type, this will either be a list of EPCs, or the combination of a Parent ID and a list of child EPCs	GTIN, SSCC, GRAI, etc.
	Parent ID		
	Child EPCs		
When	Event Time	the moment in time at which the event occurred	March 15, 2010 at 10:07am UTC
	Event Timezone Offset	indicates the local time zone in effect at the place where the event occurred. This is not needed to interpret Event Time (which carries its own timezone indicator) but instead helps software display data to users in local time	UTC -05:00
Where	Read Point	the location at which the event took place, expressed as an EPC Pure Identity URI	GLN or GLN with extension
	Business Location	the location at which the objects are presumed to be following the event until a subsequent event says otherwise, expressed as an EPC Pure Identity URI	GLN or GLN with extension
Why	Business Step	the business process taking place at the time of this event	Shipping, Receiving, Picking, etc.
	Disposition	business condition of the objects named in the <i>what</i> dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
	Business Transaction	one or more references to associated business transactions, each comprised of a business transaction type (e.g., purchase order, invoice, etc) and a globally unique reference to a specific transaction of that type	Acme Corp Purchase Order #1234

Table M: EPCIS Data

EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. To serve the needs of a particular business application, supply chain partners must come to an agreement with regard to the EPCIS events and data that will be shared. Therefore, members of the U.S. pharmaceutical industry joined forces to determine how the EPCIS shall be applied to support pedigree and track and trace.

The remainder of this document specifies how the EPCIS standard is applied to support pedigree and track and trace for the US pharmaceutical industry.

Part 5: Application of EPCIS for Serialized Product Pedigree

EPCIS events consist of data captured by each party in the supply chain as they handle a product in the course of the product's lifecycle. As such, EPCIS events provide visibility of handling operations for either internal business applications (i.e., if the EPCIS events are consumed internally), or across the supply chain (i.e., if the events are shared with trading partners). Visibility data in the form of EPCIS events may be used to automate a variety of business processes, including track and trace, pedigree, recall, etc.

This section specifies the minimum set of EPCIS events required to support the pedigree business process. A set of EPCIS events pertaining to a specific instance or instances of a product, inclusive of all events from the point of origin (i.e., commissioning) to the present, and conforming to this section provides all of the data content in a drug pedigree. Certain pedigree laws consider product and location data to be part of the pedigree. Companies that have implemented the best practice of a Master Data Management architecture, may wish to obtain and manage product and location master data separate from the EPCIS events themselves. For example, a drug pedigree includes both the unique identifier for a pharmaceutical product (i.e., the NDC and/or GTIN), as well as its dose and strength information. When using EPCIS events to provide pedigree content, the NDC and/or GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the NDC/GTIN. Those companies will use the product and location identifiers (GTIN and GLN, respectively) found in the EPCIS events as keys to "look up" the previously synchronized master data and assemble the full drug pedigree content.

Other trading partners who are unable to, or have yet to adopt a master data management strategy may require the product and location master data be provided as part of the EPCIS events. To support both scenarios, product and location master data attributes are shown as "optional" in the EPCIS events.

Supply chain parties may collect additional EPCIS events not required for pedigree but used for other business applications. These events are discussed in a Part 7 of this guideline.

12. Overview of EPCIS Events for Serialized Product Pedigree

For purposes of pedigree, each party in the supply chain must capture and share a certain set of EPCIS events. The EPCIS events that need to be captured and shared by each party depend on that party's position in the supply chain. An overview of EPCIS events for pedigree is provided below. Detailed definitions of each EPCIS event are specified in subsequent subsections.

Events captured and shared by the party at the beginning of the supply chain (e.g., manufacturer):

- **Commissioning Events (Section 17.1)** declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.
- **Packing Events (Section 17.2)** providing the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping. The beginning party does not need to reflect any internal unpacking and packing activity that may have taken place, as long as the events that are shared fully account for the hierarchy as shipped.
- **Shipping Events (Section 17.3)** indicating that objects have been shipped to a downstream trading partner and providing pedigree information governing the shipment. The shipping events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior packing events.

Events captured and shared by intermediate parties (e.g., distributor):

- **Receiving Events (Section 17.4)** indicating that objects have been received from an upstream trading partner and providing pedigree information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy (*in which case the verified levels are declared explicitly in the receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly*).
- **Unpacking Events (Section 17.5), Commissioning Events (Section 17.1), and Packing Events (Section 17.2)** as needed to reflect changes in the packaging hierarchy that have occurred prior to shipment. Commissioning events in this instance are only used to introduce new identifiers for logistic units (e.g., new SSCCs for pallets packed to order), *not to introduce new products*. The intermediate party does not need to reflect all internal unpacking, commissioning, and packing activity that may have taken place, as long as the events that are shared fully account for all changes in hierarchy between receiving and shipping.
- **Shipping Events (Section 17.3)** indicating that objects have been shipped to a downstream trading partner and providing pedigree information governing the shipment. The shipping events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior unpacking and packing events (possibly including unpacking and packing events from prior supply chain parties).

Events captured and shared by the party at the end of the supply chain (e.g., Hospital, Pharmacy, etc):

- **Receiving Events (Section 17.4)** indicating that objects have been received from an upstream trading partner and providing pedigree information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy (*in which case the verified levels are declared explicitly in the receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly*).
- **Unpacking Events (Section 17.5) and Packing Events (Section 17.2)** as needed to reflect changes in the packaging hierarchy that have occurred prior to end-of-life events. The final party does not need to reflect all internal unpacking and packing activity that may have taken place, as long as the unpacking and packing events that are shared fully account for all changes in hierarchy between receiving and end-of-life events.
- **End-of-life events including Dispensing (Section 17.6.1), Destroying (Section 17.6.3), and Decommissioning (Section 17.6.4)** indicating that specific products have been removed from the supply chain

13. Pedigree Data Elements

Drug pedigree data elements are derived from both the data in the EPCIS events themselves, as well as certain product and location master data that is referenced by product and location identifiers found in the EPCIS event. For example, a drug pedigree includes both the unique identifier for a pharmaceutical product (i.e., the NDC and/or GTIN), as well as its dose and strength information. When using EPCIS events to provide pedigree content, the NDC and/or GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the NDC/GTIN.

A list of the pedigree data elements (from GS1 / EPCglobal Pedigree Ratified Standard v1.0) with the expected source for that data is provided in Table 14 below.

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
Document Information	Pedigree serial number	Event ID
Item Information	Item serial number(s) of product(s) (if available)	EPCIS epcList
	Lot number	EPCIS ObjectEvent event where bizStep is "commissioning"
	Expiration date	EPCIS ObjectEvent event where bizStep is "commissioning"
	Quantity of saleable units in transaction	EPCIS ObjectEvent event where bizStep is "shipping"



Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
Product Information	Drug name	Product Master Data
	Manufacturer	Product Master Data
	Product code (e.g., the NDC number)	EPCIS epcList and as part of the additionalTradeItemIdentification
	Dosage form	EPCIS ObjectEvent event where bizStep is "commissioning"
	Strength	EPCIS ObjectEvent event where bizStep is "commissioning"
	Container size	EPCIS ObjectEvent event where bizStep is "commissioning"
Transaction Information	Transaction identifier (for example, invoice or purchase order number)	EPCIS ObjectEvent event where bizStep is "shipping"
	Transaction document type (e.g., Invoice, Purchase order, Return authorization)	EPCIS ObjectEvent event where bizStep is "shipping"
	Date of transaction	EPCIS eventTime and eventTimeOffset
	Transaction type (e.g., sale, transfer, return)	EPCIS ObjectEvent event where bizStep is "shipping"
Seller and Recipient Information	Business Address (see below)	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Shipping Address (see below; used only if different than Business Address)	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	License number	EPCIS ObjectEvent event where bizStep is "shipping"
	License state or region	EPCIS ObjectEvent event where bizStep is "shipping"
	License agency	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Information for seller used for authentication of transaction (see below)	EPCIS ObjectEvent event where bizStep is "shipping"
Business and Shipping Address	Business name	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Street1	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Street 2	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	City	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	State or Region	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Postal Code	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Country	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
Contact Information1	Contact Name	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Title	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Email	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Telephone	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact URL (for automated authentication)	EPCIS ObjectEvent event where bizStep is "shipping"
Receiving Information	Date received	EPCIS ObjectEvent event where bizStep is "receiving"
	Item Information (e.g., Lot, Quantity, Serial Numbers) for items in partial receipt2	EPCIS ObjectEvent event where bizStep is "commissioning"
Signer Information	Name of signer	EPCIS ObjectEvent event where bizStep is "receiving"
	Title of signer	EPCIS ObjectEvent event where bizStep is "receiving"
	Date of signature	EPCIS ObjectEvent event where bizStep is "receiving"
	Signature meaning (defines certification context such as certified outbound, received and authenticated inbound)	EPCIS ObjectEvent event where bizStep is "receiving"
		EPCIS ObjectEvent event where bizStep is "receiving"
Digital Signature Information3	SignedInfo	N/A
	SignatureValue	N/A
	KeyInfo	N/A
	SignatureProperties	N/A

Table N: Pedigree Data Elements

14. Pedigree Data Rules

14.1. EPCIS Event Time

The *Event Time* data element in an EPCIS event is defined as the moment in time when the event occurred. When sharing EPCIS events with trading partners for pedigree purposes, it is permissible for the *Event Time* to be different from the actual moment in time when the event occurred, provided that the rules in this section are followed. These rules are designed to give freedom to supply chain parties to capture the *Event Time* in a manner that is not overly burdensome and to hide certain internal business details from trading partners (e.g., the lag in time between packing a shipment and dispatching the shipment through the door), while at the same time ensuring that applications receiving EPCIS events will see a "reasonable" sequence of *Event Times*. When a party shares EPCIS events with a trading partner, the *Event Time* in those events shall conform to the following rules.

① Note that the *Event Time* shared with trading partners may differ from the *Event Time* captured internally, so long as the rules are followed; that is, a party may keep more detailed *Event Time* for internal use, but modify the *Event Time* to obscure certain details not appropriate to share with trading partners.

Rules:

- The *Event Time* shared with trading partners may differ from the *Event Time* captured internally. However, for any given event, the *Event Time* shared with trading partners shall be the same across all trading partners.
- EPCIS provides for millisecond precision in the *Event Time*. The *Event Time* shared with trading partners may be expressed with less precision, provided that the reported *Event Time* is within one minute of the actual *Event Time*.
- Business processes such as packing and shipping may take place over a span of time rather than a moment in time. Normally, the *Event Time* shared with trading partners should correspond to the time of completion of the process. However, any time within the span may be used as long as the other rules are adhered to.
- The diagram below shows the chronological sequence of *Event Times* that shall hold between events that refer to the same object identifier:
 - The *Event Time* reported for Shipping, Receiving, and end-of-life events shall reflect the true time of those events (subject to the rules above).
 - The *Event Time* for other events (e.g., commissioning, packing, unpacking) as shared with trading partners may be advanced in time up to (but not equal to) the time of the subsequent shipping or end-of-life event as long as the relationships in the diagram continue to hold.
 - Only the *Event Times* for Shipping, Receiving, and end-of-life events are relevant for pedigree purposes. The *Event Times* for other events may be advanced in order to obscure internal business details not relevant to trading partners.

Figure 16 below shows the relationships of *Event Times*. The “<” symbol indicates that the first *Event Time* must be strictly less than the second *Event Time*.

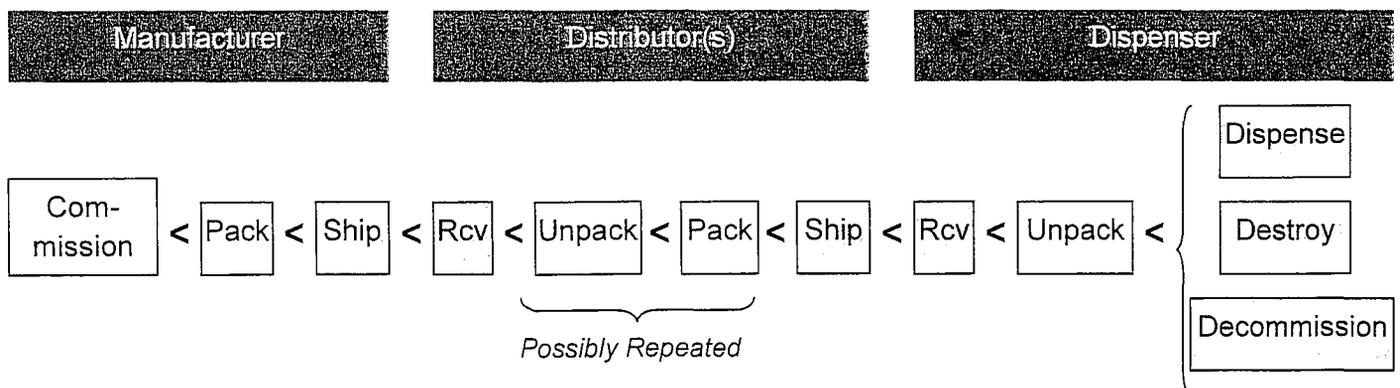


Figure 16: Event Time Relationships for Pedigree Purposes

Best Practice:

- For change of ownership situations where the process does not provide a natural change in time difference between shipping and receiving (consignment inventory), Receiving times Shall be created with a time greater than the related Shipping events (when used). When creating events to share with a trading partner, the timing of events should reflect the sequence of events that naturally would occur.
-

14.2. EPCIS Read Points and Business Locations

The EPCIS standard defines two data elements that provide the *where* dimension for an EPCIS event: *Read Point* and *Business Location*. The *Read Point* is an EPC URI that identifies the location where the event took place. The *Business Location* is an EPC URI that identifies the location where the object named in the event is presumed to be until a subsequent event says otherwise. The *Business Location* is useful for answering questions about where objects are right now (or at any prior moment between events).

Supply chain parties may capture *Read Points* and *Business Locations* at a coarse level (e.g., identifying a site or campus) or at a granular level (e.g., identifying a specific area or door within a building). A supply chain party may also choose to share location information with trading partners at a coarser level of granularity than it captures for internal purposes. For example, a supply chain party may capture the specific loading dock door where a shipping event took place for internal purposes. However, when sharing data with a trading partner, that party may only share the site without providing information about which dock door was used.

Rules:

EPCIS events shared for pedigree purposes shall conform to the following rules for *Business Locations* and *Read Points*:

- The *Business Location* for an event shall be a site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with “urn:epc:id:sgln:” and ends with “.0.”. (Note that *Business Location* is omitted from a Shipping event. See section 17.3.)
- The *Read Point* for an event shall be one of the following:
 - A site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with “urn:epc:id:sgln:” and ends with “.0.”.
 - A GLN with extension denoting a more granular location within a site, expressed as an EPC URI. Such a URI begins with “urn:epc:id:sgln:” and ends with a dot followed by the GLN extension value. In this case, the base GLN shall be the same as the site-level GLN in which the more granular location is located.
 - For example, if you have used a GLN (GLN of: urn:epc:id:sgln:0354321654923.0) to identify a warehouse location and want to identify a location in the warehouse, use the warehouse’s GLN and add an extension (urn:epc:id:sgln:0354321654923.1234).

ⓘ GS1 Standards allow more granular locations within a site to be given individual GLNs without extension. However, the above rule requires that extensions be used in this case so that applications to ascertain the GLN for the site-level location can be accomplished by simply disregarding the extension.

14.3. EPCIS Business Transactions

The *Business Transaction* list in EPCIS events is used for purchase order and invoice information to be included in shipping and receiving events. The EPCIS standard specifies that *Business Transactions* be globally unique identifiers expressed in URI syntax.

Rules:

Business Transactions in EPCIS events shall conform to the following rules:

- The *Business Transaction type* shall be one of the URIs defined in Section 7.3 of the GS1 EPC Core Business Vocabulary. Typically, this is either **urn:epcglobal:cbv:btt:po** denoting a purchase order or **urn:epcglobal:cbv:btt:inv** denoting an invoice.
- The *Business Transaction identifier* shall conform to the syntax defined in Section 8.4.2 of the GS1 EPC Core Business Vocabulary. This syntax constructs a globally unique identifier in URI syntax by combining the transaction identifier (e.g., purchase order number) with a GLN that identifies the party that issued the transaction identifier. This combined identifier is globally unique and leaves no ambiguity about the system from which a transaction identifier comes. For example, **urn:epcglobal:cbv:bt:0614141123452:A123** identifies a transaction whose native identifier (e.g., purchase order number) is A123 and which comes from a party identified by GLN 0614141123452.
- The GLN used in a *Business Transaction identifier* as specified above shall match the GLN provided in the **transferredByld** or **transferredTold** extension to a shipping or receiving event (whichever party created the transaction). Namely, the *Business Transaction identifier* shall match the **transferredByld** for an invoice, and the **transferredTold** for a purchase order. (See Section 17.3 for the definition of **transferredByld** and **transferredTold**.)

14.4. Checking EPCIS Event Contents

The following are suggested rules for verifying matching Receiving events and Shipping events.

- Pay attention to the dates. Dates should match your business expectations. Your systems should alert you to events outside of your normal business practice.
- The GTIN in the barcode should match the GTIN in the Shipping event.
- NDC in Receiving should match the Shipping NDC.
- All events SHALL conform to the attributes / extensions that are outlined in this guideline.
- Mandatory attributes SHALL exist.
- Location Identifier should belong to the expected party.

15. EPCIS Extension Elements

The EPCIS standard provides for data elements not specified in the standard to be included in EPCIS events as extensions. This is done by including additional XML elements just before the closing tag for an event, where those XML elements are in an XML namespace other than the EPCIS namespace.

All extension elements defined in this guideline are defined in the following XML namespace:

<http://epcis.gs1us.org/hc/ns>

All XML illustrations in this guideline use the prefix “gs1ushc” to denote this XML namespace. This means that an extension would look like this:

```
<epcis:EPCISDocument xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" ...>
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>...</eventTime>
        ...
        <bizTransactionList>
          ...
        </bizTransactionList>
        <gs1ushc:lotNumber>ABC123</gs1ushc:lotNumber>
        <gs1ushc:itemExpirationDate>2011-03-15</gs1ushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

i The EPCIS standard XML schema defines an element `<extension>`. This is reserved for use by future versions of the EPCIS standard to introduce new standard data elements in a forward-compatible way, and may not be used to define extensions outside of the EPCIS standard. Extensions outside the standard are defined as illustrated above (i.e., in a different XML namespace and not enclosed in the `<extension>` element).

16. Core Business Vocabulary (CBV) Extensions

The EPCIS standard specifies that the *Business Step*, *Disposition*, and *Business Transaction Type* fields of EPCIS events shall be populated with URI strings (each denoting a specific business step, disposition, or business transaction type, respectively). The GS1 EPC Core Business Vocabulary (CBV) standard provides standardized URI strings for a variety of commonly-occurring *Business Steps*, *Dispositions*, and *Business Transaction Types*.

This guideline has identified the need for additional *Business Steps* and *Dispositions* in pedigree EPCIS events for which the CBV does not provide a suitable standardized identifier. This guideline specifies URI strings to use in these situations. All such URI strings have the following form:

For business steps:

<http://epcis.gs1us.org/hc/bizstep/new-bizstep-name>

For dispositions:

<http://epcis.gs1us.org/hc/disp/new-bizstep-name>

The specific names are specified in the sections documenting the events in which they are used.

① All vocabulary values beginning with *urn:epcglobal:cbv:* are reserved for use by the CBV standard, and this prefix may not be used to define vocabulary outside the CBV. New vocabulary elements outside the CBV standard are defined by using a private URI space as illustrated above, not by using *urn:epcglobal:cbv:*.

17. EPCIS Event Details for Pedigree

This remainder of section defines individual EPCIS events for different steps in the pharmaceutical supply chain process for pedigree purposes. The EPCIS standard defines many fields of EPCIS events to be optional. In the context of a specific event defined in this guideline, a field that is optional in the EPCIS standard may be required to be present (or required to be omitted) for pedigree purposes. For clarity, the EPCIS event details tables throughout this section use the following notations to indicate what is required for pedigree purposes:

Required	The field is required in the context of this specific event. (This is always the case if the field is specified as required in the EPCIS standard.)
Optional	The field may or may not be included in the context of this specific event.
Conditional	In the context of this specific event, the field may be required, optional, or omitted depending on circumstances. The circumstances are specified in the description.
Omitted	The field is always omitted in the context of this specific event.



17.1. Commissioning

Commissioning is the process of associating an object (e.g., bottle, case, tote, pallet, etc.) with an EPC (i.e., an identifier representing a GTIN / Serial Number, SSCC, etc.). The EPC may be encoded in a data carrier (i.e., a barcode or EPC/ RFID tag) and applied to the object during this step, or the data carrier may have been previously encoded.

❖ **A Commissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. If more than one EPC is included, they shall all have the same value for extensions defined below, or shall all require these extensions to be omitted. EPCs having different values for these extensions must be shared in different Commissioning events.	Because the extensions below are <i>event-level</i> extensions, they must be the same for all EPCs in the event.
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the <i>Disposition</i> value "active" is always used with the <i>Business Step</i> "commissioning."
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 14.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in Commissioning events as there are no relevant business transactions to share.

❖ Extensions used in Commissioning Events:

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Commissioning event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
additionalTradeItemIdentification	Conditional	AdditionalTradeIdentificationType (see below)	The product code associated with all of the EPCs in the epclist of the ObjectEvent.
tradeItemMasterData	Conditional	Complex Type tradeItemMasterData (see below)	Used for trading partners who do not employ a master data management strategy
lotNumber	Conditional (see notes below)	String	The lot or batch number for all of the EPCs in the epclist of the ObjectEvent.
itemExpirationDate	Conditional (see notes below)	Date	The expiration date for all of the EPCs in the epclist of the ObjectEvent, formatted as an xsd:date. *



*** Special Notes:**

The GS1 General Specification states that, for Expiration Date (AI 17) in a barcode, if only year and month are available, the day portion of the date must be filled with two zeroes (ex: January 2013 would be represented as "130100"). The itemExpirationDate attribute uses the W3C standard date format which does not allow "00" as a day. The GS1 US Secure Supply Chain Task Force is considering options to address this in an amendment to this guideline or in a future version. In the interim, certain manufacturers have elected to use the last day of the month in the itemExpirationDate attribute, please communicate to your trading partners how you plan on addressing this so that they can understand how to interpret the expiration date they receive in your barcoded product and EPCIS Commissioning events.

2011 HDMA Barcode Guidelines: The application identifier for expiration date, AI(17), requires the "YYMMDD" (Year, Year, Month, Month, Day, Day) format. No other expiration date format is supported or allowed in the GS1 System. Yet some suppliers do not designate a day of the month as part of their expiration date. In this case "00" is used in the GS1 System as a place holder for the "DD" date segment when no day of the month is specified. The last day of the month is analogous to using 00 and is also perfectly acceptable. Whatever the human-readable format, HDMA recommends that the human-readable year always be represented in its complete "CCYY" (Century, Century, Year, Year) four-digit format.

It also is important to note that the lack of a specified day of the month in the expiration date can cause confusion as to which day of the month is the expiration date. HDMA recognizes the following excerpt from the United States Pharmacopeia* (USP) as authoritative on the subject of the date format:

USP 34–NF 29 through Second Supplement 10.40.100. Expiration Date and Beyond-Use Date:

The label of an official drug product or nutritional or dietary supplement product shall bear an expiration date. The expiration date identifies the time during which the article may be expected to meet the requirements of the compendial monograph, provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the article may be dispensed or used. Where an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month

* The USP is a non-governmental, official public standards-setting authority for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States.

❖ The AdditionalTradeltemIdentificationType elements are:

Element	Usage	Type	Value
additionalTradeltemIdentificationValue	Required	String	The product code associated with all of the EPCs in the epcList of the ObjectEvent For NDC, do not include dashes.
additionalTradeltemIdentificationType	Required	Additional Tradeltem Identification ListType (enum list)	(Mandatory) The product code type. Valid values are: NDC442, NDC541, NDC532, NDC542

❖ **The TradeItemMasterData elements are:**

Element	Usage	Type	Value
drugName	Required	String	The name of the drug as it appears on the product label.
manufacturer	Required	String	The name of the manufacturer or repackager of the drug as it appears on the product label.
dosageForm	Required	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
strength	Required	String	The strength or potency of the product, including the unit of measure (for example, 60 mg, 25 ml).
containerSize	Required	String	The number of units contained in a package of the product (for example, 60, 100). This is also known as pack size.

❖ **Commissioning ObjectEvent Rules:**

- ObjectEvents for commissioning item serial numbers SHALL include the extension elements to define the product code, lot and expiration date.
- ObjectEvents for commissioning homogenous containers (e.g., cases and pallets of the same object) MAY include the extension elements to define the product code, lot and expiration date.
- ObjectEvents for commissioning non-homogenous containers (e.g., cases and pallets of different items, lots, etc.) SHALL NOT include the extension elements to define the product code, lot and expiration date.
- All of the EPCs within a single Commissioning event must belong to only one of the categories defined in the previous three rules Multiple Commissioning events must be used for EPCs belonging to different categories.



❖ **Commissioning Event Example:**

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
          <epc>urn:epc:id:sgtin:030001.1012345.2222222222</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>

        <gslushc:additionalTradeItemIdentification>

        <gslushc:additionalTradeItemIdentificationValue>0001012345</gslushc:additionalTradeItemIdentificationValue>

        <gslushc:additionalTradeItemIdentificationType>NDC442</gslushc:additionalTradeItemIdentificationType>
        </gslushc:additionalTradeItemIdentification>
        <gslushc:tradeItemMasterData>
          <gslushc:drugName>Epcistra</gslushc:drugName>
          <gslushc:manufacturer>GS1 Pharma LLC</gslushc:manufacturer>
          <gslushc:dosageForm>PILL</gslushc:dosageForm>
          <gslushc:strength>100mg</gslushc:strength>
          <gslushc:containerSize>500</gslushc:containerSize>
        </gslushc:tradeItemMasterData>
        <gslushc:lotNumber>A123</gslushc:lotNumber>
        <gslushc:itemExpirationDate>2015-03-15</gslushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.2. Packing

Packing denotes a specific activity within a business process that includes putting an object (e.g., individuals, inners, cases, pallets, etc.) into a larger container (e.g., cases, totes, pallets, etc.) usually for the purposes of storing or shipping. Aggregation of one unit to another occurs at this point.

❖ **A Packing event shall be an EPCIS Aggregation Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) being packed into the parent in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:packing	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 14.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (with each represented as a pair of URIs)		Omitted in the packing event as there are no relevant business transactions to share.

❖ **Extensions used in Packing Events:**

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Packing event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

❖ **Packing Event Example:**

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.2222223333</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001003</epc>
        </childEPCs>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>

```

17.3. Shipping

Shipping is the process of initiating the transfer an object from one trading partner to another. A data carrier (i.e., a bar code or EPC/RFID tag) may have been read during this process. Only the outermost containers in the packaging hierarchy are included.

❖ **A Shipping event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the shipped item(s) in EPC Pure Identity URI format. Only the outermost containers in the packaging hierarchy are included.	For pedigree purposes, the Shipping event only needs the outermost identifiers because separate Packing events are used to indicate the hierarchy.
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The <i>Disposition</i> value "in_transit" is always paired with the <i>Business Step</i> "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 14.2).	EPCIS standard definition
bizLocation	Optional	URI		The <i>Business Location</i> is the location where the objects are presumed to be following the event. For a Shipping event, this is unknown until a Receiving event occurs. Therefore, <i>Business Location</i> is always omitted for a Shipping event. (Note that extension elements in this event provide "Ship from" and "Ship to" information.)
bizTransactionList	Optional	List of biz transactions (each represented as a pair of URIs)	Business transactions governing this Shipping event, which may include a purchase order or an invoice (see Section 14.3 for details).	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for P.O., Invoice or other ID's.

❖ Extensions used in Shipping Events

In addition to the EPCIS standard fields listed above, the following extensions are also included in a Shipping event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
transferredById	Required	String	The identifier of the party that transferred the goods (in the format implied by the accompanying @type attribute)
@type	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
shipFromLocationId	Conditional	String	The identifier of the location where the goods are shipped from (in the format implied by the accompanying @type attribute). Only included if different from transferredById.
@type	Conditional	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
shipFromLocationAddress	Optional	AddressType	Fully enumerated address.
transferredToId	Required	String	The identifier of the party that the goods were transferred to (in the format implied by the accompanying @type attribute). Indicates the change of ownership. Previous owner (transferredById) has transferred ownership to this party.
@type	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
shipToLocationId	Conditional	String	The identifier of the location where the goods were shipped to (in the format implied by the accompanying @type attribute). Only included if different from transferredToId.
@type	Conditional	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
shipToLocationAddress	Optional	AddressType	Fully enumerated address.



Element	Usage	Type	Value
shipFromLicenseList	Conditional	List of LicenseListType. Multiple LicenseListType instances may be included to express as many licenses as needed.	(Mandatory for compliance with CA, but may not be needed in other states.) A list of one or more state or federal license numbers for the party that sold the goods. <i>(See the list of values in the sections following this table.)</i>
shipToLicenseList	Conditional	List of LicenseListType. Multiple LicenseListType instances may be included to express as many licenses as needed.	(Mandatory for compliance with CA, but may not be needed in other states.) A list of one or more state or federal license numbers for the party that the goods were shipped to. <i>(See the list of values in the sections following this table.)</i>
soldFromContact	Optional	ContactType	Contact information for the seller

❖ **The PartyIdQualifierEnum code list values are:**

GLN	GS1 GLN for the company, expressed as a 13-digit string
SGLN	GS1 GLN for the facility, expressed in SGLN EPC Pure Identity URI format, ending in ".0" to indicate the lack of a GLN extension. (See Sections 6.3.3 and 7.3 of the EPC Tag Data Standard.)
DEA	Drug Enforcement Agency Number
HIN	HIBCC Health Industry Number

① GS1 Healthcare US recommends the use of GLN and/or SGLN as they maintain alignment with the GS1 System of Standards. GS1 Healthcare US discourages the use of identifiers from outside the GS1 System because they may not be global, and/or because issuing agencies for some identifiers do not approve of the use of their identifiers beyond the specific application for which they were issued.

❖ **The AddressType elements are:**

Element	Usage	Type	Value
street1	Required	String	The first line of the street address.
street2	Optional	String	The second line of the street address.
city	Required	String	The city.
stateOrRegion	Required	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Required	String	The ZIP or other postal code.
country	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].



❖ The LicenseListType elements are:

Element	Usage	Type	Value
licenseNumber	Required	String	A list of one or more state or federal license numbers for the trading partner.
@state	Optional	String	The state or region in which the trading partner is licensed, using the standard two letter abbreviation specified in ISO 3166-2:1998 country sub-division code. This attribute is used to give additional context to the license number.
@agency	Optional	String	The agency that granted the license (e.g., Florida DOH, NABP). This attribute is used to give additional context to the license number.

❖ The ContactType elements are:

Element	Usage	Type	Value
name	Optional	String	The name of the contact department or individual at the company.
title	Optional	String	The title of the individual.
telephone	Optional	String	The phone number of the contact department or individual at the company. This SHALL begin with the "+" character followed by the Country Calling Code.
email	Optional	String	The email address of the contact department or individual at the company.
url	Optional	String	The Web address to facilitate authentication.

❖ Shipping Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:030001.01234567890</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizTransactionList>
          <bizTransaction
            type="urn:epcglobal:cbv:btt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:
            0399999999991:XYZ567</bizTransaction>
          </bizTransactionList>
          <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
          <gslushc:transferredById type="GLN">0300011111116</gslushc:transferredById>
          <gslushc:shipFromLocationId type="GLN">0300011111116</gslushc:shipFromLocationId>
          <gslushc:shipFromLocationAddress>
            <gslushc:street1>1295 S George Ave</gslushc:street1>
            <gslushc:street2>Room 378</gslushc:street2>
            <gslushc:city>Washington</gslushc:city>
            <gslushc:stateOrRegion>DC</gslushc:stateOrRegion>
            <gslushc:postalCode>12345-6789</gslushc:postalCode>
            <gslushc:country>US</gslushc:country>
          </gslushc:shipFromLocationAddress>
          <gslushc:transferredToId type="GLN">0399999999991</gslushc:transferredToId>
          <gslushc:shipToLocationId type="GLN">0399999999991</gslushc:shipToLocationId>
          <gslushc:shipToLocationAddress>
            <gslushc:street1>230 Park Ave S</gslushc:street1>
            <gslushc:city>New York</gslushc:city>
            <gslushc:stateOrRegion>NY</gslushc:stateOrRegion>
            <gslushc:postalCode>10003-1502</gslushc:postalCode>
            <gslushc:country>US</gslushc:country>
          </gslushc:shipToLocationAddress>
          <gslushc:shipFromLicenseList>
            <gslushc:licenseNumber state="TN" agency="SLN">0000001013</gslushc:licenseNumber>
          </gslushc:shipFromLicenseList>
          <gslushc:soldFromContact>
            <gslushc:name>CONTACT NAME</gslushc:name>
            <gslushc:telephone>+1-212-555-5624</gslushc:telephone>
            <gslushc:email>contact.name@example.com</gslushc:email>
          </gslushc:soldFromContact>
        </ObjectEvent>
      </EventList>
    </EPCISBody>
  </epcis:EPCISDocument>
    
```



17.4. Receiving

Receiving is the process of completing the transfer of an object from one trading partner to another. Receiving may be recorded in one of two ways:

- 1: Only the outermost containers in the packaging hierarchy are included in the Receiving event, in which case the full hierarchy inferred from prior Packing events is inferred to have been received, or
- 2: One or more inner levels of hierarchy are declared explicitly in one or more Receiving events, in which case inference is only used for inner levels not declared explicitly (or not at all if all levels are declared explicitly)

If the Receiving event is to be recorded using the first method (i.e., where only the outermost containers are included in the Receiving event), the Receiving event shall be an EPCIS Object Event populated as specified below. If the Receiving event is to be recorded using the second method (i.e., where hierarchy is declared explicitly), share as many Receiving Events as needed to express the hierarchy. Each event shall be an EPCIS Aggregation Event where the *Parent ID* and *Child EPC List* fields express the hierarchy and all other fields (including the action and the extensions) are as specified below.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 14.1).	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the received item(s) in EPC Pure Identity URI format. *If an <i>Object Event</i> is used, only the outermost containers in the packaging hierarchy are included. * If <i>Aggregation Events</i> are used, the event contains parentID and childEPCs fields (instead of the epcList field) for expressing the observed hierarchy.	See the discussion above regarding receiving options.
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:receiving	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 14.2.)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions, (each represented as a pair of URIs)	Business transactions governing this shipping event, which may include a purchase order or an invoice. (See Section 14.3 for details.)	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for P.O., Invoice or other ID's.



❖ Extensions used in Receiving Events

In addition to the EPCIS standard fields, the following extensions are included in a Receiving event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
transferredById	Required	String	The identifier of the party that transferred the goods (in the format implied by the accompanying @type attribute)
@type	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the section following this table.)
transferredToId	Required	String	The identifier of the party that the goods were transferred to (in the format implied by the accompanying @type attribute). Indicates the change of ownership. Previous owner (transferredById) has transferred ownership to this party.
@type	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
shipToLocationId	Conditional	String	The identifier of the location where the goods were shipped to, in the format implied by the accompanying @type attribute. Only included if different from transferredToId
@type	Conditional	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
shipToLocationAddress	Optional	AddressType	Fully enumerated address.
receivedByContact	Optional	ContactType (see Section 13)	Contact information for the receiver

Best Practice:

- To help in later matching Shipping and Receiving events, if possible, use the same values found in your trading partner's "Shipping" event for transferredById and transferredToId in your "Receiving" event.



❖ **The PartyIdQualifierEnum code list values are:**

- GLN** GS1 GLN for the company, expressed as a 13-digit string
- SGLN** GS1 GLN for the facility, expressed in SGLN EPC Pure Identity URI format, ending in ".0" to indicate the lack of a GLN extension. (See Sections 6.3.3 and 7.3 of the EPC Tag Data Standard.)
- DEA** Drug Enforcement Agency Number
- HIN** HIBCC Health Industry Number

① *GS1 Healthcare US recommends the use of GLN and/or SGLN as they maintain alignment with the GS1 System of Standards. GS1 Healthcare US discourages the use of identifiers from outside the GS1 System because they may not be global, and/or because issuing agencies for some identifiers do not approve of the use of their identifiers beyond the specific application for which they were issued.*

❖ **The AddressType elements are:**

Element	R/O	Type	Value
street1	Required	String	The first line of the street address.
street2	Optional	String	The second line of the street address.
city	Required	String	The city.
stateOrRegion	Required	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Required	String	The ZIP or other postal code.
country	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

**❖ Receiving Event Example:**

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:030001.01234567890</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </bizLocation>
        <bizTransactionList>
          <bizTransaction
            type="urn:epcglobal:cbv:btt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:
0399999999991:XYZ567</bizTransaction>
        </bizTransactionList>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
        <gslushc:transferredById type="GLN">0300011111116</gslushc:transferredById>
        <gslushc:transferredToId type="GLN">0399999999991</gslushc:transferredToId>
        <gslushc:shipToLocationId type="GLN">0399999999991</gslushc:shipToLocationId>
        <gslushc:shipToLocationAddress>
          <gslushc:street1>230 Park Ave S</gslushc:street1>
          <gslushc:city>New York</gslushc:city>
          <gslushc:stateOrRegion>NY</gslushc:stateOrRegion>
          <gslushc:postalCode>10003-1502</gslushc:postalCode>
          <gslushc:country>US</gslushc:country>
        </gslushc:shipToLocationAddress>
        <gslushc:receivedByContact>
          <gslushc:name>CONTACT NAME</gslushc:name>
          <gslushc:telephone>+1-212-555-5624</gslushc:telephone>
          <gslushc:email>contact.name@example.com</gslushc:email>
        </gslushc:receivedByContact>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```



17.5. Unpacking

Unpacking denotes a specific activity within a business process that includes removing an object (e.g., individuals, inners, cases, pallets, etc.) from a larger container (e.g., cases, totes, pallets, etc.) – usually for the purposes of storing or shipping. Unpacking is the reverse of Packing, and the Unpacking EPCIS event disaggregates specific aggregation relationships created by Packing events.

❖ **An Unpacking event shall be an EPCIS Aggregation Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 14.)	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) unpacked from the parent in EPC Pure Identity URI format	EPCIS standard definition. [Although the EPCIS standard permits childEPCs to be omitted to indicate that all children are disaggregated from the parent, this usage is <u>not</u> permitted for this guideline.]
action	Required	String	DELETE	EPCIS standard definition
bizStep	Required	URI	http://epcis.gs1us.org/hc/bizstep/unpacking	Extension vocabulary element introduced in this guideline
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 14.2.)	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in the packing event as there are no relevant business transactions to share

❖ Extensions used in Unpacking Events

In addition to the EPCIS standard fields, the following extensions are included in an Unpacking event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

❖ Unpacking Event Example:

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.2222223333</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
        </childEPCs>
        <action>DELETE</action>
        <bizStep>http://epcis.gslus.org/hc/bizstep/unpacking</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.6. End of Useful Life EPCIS Events

The following EPCIS events represent business processes that occur at the end of the supply chain, typically at a hospital or pharmacy.

17.6.1. Dispensing

Dispensing is the process of removing a portion of a product for use while retaining the remainder for subsequent dispensing, such as when individual tablets are removed from a bottle to fill a prescription. The EPCIS event indicates the item from which the portion was dispensed. Unlike destroying or decommissioning, the item continues to exist after dispensing, but a special disposition value is used to indicate that the item is no longer in its original state. After all portions have been dispensed from an item, it is subsequently destroyed.

❖ **A Dispensing event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 14.)	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC of the dispensed item in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	http://epcis.gs1us.org/hc/bizstep/dispensing	Extension vocabulary element introduced in this guideline
disposition	Required	URI	http://epcis.gs1us.org/hc/disp/partial	Extension vocabulary element introduced in this guideline. "Partial" denotes that the item being dispensed from is no longer the same as originally packaged.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 14.2.)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions (each represented as a pair of URIs)		<i>The pharmacy could choose to insert the prescription ID if they wanted to extend traceability to the patient. (There may already be this type of function in the pharmacy system).</i>



❖ Extensions used in Dispensing Events

In addition to the EPCIS standard fields, the following extensions are included in a Dispensing event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

❖ Dispensing Event Example:

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>http://epcis.gslus.org/hc/bizstep/dispensing</bizStep>
        <disposition>http://epcis.gslus.org/hc/disp/partial</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.6.2. Destroying

Destroying is the process of destroying a product so that it no longer exists, as opposed to decommissioning which implies that the item may still exist even though it no longer carries serialized identification. Destroying occurs when a party at the end of the supply chain physically destroys a product.

❖ **A Destroying event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 14.1.)	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the destroyed item(s) in EPC Pure Identity URI format	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. (Action DELETE in an Object Event indicates that the EPCs no longer exist.)
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:destroying	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:destroyed	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Omitted	URI		The Business Location is the location where the object is presumed to be following the event. For a Destroying event, the object no longer exists following the event. Therefore, Business Location is always omitted for a Destroying event.
bizTransactionList	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in the Destroying event as there are no relevant business transactions to share.



❖ Extensions used in Destroying Events

In addition to the EPCIS standard fields, the following extensions are included in a Destroying event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

❖ Destroying Event Example:

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:destroying</bizStep>
        <disposition>urn:epcglobal:cbv:disp:destroyed</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

17.6.3. Decommissioning

Decommissioning is the process of removing the EPC from the item so that it is no longer tracked. Unlike the Destroying business process, the item may still physically exist after decommissioning even though it no longer carries serialized identification. Decommissioning occurs when a party at the end of the supply chain removes the serialized identification (i.e., at point of sale).

❖ **A Decommissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. See Section 14.1.	EPCIS standard definition
recordTime	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the at the time and place where the event occurred.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the decommissioned item(s) (EPC Pure Identity URI format)	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. Action DELETE in an Object Event indicates that the EPCs no longer exist
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:decommissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:inactive	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 14.2.)	EPCIS standard definition
bizLocation	Omitted	URI		The Business Location is the location where the objects are presumed to be following the event. For a decommissioning event, the location of objects can no longer be tracked following the event and so Business Location is always omitted for a Decommissioning event.
bizTransactionList	Omitted	List of biz transactions, each a pair of URIs		Omitted in the Decommissioning event as there are no relevant business transactions to share

❖ Extensions used in Decommissioning Events

In addition to the EPCIS standard fields, the following extensions are included in a Decommissioning event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

❖ Decommissioning Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:decommissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:inactive</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
    
```



Part 6: Sample Supply Chain Event Choreographies for Pedigree

18. Model & Key for EPCIS Event Choreographies

In order to understand and hold conversations about EPCIS events supporting pedigree or other processes, it is helpful to use diagrams to show the choreography (or full set of events) that take place among a given set of trading partners. The following diagram was developed as the model to use for depicting the choreography of messages between trading partners in a specific scenario.

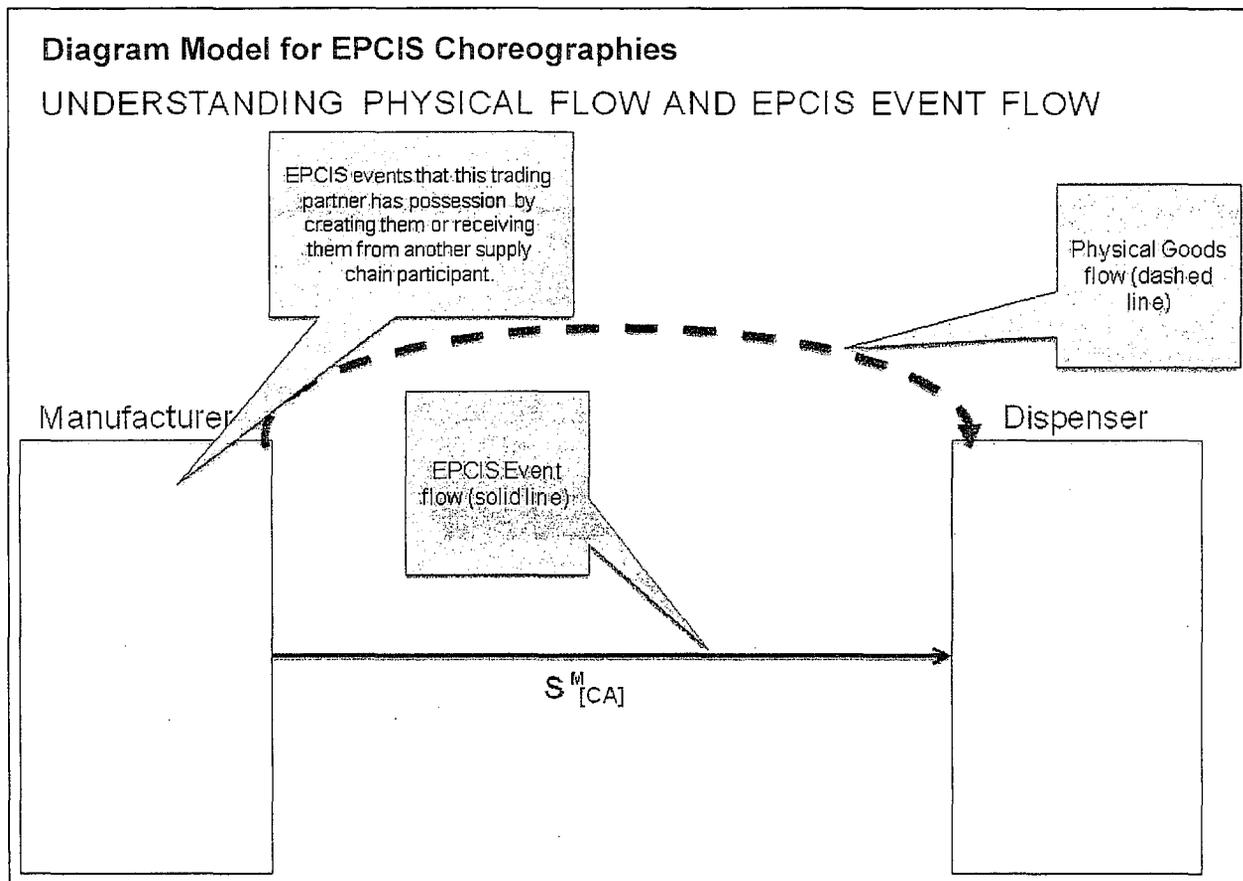


Figure 17: Model for EPCIS Choreography Diagrams

The diagram model shows the trading partners involved in the scenario, the physical flow of product (dashed line), and the EPCIS events transacted in the scenario (solid line). The EPCIS events within each trading partner's box are events that the trading partner has created themselves or received from their trading partner. Choreography diagrams help users to understand the interaction of trading partners as business processes that consume or produce EPCIS events are discussed, and as business and regulatory rules are applied. In addition, the diagrams make clear what information each trading partner has access to as the scenario progresses.

As documented in Part 5 of this guideline, each EPCIS event includes a defined set of data attributes. The following shorthand notation was developed to help communicate event data efficiently within diagrams. The shorthand notation uses an icon that represents the EPCIS event with the relevant information that is needed to understand the business and regulatory rules and constraints in the scenario.

Figure 18 provides the key to the shorthand notation used to represent EPCIS events in the choreography diagrams.

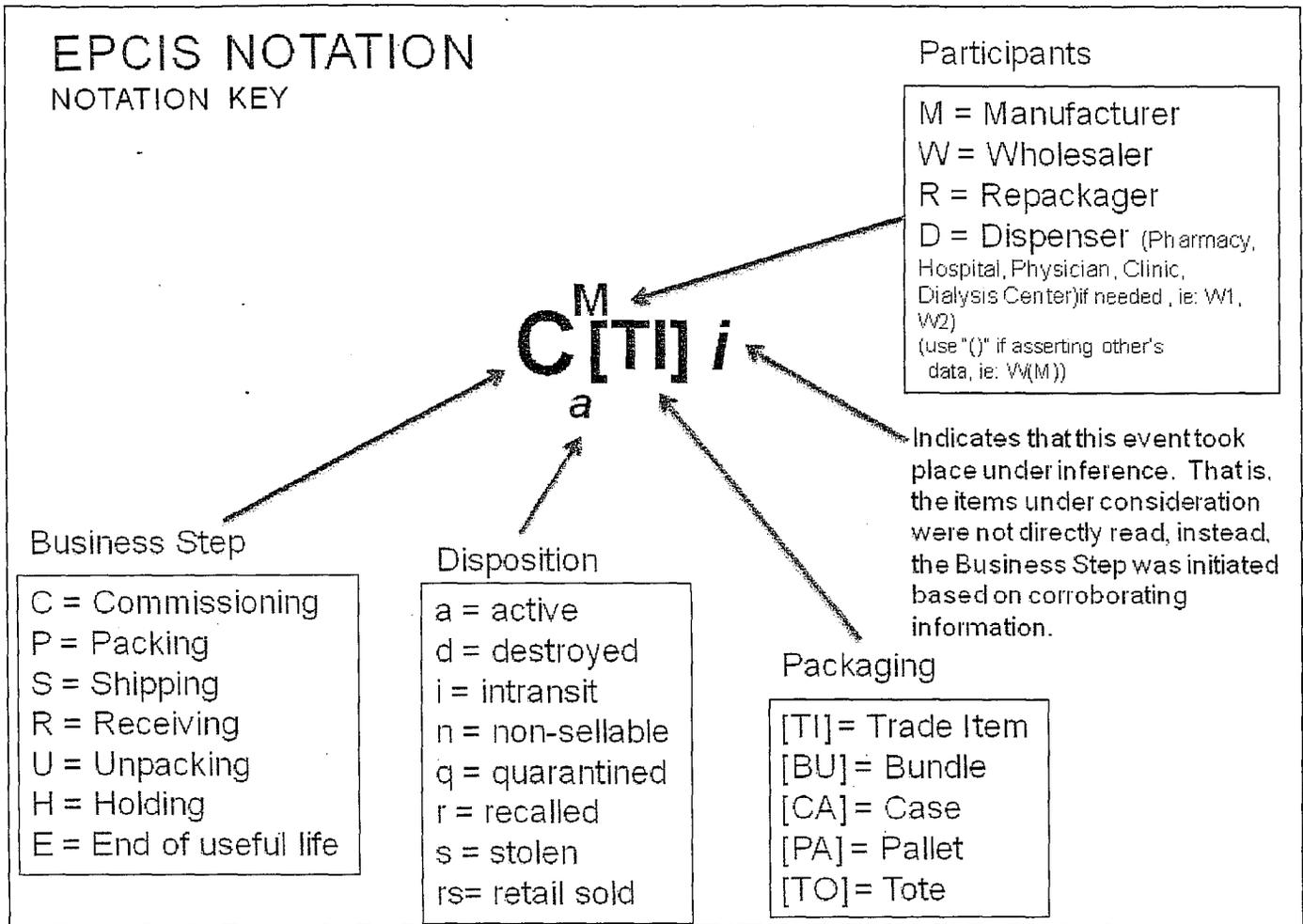


Figure 18: Shorthand Notation for Depicting EPCIS Events

① The full lists of Business Steps and Dispositions can be found in the Core Business Vocabulary Standard.

19. Forward Logistics Choreographies

The following diagrams provide examples of various scenarios that can take place as products move forward through the supply chain. This version of the guideline focuses on basic forward logistics supporting a one-up-one-down model. Future releases of this guideline will provide examples for additional forward logistics scenarios (e.g., drop shipments, repackaging, kitting, etc.), reverse logistics (e.g., recalls, returns, withdrawals, refusals, etc.) and exceptions (e.g., shortages, overages, data discrepancy, etc.).

19.1. Basic Forward Logistics

The following examples show how EPCIS events can be used to support basic forward logistics scenarios for product moving through the supply chain.

19.1.1. Ship a full case through the supply chain

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down to its cases and ships a full case to the Dispenser warehouse.

In the Figure 19 scenario, each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

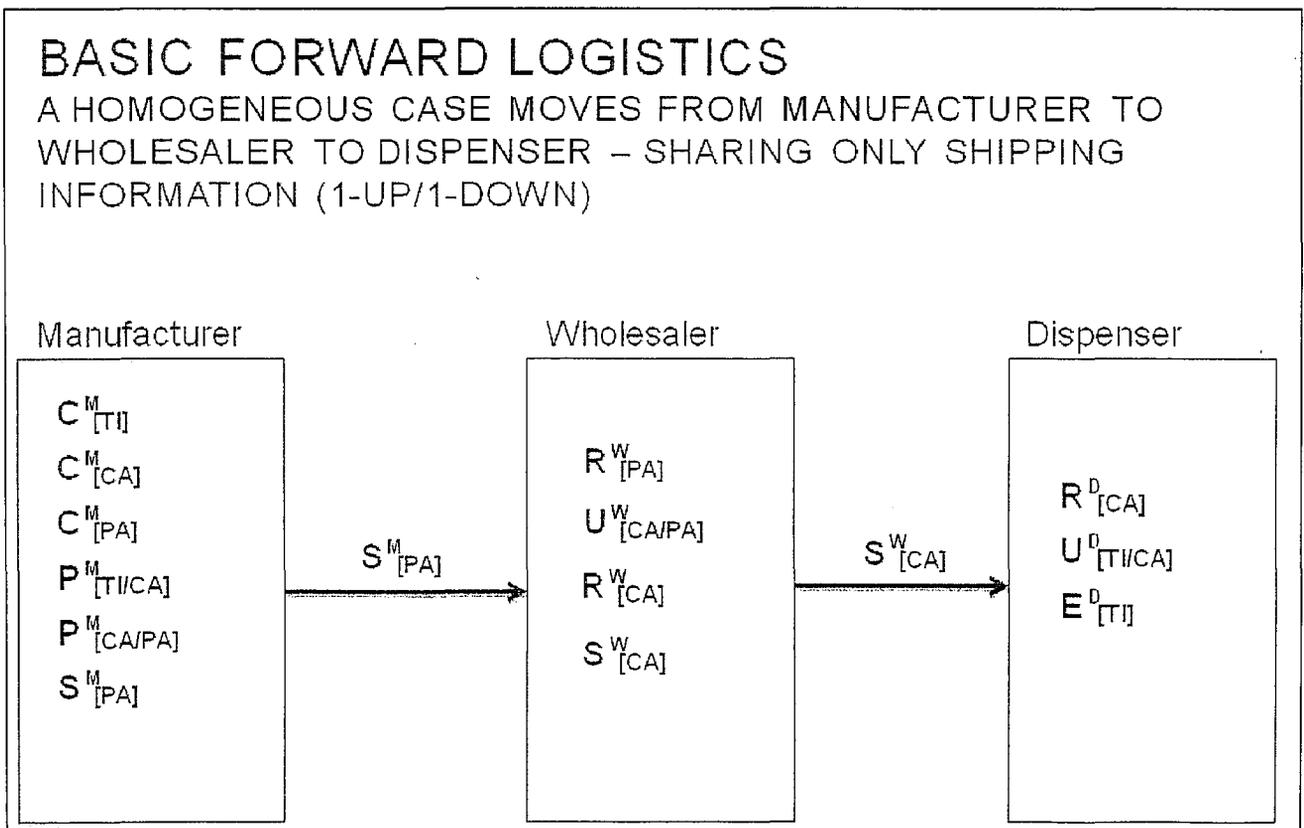


Figure 19: Ship full case through supply chain -- sharing *Shipping* events only

In the Figure 20 scenario, each trading partner captures the correct EPCIS events; however, they only share certain *pedigree events* to fulfill a one-up/one-down model. Note that the Wholesaler is shown to be asserting that the Manufacturer commissioned the trade item that the Wholesaler has shipped to the Dispenser.

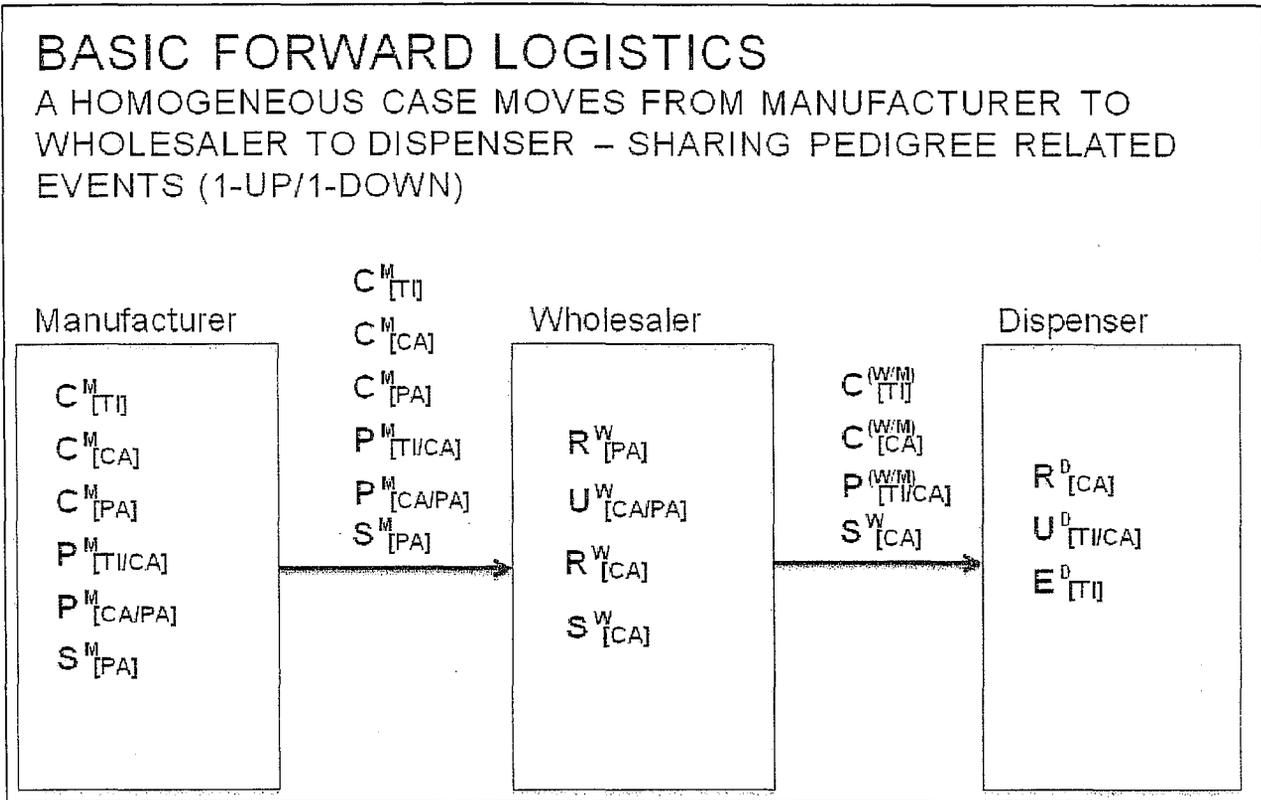


Figure 20: Ship full case through supply chain -- sharing *pedigree-related events*

19.1.2. Ship a pallet, break-down to trade items, pack and ship tote

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down into cases and then to the individual trade items. The Wholesaler then packs the trade items into a tote and ships the tote to the Dispenser.

In the Figure 21 scenario each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

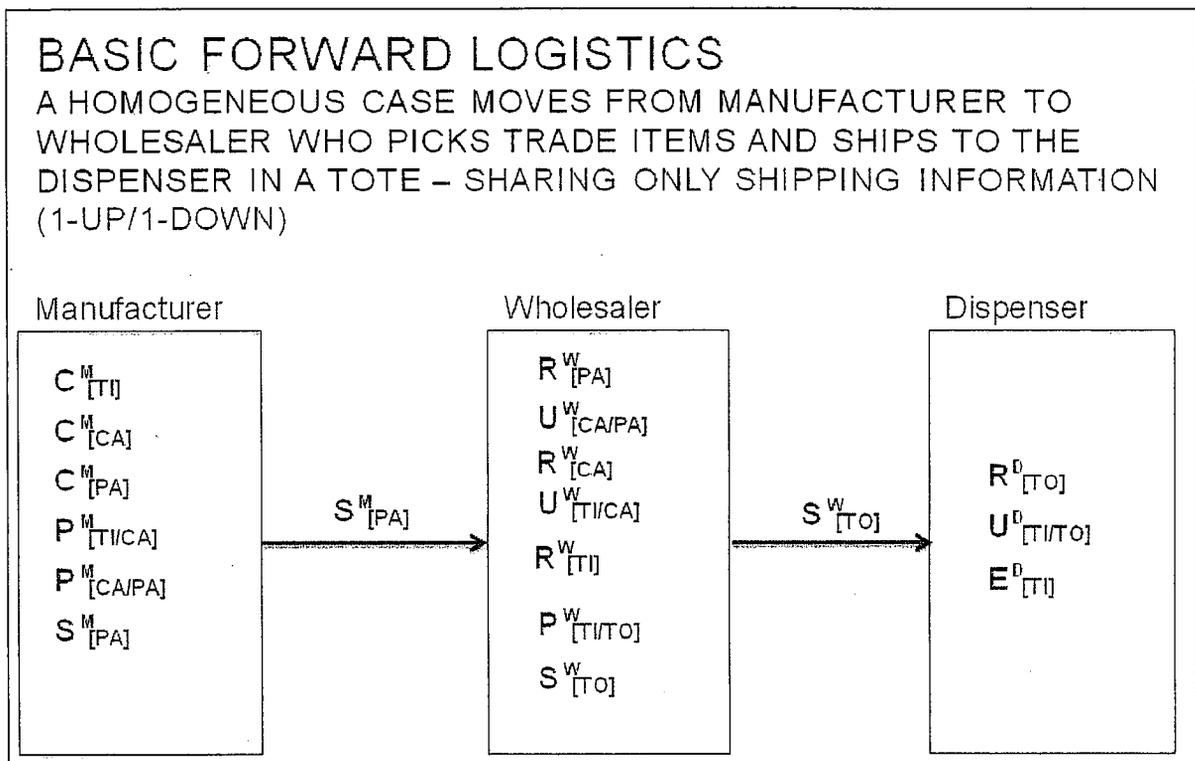


Figure 21: Ship pallet, break down to trade items, pack/ship totes -- sharing *Shipping* events only

In the Figure 22 scenario, each trading partner captures the correct EPCIS events; however, they only share certain *pedigree events* to fulfill a one-up/one-down model. Note that the Wholesaler is shown to be asserting that the Manufacturer commissioned the trade item that the Wholesaler has shipped to the Dispenser.

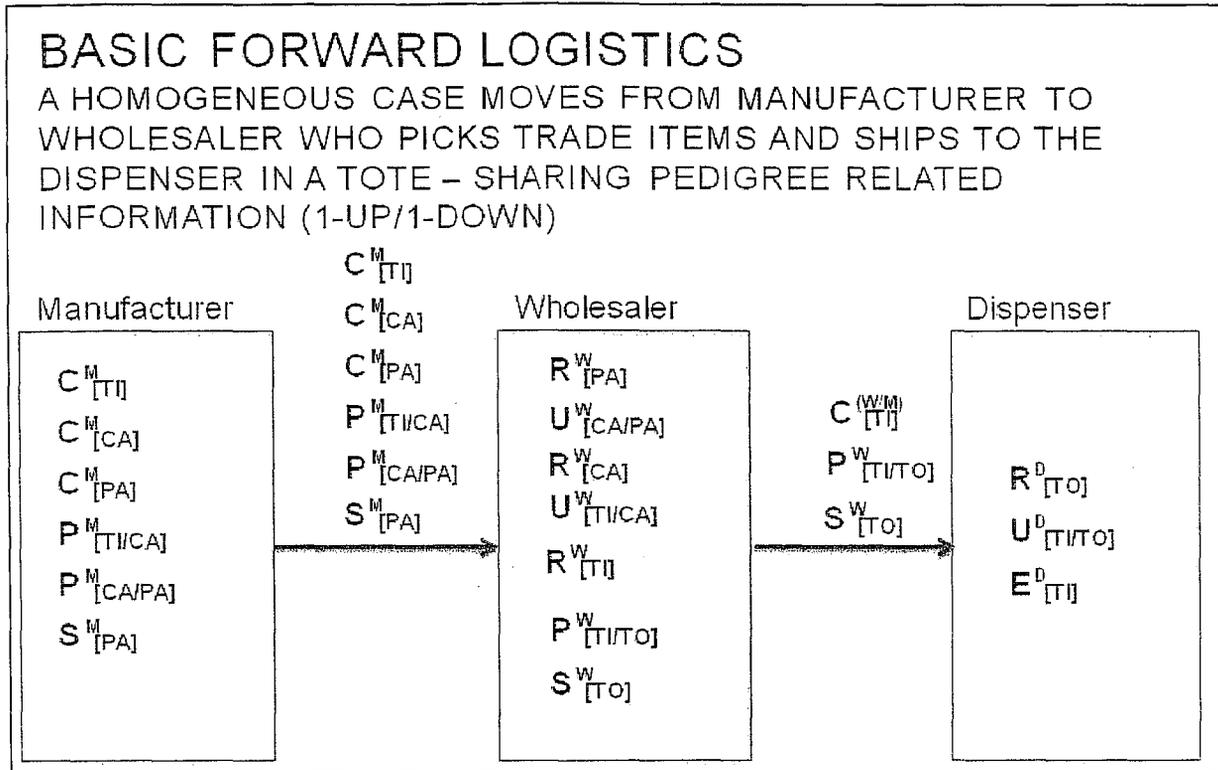


Figure 22: Ship pallet, break down to trade items, pack/ship totes -- sharing *pedigree-related* events

Part 7: Exceptions Processing

This section was developed by the GS1 Healthcare US Secure Supply Chain Task Force as a means to start assessing how supply chain partners might further leverage the EPCIS standard to address exceptions within supply chain business processes that impact serialization and visibility.

20. Overview

Managing serialized products throughout the supply chain is an order of magnitude change for trading partners. As the industry prepares to manage serialized products while simultaneously tracking pedigree data for each and every saleable unit, it is likely that exceptions regarding pedigree-related data will occur early on. This section was developed by the GS1 Healthcare US Secure Supply Chain Task Force as a means to start assessing how supply chain partners might further leverage the EPCIS standard to address exceptions within supply chain business processes that impact serialization and visibility. It will be updated with additional insights into exception processing from actual implementations, pilots and healthcare visibility programs. The primary goal is to address those exceptions that are likely to occur during the transition to serialized products.

This section identifies each known exception, defines the impact on the trading partners, and depicts how the trading partners could use EPCIS to notify each other that an exception had occurred. Later versions of this document may go further to define the full choreography of messages or EPCIS events needed to resolve the exceptions. While this section provides examples of exception processing using the EPCIS standard, it is recognized that there are other methods [e.g., Electronic Data Interchange (EDI), etc.] that may be used by individual trading partners.

It is anticipated that future versions of this guideline will provide detailed guidance on how companies may manage exceptions that can occur in a serialized, pedigreed world. The goal is to enable company systems to resolve exceptions with minimal human interaction by specifying EPCIS event choreographies that are aligned with the company's business rules and processes.

21. List of Exceptions

To date, the GS1 Healthcare US Secure Supply Chain Task Force has identified the following list of exceptions that could occur. As these exceptions and their resolutions are documented, it may be that some have the same root cause and will be consolidated. Likewise, as pilots and implementations continue to inform the content of this guideline, other exceptions may be uncovered and documented in this section in future releases.

Exception List:

- 1: Overage
- 2: Shortage
- 3: Pedigree Serial Number discrepancy
- 4: Pedigree Lot Number discrepancy
- 5: Pedigree Serial Number and Lot Number incorrect
- 6: Product inference problem
- 7: Quantity inference problem
- 8: Physical inventory overage
- 9: Physical inventory overage (concealed)



- 10: Physical inventory shortage (concealed)
- 11: Pedigree contains incorrect customer or location information
- 12: Pedigree contains incorrect product information
- 13: Pedigree contains incorrect reference number information
- 14: Pedigree (or EPCIS Ship Business Step) not received by customer
- 15: Undelivered shipment
- 16: Lost shipment
- 17: Received physical product from an unidentified sender
- 18: *Resolved (number maintained as placeholder)*
- 19: Could not read pedigree data due to security mismatch
- 20: Pedigree data not in correct format
- 21: Good product - damaged barcode or RFID
- 22: Damaged product - good barcode or RFID
- 23: Damaged product - damaged barcode or RFID
- 24: Damaged shipment
- 25: *Resolved – accounted for in other exceptions*
- 26: *Resolved – accounted for in other exceptions*
- 27: No parent – child aggregation
- 28: Pedigree data incomplete
- 29: Pedigree data has broken chain
- 30: Shipped product to wrong customer and pedigree data to correct customer
- 31: Customer refuses order
- 32: Unauthorized return
- 33: Shipment for Wholesaler “Y” arrives at Wholesaler “X”



Part 8: Appendices



22. Converting an 11-digit NDC to a 10-digit NDC

This section is provided for the benefit of billing system suppliers and users. Many National Drug Codes (NDCs) are displayed on drug packaging in a 10-digit format. Many billing systems require an 11-digit NDC number in a 5-4-2 format. The following table shows common 10-digit NDC formats indicated on packaging and the appropriate conversion to an 11-digit format for billing systems.

In the table below:

- The additional "0" in the 11-digit converted example is shown in **bold** and underlined.
- Hyphens have been inserted for visual clarity to illustrate the various formatting examples of NDCs. Do not use hyphens when entering the NDC in your claim.

10-Digit Format on Package	10-Digit Format Example	11-Digit Format	11-Digit Converted Example
4 - 4 - 2	0002-7597-01 Zyprexa 10mg vial	5 - 4 - 2	<u>0</u>0002-7597-01
5 - 3 - 2	50242-040-62 Xolair 150mg vial	5 - 4 - 2	50242- <u>0</u> 040-62
5 - 4 - 1	60575-4112-1 Synagis 50mg vial	5 - 4 - 2	60575-4112- <u>0</u>1

Table O: Key to Assigning, Storing and Encoding GTINs

23. GS1 Standards

From an information management point of view, supply chain applications like pedigree and track and trace require all parties to systematically associate the physical flow of products with the flow of information about them. This is best attained by deploying a common business language within the framework of a comprehensive standards system. The GS1 System is such a system, providing a comprehensive platform for companies to identify products and other business entities, capture supply chain data, and share data with trading partners.

The GS1 System encompasses identification standards, data standards, automatic identification data capture (AIDC) standards, and data communication standards. Table 16 below summarizes some of the GS1 Standards that support pedigree and track and trace.

GS1 Standards Supporting Pedigree and Track & Trace			
Identification Standards	Trade Items	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
	Individual Assets	Global Individual Asset Identifier (GIAI)	
	Returnable Assets	Global Returnable Asset Identifier (GRAI)	
AIDC Standards	GS1 Barcodes	GS1-128 GS1 DataMatrix RSS EAN/UPC ITF-14 Composite Component	
	GS1 EPC/RFID		
Data Standards	Master Data: Global Data Dictionary Item Business Messaging Standard Party Business Messaging Standard	Transactional Data: eCom/EDI	Event Data: EPCIS Schema EPCIS Core Business Vocabulary
	Sharing & Communication Standards	Master Data: GDSN GLN Registry EPCIS Master Data	Transactional Data: AS2
			Event Data: EPCIS Capture EPCIS Query Discovery Services

Table P: Overview of GS1 Standards to Support Pedigree and Track & Trace

24. Resource Links

- GS1 Healthcare US Website: <http://www.gs1us.org/healthcare>
- GS1 Healthcare US Tools and Resources: <http://www.gs1us.org/hctools>
- GLN Registry: <http://www.gs1us.org/glnregistry>
- *Healthcare Provider Tool Kit for GS1 Standards*: <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier Tool Kit for GS1 Standards*: <http://www.gs1us.org/hctoolkit>
- GS1 Healthcare US 2015 Readiness Program Report - Phase 1: Basic Forward Logistics: <http://www.gs1us.org/hctools>
- GS1 Healthcare US 2015 Readiness Program Report - Phase 2: Additional Forward Logistics: <http://www.gs1us.org/hctools>
- 2015 Readiness Pilot Reports: <http://www.gs1us.org/hctools>
- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain*: <http://www.gs1us.org/hctools>
- *GS1 US Visibility Framework White Paper*: <http://www.gs1us.org/visibility>
- *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* – Available on the GS1 US website at www.gs1us.org/hctools
- *Procedure for Responding to Troublesome Barcodes* – Available on the GS1 US website at www.gs1us.org/hctools
- *GS1 RFID Bar Code Interoperability Guideline* - Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmc/kc/barcodes>



25. Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
DPMS	Drug Pedigree Messaging Standard
EPC/RIFD	Electronic Product Code / Radio Frequency Identification
EPCIS	Electronic Product Code Information Services
XML	eXtensible Markup Language
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
NDC	National Drug Code
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
SGLN	Serialized Global Location Number (GLN)
SGTIN	Serialized Global Trade Item Number (GTIN)
U.P.C.	Universal Product Code (U.P.C.)
URI	Uniform Resource Identifier
URN	Uniform Resource Name



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ATTACHMENT 4

Proposed Draft to Enforcement and E-Pedigree Committee

March 2013

Inference

(a) Pursuant to Business and Professions Code sections 4034 and 4163.3, participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, shall distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, except where the board by regulation defines circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit. This regulation defines the limited circumstances under which such an inference will be acceptable.

(b) For the purposes of this section, to “infer” or to rely on an “inference” means that a supply chain participant, in reliance on electronic pedigree information received from a trusted trading partner which provides hierarchical relationships between those unique identifiers affixed to the smallest packages or immediate containers and those unique identifiers affixed to the aggregate container (a case or pallet) into which the smallest packages or immediate containers are placed for purposes of distribution, substitutes scan or review of the unique identifier affixed to the aggregate container for a scan or review of the unique identifiers affixed to the smallest packages or immediate containers contained therein, for purposes of certifying delivery or receipt. The supply chain participant then “infers” that the smallest packages or immediate containers within the aggregate container are what they are expected to be, based on the hierarchical pedigree information, and pairs expected shipments and receipts with the actual physical individual units without opening the sealed aggregate container and scanning or reviewing its contents.

(c) Recipients in the supply chain may infer the smallest package or immediate container contents of a sealed case bearing the original, unbroken, seal or tape affixed by the manufacturer, without breaking the seal, thereby relying on the unique identifier affixed to the sealed case and the inference that hierarchical data relationships between the case identifier and the individual unit identifiers as stated in the electronic pedigree have been correctly stated and remain true, and accurately describe the case contents, only under the following circumstances:

- (1) Where the source has transmitted to the recipient prior to receipt of the sealed case a certified electronic pedigree record establishing a hierarchical data relationship between the unique identifier affixed to the sealed case and the individual unit identifiers;
- (2) Where the electronic pedigree data was received via a secured electronic transmission, and includes a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the source;
- (3) Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened;

- (4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product, and contains no more than forty-eight (48) units of that dangerous drug product;
- (5) Where the sealed case and accompanying pedigree data were received from a trusted trading partner. For the purposes of this section, a “trusted trading partner” is a source:
 - a. with which the recipient has an established relationship and existing contract;
 - b. for which the recipient has verified the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient;
 - c. with which the recipient has established agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered;
 - d. from which the recipient has received at least five (5) shipments of sealed cases containing homogenous products, has physically verified the individual unit contents, and certified 100% accuracy of the electronic pedigree data received – detailed records of this verification process and the results of the inspections shall be kept and made available for inspection upon request by an authorized officer of the law or by an authorized representative of the board;
 - e. for which there has been no prior need for manual intervention with regard to any sealed cases previously received, other than individual unit identifier scans;
 - f. for which there is written approval by the recipient’s compliance manager, signed under penalty of perjury and maintained for review by the board for as long as the status persists, of “trusted trading partner” status for the source; and
 - g. with which there is a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received;
- (6) Where the source and recipient have agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered, and where the source and recipient have a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received, either or both of which shall be made immediately available for inspection by an authorized officer of the law or by an authorized representative of the board, upon request;

ADDITIONAL CONCEPTS:

- (A) Sampling/audits must be at least at the level of ANSI/ASQZ1.4-2008, Special Level S-1 and the single sampling plan for normal inspections;
- (B) When sealed case is opened, its entire contents must be immediately scanned;
- (C) Any discrepancies discovered in data or products must be remedied within 48 hours;

- (D) The pedigree data must indicate that an inference was deployed for the certifications;
- (E) Liability must be shared by all parties propagating or relying on the inference.

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* HDMA

Certification

(a) For the purposes of Business and Professions Code section 4034, and the delivery and receipt of electronic pedigrees, "certification" shall refer to the process by which each participant in the supply chain confirms and attests to the accuracy of electronic pedigrees transmitted or received in conjunction with delivery, transfer, receipt, or acceptance of corresponding dangerous drugs.

(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the delivering or transferring party (hereinafter, the "source") shall ~~transmit~~ provide to the buying, receiving, or accepting party (hereinafter, the "recipient") via a secured electronic transmission, the electronic pedigree data corresponding to the dangerous drug being delivered or transferred, including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d). The electronic pedigree ~~transmitted by the source to the recipient~~ shall include, as to each such individual unit, at least the following:

- (1) The name and principal address of the source, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.
- (2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
- (3) For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address, and federal or state registration and/or license number(s) permitting sale or transfer, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- (4) A certification under penalty of perjury from a responsible party of the source that the information contained in the pedigree is true and accurate.
- (5) The unique identification number affixed to the smallest package or immediate container.

The electronic pedigree provided by the source to the recipient shall ~~include a digital signature by a responsible party for the source that be transmitted via a secure data exchange methods in order to help~~ prevents any alteration, tampering, or other change to the pedigree, and that guarantees that the data is immutable and non-repudiable by the source.

The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine, the information contained in the pedigree is true and accurate. ~~By so attesting, the responsible party confirms that the source has verified the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, and that there is nothing in the prior transaction history that raises~~

suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

(c) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of an electronic pedigree, the recipient shall receive an electronic pedigree from the source that corresponds to the dangerous drug being delivered or transferred. The entity selling the dangerous drug shall include in its data transmission a certification that, to the best of its knowledge, there is nothing in the transaction history that raises suspicion, and shall transmit the information in a secure method that helps to prevent any alteration, tampering or other change to the pedigree. ~~The recipient shall certify receipt of the dangerous drug by verifying the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, confirming there is nothing in the transaction history that raises suspicion, verifying correspondence between the pedigree data and the dangerous drug received, and by including in the pedigree a digital signature by a responsible party for the recipient that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the recipient.~~

DRAFT

Inference

(a) Pursuant to Business and Professions Code sections 4034 and 4163.3, participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, shall distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, except where the board by regulation defines circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit. This regulation defines the limited circumstances under which such an inference will be acceptable.

(b) For the purposes of this section, to “infer” or to rely on an “inference” means that a supply chain participant ~~---~~, in reliance on electronic pedigree information (received from a trusted trading partner) which provides hierarchical relationships between those unique identifiers affixed to the smallest packages or immediate containers and those unique identifiers affixed to the aggregate container (a case or pallet or other aggregate of individual units) into which the smallest packages or immediate containers are placed for purposes of distribution ~~---~~, substitutes the scanning or review of the unique identifier affixed to the aggregate container for a ~~scan~~the scanning or review of the unique identifiers affixed to the smallest packages or immediate containers contained therein, for purposes of ~~certifying~~ confirming delivery or receipt. The supply chain participant may then “infer” that the smallest packages or immediate containers within the aggregate container are what they are expected to be, based on the hierarchical pedigree information, and ~~pairs~~ expected shipments and receipts with the actual physical individual units without opening the sealed aggregate container and scanning or reviewing its contents.

(c) Recipients in the supply chain ~~may~~ infer the smallest package or immediate container contents of a sealed case, pallet or aggregated container -bearing the original, unbroken, seal or tape affixed by the manufacturer, without breaking the seal, thereby relying on the unique identifier affixed to the sealed case and the inference that hierarchical data relationships between the case identifier and the individual unit identifiers as stated in the electronic pedigree have been correctly stated and remain true, and accurately describe the case contents, only under the following circumstances:

- (1) Where the source has transmitted to the recipient prior to receipt of the sealed case an certified-electronic pedigree record-record containing the case (or pallet) identifier and corresponding serial numbers of the case (pallet) contents, and establishing a hierarchical data relationship between the unique identifier affixed to the sealed case and the individual unit identifiers;
- (2) Where the electronic pedigree data was received via a secured electronic transmission, and includes a digital signaturerecertification by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree and ~~that guarantees~~ that the data is immutable and non-repudiable by the source;
- (3) Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened;

- (4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product, ~~and contains no more than forty-eight (48) units of that dangerous drug product;~~
- (5) Where the sealed case and accompanying pedigree data were received from a trusted trading partner. For the purposes of this section, a “trusted trading partner” is a source:
- a. ~~with which the recipient has an established business relationship and existing contract;~~
 - b. for which the recipient has verified the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient;
 - c. ~~with which the recipient each party which has established agreed standard operating procedures (SOPs) and mutually executed standard operating procedures (SOPs) that define, at minimum, the entity’s requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases or pallets for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered;~~
 - d. from which the recipient has received at least five (5) shipments of sealed cases containing homogenous products, has physically verified the individual unit contents, and certified 100% accuracy of the electronic pedigree data received – detailed records of this verification process and the results of the inspections shall be kept and made available for inspection upon request by an authorized officer of the law or by an authorized representative of the board;
 - e. ~~for which there has been no prior need for manual intervention with regard to any sealed cases previously received, other than individual unit identifier scans;~~
 - e. in the event manual intervention is necessary with regard to a specific sealed case or pallet, (e.g., broken seal or damaged container), inference may not be used for receipt of the contents of that container.
 - f. for which there is written approval by the recipient’s compliance manager (?), signed under penalty of perjury and maintained for review by the board for as long as the status persists, of “trusted trading partner” status for the source; and
 - g. ~~with which there is a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received;~~
- (6) ~~Where the source and recipient have agreed and mutually executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered, and where the source and recipient have a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received, either or both of which shall be made immediately available for inspection by an authorized officer of the law or by an authorized representative of the board, upon request;~~

~~(7)~~

ADDITIONAL CONCEPTS:

- (A) ~~Sampling/audits must be at least at the level of ANSI/ASQZ1.4 2008, Special Level S-1 and the single sampling plan for normal inspections;~~
- (B) When sealed case is opened, its entire contents must be immediately individually scanned;
- (C) Any discrepancies discovered in data or products must be ~~remedied~~ addressed within 48 business hours;
- (D) ~~The pedigree data must indicate that an inference was deployed for the certifications;~~
- (E) Liability must be shared by all parties propagating or relying on the inference for errors should be borne by the entity supplying the aggregated product and information.

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Inspection

(a) Pursuant to Business and Professions Code sections 4081 and 4105, electronic pedigree records are among the records of manufacture, sale, acquisition, or disposition of dangerous drugs that shall be at all times during business hours open to inspection by authorized officers of the law, that shall be preserved for at least three years from the date of making, and that shall be at all times retained ~~on the licensed premises~~ in a readily retrievable form.

(b) Electronic pedigree records shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of the electronic pedigree records.

(c) Upon request by an authorized officer of the law or by an authorized representative of the board, the electronic records shall be made ~~immediately available~~ within 48 business hours in electronic format for duplication or download, duplicated or printed into a paper format, or both, as directed.

~~(d) Each licensed premises shall have available a scanner and terminal that may be used by an authorized officer of the law or by an authorized representative of the board to access electronic pedigree record information regarding the smallest package or immediate container for any dangerous drug by, among other things, scanning the unique identification number affixed to the smallest package or immediate container and accessing the corresponding pedigree.~~

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Comments on the California Board of Pharmacy's Initial Inference Regulation Draft

The following comments are submitted on behalf of Medline Industries, Inc., a manufacturer and distributor of medical products. In the context of California's ePedigree law, Medline's interest is primarily related to our activities as a secondary wholesaler of prescription drugs.

We appreciate the opportunity to express our views on inference. We thank the Board for its hard work and dedication on this important issue. We understand that this draft is meant to help solicit additional industry feedback and inform the rulemaking process. To that end, we believe this discussion draft will prove a very constructive step in that iterative process.

Importance of Inference

The use of inference throughout the supply chain is of critical importance. If wholesalers are required to manually unpack each case and scan each individual unit, the entire pharmaceutical distribution chain will break down—endangering public health and safety by significantly exasperating drug shortages while drastically increasing the cost of pharmaceuticals for California consumers. Furthermore, unnecessarily opening sealed cases is not only costly and time consuming but it will also measurably elevate risks to the product. The act of opening a case destroys the manufacturer's tamper evident tape and leaves the case vulnerable to tampering, theft and product mix-up. In fact, many larger customers will only accept products in the manufacturer's sealed case. For these reasons, industry best practice is to leave a case's security tape intact until units from that case are needed. We urge the Board not to disrupt this important safety and security practice.

In establishing its regulations on inference, we urge the Board to carefully consider the impact its regulations will have on competition in the state. While the draft regulation does not seem to prohibit secondary wholesalers from participating in inference, comments by the Board's staff have suggested that this may in fact be the case. Secondary wholesalers, play an invaluable role in the supply chain, providing timely and cost effective delivery of prescription drugs to a variety of dispensaries—including community pharmacies, surgery centers, physician offices and long-term care facilities. Many of these facilities rely on just in time delivery of small quantities of products, often coupled with the delivery of other medical products. These services are often only provided by secondary wholesalers. Any rule that allows the use of inference by primary wholesalers but not by secondary wholesalers would be unjust and potentially anti-competitive.

Medline estimates that between 60% and 80% of our incoming prescription drug product arrive in sealed homogeneous cases. Outbound, we distribute between 10% and 20% of our prescription drug products in sealed homogeneous cases. Any rules or regulations preventing our use of inference on these products would have a negative impact on supply chain integrity and efficiency.

Specific Feedback on the Draft Inference Regulation

Below please find specific feedback on the text of the draft regulation:

- Section (c)(1) requires that electronic pedigree record be transmitted to the recipient prior to the receipt of product. While we suspect that the vast majority of our transactions will transpire in this manner, we believe that it is important that the Board consider special circumstances, especially related to drop shipments, where this requirement could be waived. We understand the Board is working on this issue and look forward to providing additional comments in the future. Furthermore, the Board should clarify this subsection to clearly allow for a shipment and its corresponding ePedigree information to arrive simultaneously.
- Section (c)(4) attempts to define a case as a container with no more than forty-eight (48) units. Cases come in a variety of shapes and sizes. There is no uniform case size – in terms of number of units, weight, or dimensions. We currently distribute cases that range in size from four (4) units to one-hundred (100) units. The use of inference on a case that meets the other requirements of the regulation is no less safe if it contains fifty (50) or one-hundred (100) units than if it contained four (4) or forty-eight (48) units. Attempting to define a case by its size is arbitrary and unnecessary.
- In section (c)(5), it is not entirely clear what the Board means by the word “source.” Is the source the immediate trading partner a recipient purchases product from and/or receives product from or is it the original source of the product (i.e. the manufacturer). We assume in this context source means the trading partner a recipient purchases product from and/or receives product from but it is not entirely clear.
- In section (c)(5)(a), what does contract mean? In this context, does a purchase order qualify? Trading partners do not always have formal contracts with one another. The absence of a formal contract does not prevent trading partners from establishing a trusted trading partner relationship.
- Section (c)(5)(c) introduces the concept of mutually-executed standard operating procedures (SOPs). We are concerned with this concept. As the supply chain is interconnected, this seems to require either that the entire supply chain operate under one set of SOPs or that each trading partner would have a different set of SOPs for each source/recipient. Additionally, within this section we are particularly concerned with the concept that the source seemingly has the ability to set requirements for gaining and maintaining “trusted trading partner” status above and beyond the requirements set forth in this regulation. This could unintentionally allow for a situation where a source prohibits a recipient from using inference for anticompetitive reasons. We recognize that each set of trading partners will need to agree on how discrepancies will be remediated but the rest of the subsection seems impractical and unnecessary.

- Section (c)(5)(e) seems to indicate that a single inference error by a source will prevent the use of inference on all products from that source. Were this provision to be maintained, it would in effect prohibit the use of inference. Inference errors, though rare, are unavoidable. Every trading partner is likely to experience inference errors from time to time. A single inference error should not negate trusted trading partner status. We recommend the deletion of this subsection.
- In the additional concepts section, the Board suggests that all discrepancies should be remedied within forty-eight (48) hours. While typically forty-eight (48) hours is sufficient to address a discrepancy, we urge the Board to change this to three (3) business days. Addressing a discrepancy may require engaging several supply chain partners and/or regulatory bodies. Resolving and reporting discrepancies within forty-eight (48) over a holiday or weekend will be extremely challenging.

Should the Board have any questions, please do not hesitate to contact Rob Calia at the contact information detailed below.

Sincerely,

Rob Calia
Government Affairs Specialist
Medline Industries, Inc.
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RECEIVED APR 18 2013

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834



Subject: Merck & Co., Inc.'s Comments on Draft Language Regarding Inference, Certification and Inspection

Dear Ms. Herold:

Merck & Co., Inc. (Merck) appreciates the opportunity to comment on the important matters regarding drug pedigree that the California Board of Pharmacy (the Board) is considering, including the draft language published in March regarding Inference, Certification and Inspection.

Merck is fully supportive of efforts to ensure that the drugs that reach patients are safe, high quality, and efficacious. Further, Merck's central mission is to help patients *be well*, which includes helping to ensure that the pharmaceutical supply chain is protected and that patients have a high degree of certainty that the medication prescribed is what they are receiving.

Merck is also committed to patient access to medicines. In addition to Merck's patient assistance programs (merckhelps.com), we have efforts ongoing throughout the Company to reduce the cost of producing and distributing our medicines, which in turn increases the ability of patients to access Merck drugs. California's drug pedigree requirements will impose additional requirements for manufacturers, distributors and pharmacies; these additional requirements add significant cost to the pharmaceutical supply chain. California should ensure that increased system costs do not add an unnecessary financial burden on the healthcare system, with the result of decreasing patient access to medications.

Therefore, our core message to the Board regarding implementation of current law is to enact regulations that **achieve the benefits of drug pedigree at the lowest cost to the healthcare system**. Most of our comments today are centered around this concept – how to deliver the *intent* of the law in the most cost efficient manner. We urge the Board to consider our comments in this light.

Below we provide first our general overall comments, and then specific comments on the draft language for certification, inference and inspection.

1. Inference should include tolerances for scanning and packaging errors

Inference is essential for the efficient operation of the supply chain; without it, distributors and pharmacies would be required to scan every individual package, significantly increasing the burden, cost and time to deliver medicines to patients.

As drafted, however, inference would only be allowed in very specific situations, would be burdensome to establish, and would be prohibited in many circumstances. For example, if there ever was a single instance of manual intervention, that trading partner would lose its "trusted" status and subsequently all cases would require individual package scanning (see **Inference**, (c)(5)(e)).

An important intent of the drug pedigree law is to reduce counterfeiting. Counterfeiters work with large quantities of falsified products, e.g. numerous cases, if not shipments. The motivation for this behavior is entirely financial; as such, it would be unheard of if the counterfeiting involved a single package, or one or two counterfeit packages were inserted into dozens of individual cases. This behavior would be costly for the perpetrator and counter to the intent of the illegal activity.

Currently, the technologies used to serialize and aggregate product into cases are not 100% accurate. Packaging lines are high speed and extremely complex operations, and involve the intensive integration of equipment and systems. Sampling both in-line and after the lot is common, and adds additional complexity. Requiring manufacturers and other supply chain partners to certify to 100% accuracy would be impossible, and have the effect of preventing inference from being used. Further, it would impose significant additional costs on the supply chain, resulting in an unnecessary burden on the healthcare system.

The good news is that there is a clear, discernible difference between these types of errors and counterfeit activity. If two or three packages in a case of 100 are out of place, for example, we can say with a high degree of certainty that this is the result of a technology error, rather than the work of a counterfeit.

Therefore, the Board should allow for a small percentage of errors when inferring the contents of a case. **Inference under the Board's regulation should allow for accuracy of inference at 95%, or an error of 5% or 5 packages per case, whichever is smaller.** This tolerance will preserve the intent of the law, which is to reduce counterfeit products in the supply chain, while acknowledging the limitations of the technology involved in serialization.

The 5% or 5 packages per case would appropriately account for the diversity of case counts that currently exists. For low count cases (5-20, for example), the inference would allow zero, or at most 1 package to have defective serialization. For high count cases (200-1000, for example), the limit would be 5 packages. As the technology and the industry's ability to aggregate packages within cases improve, manufacturers and

distributors would be free to increase their case counts and improve the efficiency gains for inference by inferring a larger number of packages to a single case serial number.

Not addressed by this tolerance would be if the inference for an entire case was incorrect, or if the above tolerances were exceeded. In these instances – whenever the 5% tolerance was exceeded -- the supply chain member should be required to investigate the nature of the problem with the case.

In all instances this tolerance would preserve the intent of the law in a more cost-efficient manner.

2. Pedigree Data should Reside in a Centralized Data Repository, Rather than Transferred to Each Member of the Supply Chain

As currently written, the regulations require each member of the supply chain to add its information to the individual's package, certify the accuracy of the entire pedigree, and transfer that information down to the next party in the chain. In this manner, the current pedigree information is only available to the last member of the supply chain.

Investigating a potential incident would require contacting multiple parties to understand the last legitimate entry into the suspected packages' pedigree. Use of a centralized data repository would permit rapid investigation and support streamlined transfer of data.

Each party would simply connect to the data repository instead of establishing separate data connections with each partner. A central repository would provide the Board with supply chain visibility in real-time, rather than subsequent to the final disposition of the product.

An additional benefit of such a database would be to eliminate the need for many of the inspection requirements detailed in the **Inspection** section. Many of these requirements will be burdensome for pharmacies; it would reduce the cost burden on the healthcare system if California relied on a secure, centralized data repository to accomplish many of the actions outlined in this section.

3. Supply Chain Members Should be Permitted to Certify Once Per Month, Rather Than for Every Package

The purpose of the certification provisions is to provide assurance to the Board and the public that the supply chain participants are working to ensure that the pedigree information is accurate. This effort implies an *intention* on behalf of the partner to do its best to provide accuracy. Certification per package would of necessity be done via automated systems; it would be unrealistic to expect manufacturers, for example, to separately certify each individual package. Consequently, there is no material difference between periodically certifying the accuracy of the pedigree information, and certifying per package.

Since there is no difference, Merck recommends that certification be required on a monthly basis. Some type of “grouped” certification is already suggested in the language (see **Certification**, (b)(2), “. . . the number of containers, the expiration dates, and the lot numbers.”). Periodic certification would reduce the data bandwidth needed by eliminating the required language to accompany each package.

4. The Concept of “Trusted Trading Partner” is Burdensome and Unnecessary

The Board devotes a full nine paragraphs to the concept of establishing a “trusted trading partner” (**Inference**, (b)(5) and (6)). The extensive requirements establishing a “trusted trading partner” (**Inference**, (c)(5) and (6)), are burdensome, unnecessarily stringent, and provide little benefit to the public regarding anti-counterfeiting.

As discussed in our August 31, 2012 letter to the Board, Merck and most supply chain participants rely on inference for every shipment every day – for transmission of lot numbers, expiration dates, and importantly, package count. The industry routinely allows partners to bill them for package counts that are simply inferred from case and pallet counts. This implied trust is substantial and is monitored by our accounts receivable function. If a partner proves to be untrustworthy – for example, after repeated false claims of incorrect counts – we would likely find another partner with which to do business. This financial trust is essential for the smooth operation of the supply system, and because it involves substantial financial value, it is driven by business interests.

Any attempt by the board to impose a separate and differing standard for “trust” would be duplicative and unnecessary. Supply chain security would be not be enhanced in any amount by application of these requirements. On the contrary, these requirements would limit the number of partners with whom manufacturers would do business, having a chilling effect on the availability of important medicines in the marketplace. This could exacerbate the issue of drug shortages; it would also dramatically increase the cost of complying with drug pedigree regulations by making full case scanning a regular, expensive, and non-value adding activity. Merck urges the Board to delete paragraphs **Inference** (c)(5) and (6).

5. Merck Comments on Specific Provisions of the Draft Certification Language

The following table provides Merck’s comments on specific provisions of the draft Certification language.

Section	Comment	Suggested Alternate Language
(b)	Many of the data elements required for certification should be established in a periodic (monthly) certification, allowing the contemporaneous transfer of pedigree information to be limited to name and address of the source, data specific to the package itself (name, quantity, date of transaction, expiration date, lot number, serial number).	Add a new paragraph allowing periodic (monthly) certification of data listed in (b)(1), (b)(3), and (b)(4).
(b)	The terms in the paragraph following (b)(5) introduce onerous and unachievable standards for digital signature: “. . . prevents alteration . . .” and, “. . . guarantees that data is immutable . . .”	Change sentence to: “The electronic pedigree provided by the source to the recipient shall include a digital signature by a responsible party for the source.” Corresponding changes would be required for paragraph (c).
(b)	The certification by the source, in the second paragraph following (b)(5), should only be to attest to the accuracy of the pedigree data regarding the transactions for which it is involved; that is, the party upstream and the party downstream. It is unreasonable to expect a pharmacy, for example, to certify that the pedigree information provided two or three parties upstream is true and accurate. Of course these certifications would be unnecessary if each party transferred its pedigree data to a central repository.	Change language to: “The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine , the information contained in the pedigree <u>for the transactions for which they are a party</u> , is true and accurate.” Corresponding changes would be required for paragraph (c).
(b)(2)	Clarify that the term “quantity” can be interpreted by the manufacturer to mean number of tablets, weight of product, volume of product, etc., depending on the form of the drug.	“. . . the quantity of the dangerous drug (e.g., number of tablets, or volume, or weight, etc. as determined by the manufacturer) . . . “

6. Merck Comments on Specific Provisions of the Inference Draft Language

The following table provides Merck's comments on specific provisions of the draft Inference language.

Section	Comment	Suggested Alternate Language
(c)(2)	The terms in the paragraph introduce onerous and unachievable standards for digital signature: "... prevents alteration ..." and, "... guarantees that data is immutable ..."	Change sentence to: "Where the electronic pedigree data was received via a secured electronic transmission, and includes a digital signature by a responsible party for the source."
(c)(3)	This paragraph requires the use of tamper-evident seal or tape. This requirement is unnecessary – the trust between the supply chain partners – as is demonstrated today with the use of inference on package counts – is sufficient to assure that the inference is correct. This paragraph is unnecessary, especially in light of Merck's comments #1 (inference tolerance) and #4 (no need for "trusted trading partner.")	Delete paragraph (c)(3).
(c)(4)	The requirement that the case be homogenous is burdensome and unnecessary. This implies that somehow pedigree information is more accurate for a homogenous case than one that contains more than one type of product. Aggregation systems will need to be accurate (95% accurate, as proposed in #1) regardless of the homogeneity of the case. This requirement would be unduly burdensome for Order Fulfillment Centers, and result in the wasteful use of multiple cases for each type of product when a single case would suffice – an unintended, environmentally irresponsible consequence of this paragraph.	Delete paragraph (c)(4).

Section	Comment	Suggested Alternate Language
(c)(4)	<p>The requirement limiting the case count to no more than 48 is arbitrary and unwarranted. No case count limit would be necessary if Merck's comment regarding inference tolerance is implemented. Such a requirement fails to take into account the diversity of pack sizes and economic case quantities that exists in the market today. It would have the unintended consequence of unnecessarily increasing supply chain costs by forcing manufacturers to use non-economically driven case sizes.</p>	<p>Delete paragraph (c)(4).</p>
<p>Additional Concepts (A)</p>	<p>The sampling specification is unnecessarily specified and burdensome, and is not being applied correctly. The ANSI standard referenced is based on manufacturing process – and relies on specifying lot size. What would the lot size be for an order? To use this standard many other definitions would be required to transition standard from manufacturing context to a shipment. Instead, sampling should be allowed based on the risk that the manufacturer and distributor are willing to take; it also should reflect the 95% tolerance threshold discussed in Merck's comment #1.</p>	<p>Delete paragraph (A).</p>
<p>Additional Concepts (C)</p>	<p>The draft language imposes an unnecessary time limit of 48 hours for resolving discrepancies. Because any inference discrepancy would result in the product being removed from commerce, the trading partner would be financially incented to resolve the issue in a timely manner. The time required should be determined on a case by case basis, considering the magnitude (financially and logistically) of the discrepancy and the difficulty in resolving and re-aggregating the questioned product.</p>	<p>Delete paragraph (C).</p>

Section	Comment	Suggested Alternate Language
Additional Concepts (E)	The requirement to share liability by all parties relying on inference is unclear, unnecessary and capricious. Why would a supplier, for example, share liability if a downstream partner scrambles the pedigree data, making inference impossible? As discussed above, inference is based on the established financial trust between trading partners; these relationships already have established liability. It is duplicative for the Board to seek to modify these relationships.	Delete paragraph (E).

Merck remains committed to the implementation of a well-constructed, effective and cost-efficient drug pedigree law in California. We urge the Board to carefully consider the above comments as they move to promulgate provisions on inference, certification and inspection. We are available to provide additional comments, or other supporting information related to serialization as requested. Thank you for your consideration.

Sincerely,



Brian Tarantino
Director, Global Serialization Strategy

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April 22, 2013

Virginia Herold
Executive Administrator
California Board of Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834

Dear Giny,

Thank you for distributing draft rules and concepts on the issues of certification and inference at the recent Enforcement Committee meeting on March 14th. Following are GPhA comments, questions and suggestions on the draft rules. Each GPhA member has different challenges with respect to California ePedigree compliance due to differences in size, specific logistical and supply chain business decisions, production and packaging strategies, product mix and their IT infrastructure. Given these different challenges, in addition to the following consolidated comments from the trade association, we have encouraged members to comment on behalf of their individual companies to detail the specific challenges they face.

1. Certification. Timing of delivery of ePedigree to customer.

- *(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the delivering or transferring party (hereinafter, the "source") shall transmit to the buying, receiving, or accepting party (hereinafter, the "recipient") via a secured electronic transmission, the electronic pedigree corresponding to the dangerous drug being delivered or transferred, including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d).*

GPhA Comment:

The timing issue with respect to a pedigree containing transactional information being submitted to a trading partner before or concurrent with delivery of drug units is a problem for several generic manufacturers. There are two specific scenarios where this becomes an issue for our members:

1. Same day delivery situations. Where a product is in short supply or whether an accommodation must be made for a customer involving same day delivery, the invoicing is typically not done on a same day basis.

2. When a 3PL is used, coordination of delivery and transactional events on rush orders to meet these rules will be difficult to coordinate.

GPhA Recommendations:

As a short term fix, another identifier to associate a transaction to a shipment could be used such as a sales order number. Information such as this could be related to the ultimate invoice number if that invoice number is not available when the product is shipped.

As an alternative, a long-term suggestion is for the Board of Pharmacy to consider the use of EPCIS events to satisfy the pedigree requirement. Because EPCIS events are posted with time and date stamping, the shipping of a given unit could be considered one event and the transactional billing of that unit could be considered a separate event related to the unit in question. These might happen at different times, however since both events would be related to that unit, the same information as required in the pedigree law would be available as it is sent to the purchaser of that given unit.

A modification such as this would likely require changes made to the EPCIS format by the industry and GS-1 standards body. In addition, questions involving certification of EPCIS events would need to be solved to allow EPCIS events to satisfy the pedigree requirements. GPhA suggests a method for doing this could be through the submission of standard operation procedures (SOPs). A generic manufacturer could certify their processes - SOPs on a "best efforts" basis, rather than a certification on specific units. For manufacturers, certifications under the currently understood regulations would, in most instances, take place in a partially-automated process. We believe that certifying the process used to produce the serialization information would have a similar effect on safety as placing an automated certification statement and digital signature on each unit. This would allow manufacturers to use EPCIS events rather than convert EPCIS to a document pedigree format, and then have our customers input the information from the document pedigree and then in turn, perform a similar data conversion function when they sell the given unit to their customer. We believe that this modification could reduce errors and certainly would reduce data overhead. GPhA believes that the EPCIS approach is consistent with systems currently being developed and sold by vendors for California compliance, involves less data overhead than the document approach, and enables information about a particular unit to be updated within current manufacturing, warehousing, logistical and billing practices.

GPhA members further understand the certification under the law to take place when the product is sold and leaves our premise. Even without the EPCIS modification we recommend above, manufacturers can only certify according to the SOPs we file with the Board of Pharmacy and would not be able to certify product once it is not our property or no longer in our possession.

2. Certification Language. Two separate descriptions of certification exist in the draft rules.

In the Certification Section (b) 4.

(4) A certification under penalty of perjury from a responsible party of the source that the information contained in the pedigree is true and accurate.

In the certification statement section just below this,

The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine, the information contained in the pedigree is true and accurate. By so attesting, the responsible party confirms that the source has verified the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, that there is nothing in the prior transaction history that raises suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

GPhA Comment & Request:

GPhA requests that the language describing the certification requirement be consistent in the different sections.

3. Certification. Clarity around "smallest saleable unit" language.

In the Certification section, (b) 5.

(5) The unique identification number affixed to the smallest package or immediate container.

GPhA Comment & Request:

GPhA members would like more clarity on specifically how a unit is defined. As an illustration, the following example was given by a member. A member company manufactures a product which is an injectable. This product is not sold as individual vials, but rather as cartons of 10 or 15 vials. The trade associations opinion is that the cartons containing multiple vials are the "smallest saleable unit", not the vials themselves. Our members would like for this distinction to be formally adopted in the rules. The manufacturer of the specific product above believes that serialization at the individual vial level could not take place due to "real estate" issues, and moreover attempting to do so would cause hardship to vendors of these types of products.

4. Certification Statement. Verification of prior transaction history.

In the Certification Statement section:

By so attesting, the responsible party confirms that the source has verified the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, that there is nothing in the prior transaction history that raises suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

GPhA Comment and Request:

In our understanding of the ePedigree law, the pedigree itself contains the prior transactional history of a given unit. Does this draft certification statement indicate that manufacturers will receive verification requests for each subsequent sale of a given unit, or does the certified pedigree itself accomplish this? If manufacturers are expected to have a verification capability, does the Board of Pharmacy plan to issue rules on what would be required?

GPhA believes that the pedigree certification accomplishes this goal, and assuming no other requirements are issued, believes that this certification should satisfy this requirement for all downstream transactions.

5. Inference Section. Definition of a case.

In the Inference section, (c) 4,

(4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product, and contains no more than forty-eight (48) units of that dangerous drug product;

GPhA Comment & Request:

GPhA members believe that a case is a longstanding term understood in common industry practice and need not be defined by the amount of units contained, the size, footprint or weight. Members believe that the unintended result of defining a case by the number of units could be insistence by customers that manufacturers change their packaging specifications to accommodate inference, which would further increase the cost and complexity of compliance to the California requirements. Additionally, members believe that producing more cases with fewer contained units, would ultimately create an increase in environmental waste. If it is necessary to define the term case in the rules, our members believe that a case ought to be homogenous regardless of size, weight or contents .

6. Inference Section. Manufacturer seals on cases.

In the Inference Section, (c) 3.

(3) Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened;

GPhA Comment & Request:

GPhA members expressed concern that some cases have tape applied a bit off-center, frequently requiring a second piece of tape to be additionally applied to seal securely. The concern is that this practice is fairly common on automated case packing lines and, while not indicative of any problem with

a specific case, could serve to slow down customer processes by mistakenly suggesting that a case had been opened and resealed.

7. Additional Concepts. Sampling methods and hurdles.

In the Additional Concepts section, (A.),

(A) Sampling/audits must be at least at the level of ANSI/ASQZ1.4-2008, Special Level S-1 and the single sampling plan for normal inspections;

GPhA Comment and Request:

GPhA members provided comments on the specific sampling method cited in the rules draft. Some pointed out that an "Acceptance Quality Limit" (AQL) is needed to know how many samples to pull and how to judge the results. On a 10,000 unit shipment, for example, the sample size could be anywhere between 5 and 1,250 units. A member suggested that a recommended AQL should be 0.65, which translates to 0.65 defects per 100. GPhA believes that the ultimate sampling method should be left to the individual trading partner who would then be responsible to certify when they sell the product.

8. Additional Concepts Section. Indication on ePedigree that inference was used on a particular unit.

In Additional Concepts, point D,

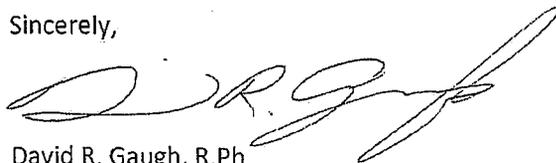
(D) The pedigree data must indicate that an inference was deployed for the certifications;

GPhA Comment & Request:

GPhA members understand that this requirement is not part of the current version of the GS-1 standards on DPMS or EPCIS, so we suggest that, if this requirement becomes part of finalized rules, that GS-1 be consulted to understand how long it might take to revise the specifications and then have system vendors build to the revised specification. With the compliance date for manufacturers less than two years away, members are concerned that additional specification requirements could slow efforts to comply.

Thank you very much for the opportunity to comment on the draft rules. We look forward to working with you to provide details on how these requirements effect our members businesses as well as collaborating on how to accomplish the goals of the legislation in the most efficient way possible.

Sincerely,



David R. Gaugh, R.Ph

Senior Vice President for Sciences and Regulatory Affairs
Generic Pharmaceutical Association



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



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association



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April 24, 2013

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, CA 95834

RE: Comments regarding Draft Regulations for Inference, Certification and Inspection –
Drug Pedigree Law

Dear Executive Officer Herold:

The California Retailers Association¹ (CRA), the National Association of Chain Drug Stores² (NACDS), and the California Pharmacists Association (CPhA)³ thank the Board of Pharmacy (“Board”) for the opportunity to submit written comments in response to the draft regulations for Inference, Certification and Inspection distributed by the Board at the March meeting of the Enforcement Committee.

The pharmacy industry is committed to maintaining and enhancing the safety and security of the U.S. drug distribution supply chain through feasible and workable means. CRA, CPhA and NACDS believe that the United States prescription drug distribution system is one of the safest in the world, if not the safest. A number of proactive safety measures in the private sector and a comprehensive set of federal and state laws and regulations contribute to this safety.

General Comments

We appreciate the Board’s efforts and work to develop regulations to implement the electronic pedigree law. We urge the Board to draft regulations that are within the scope of the implementing law, are not arbitrary or unreasonable, and would not place undue regulatory burdens. While we do not believe that this was intended, we believe that these draft regulations would in a number of instances result in such effects.

We urge the Board to work with pharmacies to develop these regulations in a manner that meets the goals of the electronic pedigree law that reaches an appropriate balance. We stand ready to work with you.

Draft Inference Regulation

Inference is a significant and necessary component for maintaining supply chain integrity under California’s electronic pedigree law. We strongly recommend that the Board recognize that inference provides supply chain security and enhances patient safety by preserving the integrity of the pallet, case, tote or other aggregated distribution unit. The

use of inference should not be subject to unreasonable and arbitrary limitations and hindrances.

Inference promotes supply chain integrity. Without inference, the aggregated product containers, e.g. pallets, cases, totes, would need to be opened, creating the potential for loss of product, diversion, and risks to the safety and security of the supply chain. *We believe that inference enhances supply chain security by maintaining the integrity of the aggregated containers (case, pallet and tote).*

Further, inference protects patient safety by allowing drug products to be available for patients. Without inference, each pallet, case, or tote would have to be opened and each individual drug package scanned leading to an inefficient, costly, and time consuming process. This would cripple the entire drug distribution supply chain likely resulting in insurmountable delays in pharmacies meeting the medication needs of their patients. Placing arbitrary, unreasonable limits on use of inference on pharmacies and other healthcare providers makes little sense.

In the attachment, we have drafted amendments to the Board's draft Inference regulation that we believe reach an appropriate balance of regulatory oversight, meet the test of adding supply security, avoid unreasonable, arbitrary, vague, and duplicative requirements such as a 48 package limit, duplicative, overlapping or vague requirements that can be met through the standard operating procedures (SOPs), clarifying the terminology e.g. using the term container or aggregate container, and that allow wholesalers to prepare aggregate containers by recognizing that their SOPs meet supply integrity criteria.

Draft Certification Regulation

We understand that the electronic pedigree law includes the requirement for certification. That provision states: "a certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate."

The regulation as drafted exceeds the statutory authority by requiring the source of the pedigree to verify the prior transaction history and corresponding certifications. The statute requires the source to certify the pedigree. It does not state that the source must certify all prior pedigrees or certify the pedigrees issued by prior sources. It is not feasible for a source to certify the work of the sources above them that provided pedigrees. For example, how could they know what the source above them did in providing the pedigree? Moreover, if each source on change of ownership certifies their pedigree, then that pedigree has been certified. Requiring a duplicative certification by a downstream supply

Virginia Herold
Executive Officer, California Board of Pharmacy
April 24, 2013
Page 3 of 4

chain participant such as a pharmacy that did issue or oversee the upstream pedigree is not required by the law, is not a reasonable interpretation of the law, nor feasible.

Our amendments in the attachment are directed at clarifying and addressing these issues.

Draft Inspection Regulation

For the draft inspection regulation, our attachment offers amendments directed at clarifying the language, removing duplicative language, and adding feasible reasonable conditions for providing the pedigree records.

These changes are necessary so that pharmacies are not faced with unreasonable requests for pedigree records. As the Board may know the volume of pedigree records will be overwhelming as there is a record for each individual package and pharmacies at the end of the supply chain will receive the largest volume of pedigree data. Making such a massive amount of records available immediately will present unprecedented challenges for pharmacies and could easily swamp their system capabilities, leading to disruptions in patient services. As such, allowing for reasonable access and options for providing pedigree records makes sense and serves the purpose of the law. Our edits provide a reasonable balance at providing access while also recognizing that pharmacy pedigree records will be voluminous and that therefore reasonable flexibility in appropriate.

Conclusion

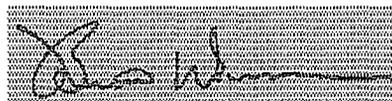
We thank you for consideration of our comments, and look forward to working with the Board as the regulatory process continues. Please do not hesitate to contact Mandy Lee with CRA at mlee@calretailers.com or 916-425-8481, Brian Warren with CPhA at bwarren@cpha.com or 916-779-4517, or Mary Staples with NACDS at mstaples@nacds.org or 817.442.1155 if we can provide further assistance.

Sincerely,

Sincerely,



Mandy Lee
Director, Government Affairs
California Retailers Association



Brian Warren
Director of Government Affairs
California Pharmacists Association



Mary Staples
Director, Government Affairs
NACDS

¹ The California Retailers Association (CRA) is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, fast food restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware and home stores. CRA works on behalf of California's retail industry, which currently operates over 164,200 stores with sales in excess of \$571 billion annually and employing 2,776,000 people—nearly one fifth of California's total employment. The retail industry in California represents one in every four jobs in the State, a total of nearly 5 million jobs (2009), and accounts for 17.8% of the State's GDP.

² The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. Our members dispense over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. In the state of California, NACDS represents 20 companies operating 3,916 pharmacies.

³ The California Pharmacists Association (CPhA) is the largest statewide association representing pharmacists, with over 5,000 members. CPhA's members include pharmacists in all practice settings, and includes independent pharmacy owners.

CERTIFICATION

(a) For the purposes of Business and Professions Code section 4034, ~~and the delivery and receipt of electronic pedigrees,~~ “certification” shall refer to source that prepared the container and the process by which *the responsible person on behalf of the delivering or transferring party (hereinafter, the “source”)* of the dangerous drug each participant in the supply chain confirms and attests to the accuracy of *the source’s electronic pedigree and that the source is transmitting the associated* electronic pedigrees *received from prior source with the same form and content as received from the prior source* ~~transmitted or received in conjunction with delivery, transfer, receipt, or acceptance of~~ *for the* corresponding dangerous drug drugs.

(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug *where a change of ownership has occurred* pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the source delivering or transferring party (hereinafter, the “source”) shall transmit to the buying, receiving, or accepting party (hereinafter, the “recipient”) via a secured electronic transmission, the source’s electronic pedigree corresponding to the dangerous drug being delivered or transferred, *and the other electronic pedigree(s) received by the source for including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d).* The electronic pedigree transmitted by the source to the recipient shall include, as to each such individual unit, at least the following:

- (1) The name and principal address of the source, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.
- (2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
- (3) For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address, and federal or state registration and/or license number(s) permitting sale or transfer, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- (4) A certification under penalty of perjury from a responsible *person on behalf* party of the source that the information contained in the pedigree *issued by the source* is true and accurate *and that the source is transmitting any associated* electronic *pedigree(s) pedigrees received from prior source(s) with the same form and content as received from the prior source(s).*
- (5) The unique identification number affixed to the smallest package or immediate container.

CERTIFICATION

The electronic pedigree provided by the source to the recipient shall include a digital signature by a responsible person on behalf of party for the source that prevents any alteration, tampering, or other change to the pedigree, and that guarantees that the data is immutable and non-repudiable by the source.

The certification under penalty of perjury by a responsible party for person on behalf of the source shall attest that, to the best of the ability of the responsible person party to know or determine, the information contained in the pedigree is true and accurate. By so attesting, the responsible party confirms that the source has transmitted verified the prior transaction history and corresponding certifications for the dangerous drug that the source received from prior sources to the best of its ability, that there is nothing in the prior transaction history that raises suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

A source shall not deliver or transfer a dangerous drug and its associated pedigree information to a recipient if the source knows or has a reasonable belief or suspicion that a dangerous drug product is counterfeit or adulterated or otherwise unfit for distribution in the supply chain. In such instance, the source shall notify the Board of Pharmacy and quarantine the dangerous drug product to prevent further distribution except that this shall not prohibit the suspect dangerous drug product from being returned to the drug manufacture for investigation and disposal.

(c) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of an electronic pedigree, the recipient shall receive an electronic pedigree from the source that corresponds to the dangerous drug being delivered or transferred. The recipient shall certify receipt of the pedigree for the dangerous drug by ~~verifying the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, confirming there is nothing in the transaction history that raises suspicion, verifying correspondence between the pedigree data and the dangerous drug received, and~~ by including in the pedigree a digital signature by a responsible party for the recipient that confirms receipt of the pedigree and certifies that the recipient will maintain the pedigree as received from the source without prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the recipient.

INFERENCE

(a) Pursuant to Business and Professions Code sections 4034 and 4163.3, participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, shall distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, except where the board by regulation defines circumstances under which participants in the distribution chain may infer the contents of a case, pallet, tote, or other aggregate container of individual units, packages, or containers of dangerous drugs (hereinafter a "container" or "aggregate container"), from a unique identifier associated with the container ~~case, pallet, or other aggregate~~, without opening each container ~~case, pallet, or other aggregate~~ or otherwise individually validating each unit. This regulation defines the ~~limited~~ circumstances under which such an inference will be acceptable.

(b) For the purposes of this section, to "infer" or to rely on an "inference" means that a supply chain participant, in reliance on electronic pedigree information received from a trusted trading partner which provides hierarchical relationships between those unique identifiers affixed to the smallest packages or immediate containers and those unique identifiers affixed to the aggregate container (~~a case, or pallet~~) into which the smallest packages or immediate package sizes containers are placed for purposes of distribution, substitutes scan or review of the unique identifier affixed to the aggregate container for a scan or review of the unique identifiers affixed to the smallest packages or immediate package sizes containers contained therein, for purposes of certifying delivery or receipt. The supply chain participant then "infers" that the smallest packages or immediate package sizes containers within the aggregate container are what they are expected to be, based on the hierarchical pedigree information, and pairs expected shipments and receipts with the actual physical individual units without opening the sealed aggregate container and scanning or reviewing its contents.

(c) Recipients in the supply chain may infer the smallest package or immediate package size container contents of a sealed container case bearing the original, unbroken, seal or tape affixed by the manufacturer or wholesaler, without breaking the seal, thereby relying on the unique identifier affixed to the sealed case and the inference that hierarchical data relationships between the case identifier and the individual unit identifiers as stated in the electronic pedigree have been correctly stated and remain true, and accurately describe the case contents, only under the following circumstances:

- (1) Where the source has transmitted to the recipient prior to receipt of the sealed container case a certified electronic pedigree record establishing a hierarchical data relationship between the unique identifier affixed to the sealed container case and the individual unit identifiers;
- (2) Where the electronic pedigree data was received via a secured electronic transmission, and includes a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the source;
- (3) Where the container case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer or by the wholesaler and shows no signs of tampering or being opened;

INFERENCE

- (4) Where the sealed container case is (a) homogenous, i.e., contains only one dangerous drug product, and contains the number of no more than forty-eight (48) units of that dangerous drug product as packaged by the manufacturer or (b) a homogeneous or nonhomogeneous container as packaged by the wholesale drug distributor;

4

- (5) Where the sealed container case and accompanying pedigree data were received from a trusted trading partner. For the purposes of this section, a “trusted trading partner” is a source:
- a. with which the recipient has an established relationship and existing contract;
 - b. for which the recipient has verified the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient;
 - c. with which the recipient has established agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered;
 - d. from which the recipient pharmacy company or independent pharmacy has received at least five (5) shipments of sealed containers cases containing homogenous products, has physically verified the individual unit contents, and certified 100% accuracy of the electronic pedigree data received – detailed records of this verification process and the results of the inspections shall be kept and made available for inspection upon request by an authorized officer of the law or by an authorized representative of the board;
 - e. ~~for which there has been no prior need for manual intervention with regard to any sealed cases previously received, other than individual unit identifier scans;~~
 - f. ~~for which there is written approval by the recipient’s compliance manager, signed under penalty of perjury and maintained for review by the board for as long as the status persists, of “trusted trading partner” status for the source; and~~
 - g. ~~with which there is a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received;~~

- (6) Where the source and recipient have agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, containers homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered, and where the source and recipient have a written agreement in place specifying the means and time limits of remediation of, and the standard operating procedures (SOPs) for handling apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received, either or both of which shall be documented and the records maintained ~~made immediately available~~ for inspection by an

INFERENCE

authorized officer of the law or by an authorized representative of the board, upon request;

ADDITIONAL CONCEPTS:

- (A) Sampling/audits must be at least at the level of ANSI/ASQZ1.4-2008, Special Level S-1 and the single sampling plan for normal inspections;
- (B) When sealed case is opened, its entire contents must be immediately scanned *if the recipient of the sealed case has reason to believe that a problem exists;*
- (C) Any discrepancies discovered in data or products must be remedied within *a reasonable period of time* ~~48 hours;~~
- (D) ~~The pedigree data must indicate that an inference was deployed for the certifications;~~
- (E) ~~Liability must be shared by all parties propagating or relying on the inference.~~

June 21, 2013

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd, N219
Sacramento, CA 95834

Re: Draft Electronic Pedigree Regulations on Certification, Inference, and Inspection

Dear Ms. Herold:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is pleased to submit the following comments with respect to the draft language for electronic pedigree regulations presented at the California Board of Pharmacy’s Enforcement Committee and E-Pedigree Public Meeting held on March 14, 2013 (the “draft language”).¹

PhRMA is a voluntary, nonprofit association that represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures and treatments, and are the source of nearly all new drugs discovered and marketed throughout the world.

PhRMA appreciates the opportunity to provide comments to the California Board of Pharmacy (“the Board”) on the draft regulations on certification, inspection, and inference as part of the electronic pedigree provisions. Our comments highlight several issues presented by the draft language, including that certain aspects of the draft language would, we believe, exceed the authority granted to the Board by the California legislature (the “Legislature”) under the electronic pedigree legislation (Senate Bill 1307) and under the California Business and Professions Code (the “Code”), generally. In addition, certain requirements of the draft language are impractical or unclear. PhRMA’s concerns and comments are described below, and have been organized according to the sections of the draft language (*i.e.*, “Certification,” “Inference,” “Inspection”) to which they relate.

I. Certification

The draft language would require a responsible party for the source of a drug to certify “to the best of the ability of the responsible party to know or determine” that the information included in the pedigree is true and accurate.² The regulation would specifically require the responsible party to confirm that the “source has verified the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, [and] that there is nothing in the

¹ The draft language is set forth under Agenda Item II of the “Additional Materials” made available in connection with the meeting, and is available at http://www.pharmacy.ca.gov/meetings/agendas/2013/13_mar_enf_mat2.pdf

² See the third paragraph of section (b), under “Certification.”

prior transaction history that raises suspicions []." ³ PhRMA believes that this would impose obligations, and potential liability, on the source that exceed those set out in the Code, which simply requires that a responsible party certify "that the information contained in the pedigree is true and correct."⁴ There is no evidence that the Legislature intended that a participant in the drug supply chain could not rely on information provided in an electronic pedigree or that it expected a participant to take additional steps to "determine" the truth and accuracy of the electronic pedigree information, or to "verify" a prior transaction history.

Similarly, section (c) of the "Certification" provisions would require a recipient of a drug shipment to "certify" receipt of the shipment by, among other things, "verifying" the prior transaction history and the "corresponding certifications." There is no basis in the Code for creating such obligations on the recipient, and PhRMA believes that such requirements would create a significant administrative burden without meaningfully serving the goal of ensuring the safety of the drug supply.

PhRMA also requests that the Board provide a definition of "responsible party" in the draft language, as that term is used in section (b)(4) of the "Certification" provisions and elsewhere.

Section (b) of the "Certification" provisions states that the electronic pedigree provided by a source to a recipient must include a "digital signature" that "prevents any alteration, tampering, or other change to the pedigree, and that guarantees that the data is immutable and non-repudiable by the source." Again, these draft provisions exceed the scope of the Board's authority, in our view. Nothing in the Code requires a digital signature; rather, only a certification that the information is true and accurate is required. If the Board proceeds with the notion of requiring a digital signature, PhRMA requests that the Board clarify what will be required for such a digital signature. PhRMA also requests clarification as to whether the digital signature will need to comply with the provisions of the Food and Drug Administration's regulations for electronic records and electronic signatures (21 C.F.R. Part 11).

Section (c) would require a responsible party to include a digital signature in the pedigree for dangerous drugs that "guarantees that the data is immutable and non-repudiable []." PhRMA also requests that the Board clarify the meaning of "guarantees" as used in this section. In addition, this concept, and the terms "immutable" and "non-repudiable" in particular, do not appear in the applicable provisions of the Code, and thus, we believe these regulatory provisions in the draft regulations exceed the Board's statutory authority.

II. Inference

PhRMA is pleased that the Board has taken the step of describing the conditions under which recipients of drug shipments will be permitted to infer the identity of packages within a larger container. As the Board is aware, the ability to make such inferences will be an essential aspect of any electronic pedigree system. Moreover, the Legislature recognized that inference will be

³ Id.

⁴ See Code § 4034(b)(4).

necessary to “facilitate efficiency and safety in the distribution chain [],” and, to that end, required the Board to develop regulations describing the circumstances under which inference could be used.⁵ The draft language represents a useful first step in this process.

As a general matter, though, PhRMA believes that the conditions described in the draft language are much more restrictive than the Legislature intended and are likely to limit the overall use of inference, contrary to the Legislature’s expectation. The statute provides that participants in the drug supply chain be able to “infer the contents of a *case, pallet, or other aggregate* of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the *case, pallet or other aggregate* [].”⁶ Although the draft language recognizes this statutory mandate, the operative provision would permit inference only with respect to a case (not a pallet or other aggregate), and only where the case contains no more than 48 units of drug product.⁷ PhRMA believes that the relevant “aggregate” size container for which inference will be permitted must be significantly larger in order for the electronic pedigree system to be practical and efficient. And, PhRMA believes that the maximum container size should not be defined by reference to the number of units it includes.

PhRMA notes that section (a) of the draft “Inference” language includes a description of the statutory background giving rise to the inference regulations. The draft language states that the Code would require participants in the drug supply chain to “verify and validate the delivery and receipt of dangerous drugs against [] pedigrees at the unit level, *except where* the board by regulation defines circumstances under which” inference may be used (emphasis added). PhRMA believes that this mischaracterizes the relevant provisions of the Code and understates the emphasis that the Legislature placed on the role of inference. Sections 4163.3(a) of the Code states that the Legislature’s intent is that participants “verify and validate the delivery and receipt of dangerous drugs against [] pedigrees at the unit level [].” Section 4163.3(b) then explains that the criteria for inference will serve “[t]o meet this goal”. In other words, inference serves the goal of ensuring that drug shipments are verified and validated at the unit level; the Legislature did not intend it as only a narrow exception to a general rule. In light of this, and to avoid future confusion, PhRMA requests that the Board clarify that, consistent with the Code, the phrase “verify and validate...at the unit level” is consistent with inference and does not mean that physical inspection at the unit level is required.

PhRMA also has concerns with respect to the requirement that, for inference to be used, the source of a drug shipment would be required to transmit an electronic pedigree in *advance* of the shipment, as described in section (c)(1). This would be impractical in many instances, and there is no reason that providing the electronic pedigree contemporaneously (or even after) the shipment is delivered could not serve the same end. Moreover, there is nothing in the Code requiring that a pedigree be provided in advance of any drug shipment in California.

⁵ See Code § 4163(b) (emphasis added).

⁶ Code § 4163(b) (emphasis added).

⁷ See “Inference”, section (c)(4).

The draft language would permit inference only for drug product received from a “trusted trading partner,” as defined in section (c)(5). While recognizing the merits of the restriction in concept, PhRMA believes that the requirements to qualify as a “trusted trading partner” are in some cases problematic. In particular, it is unclear, and may give rise to confusion, to say that there must be an “established relationship” and an “existing contract” in place, and these requirements seem redundant with other, more specific limitations described in the definition. It is also impractical to require the parties to enter into a “mutually-executed standard operating procedure” (SOP) meeting the criteria described. While section 4163.3(c) and (d) of the Code require participants in the drug supply chain to document their inference procedures in their SOPs, and to include procedures for statistical sampling, the draft language’s SOP requirements go far beyond what the legislature contemplated in this regard.

PhRMA notes that the legislature directed the Board to specify the liability associated with the use of inference.⁸ The “Additional Concepts” section of the draft language includes a statement that “[l]iability must be shared by all parties propagating or relying on the inference.” PhRMA suggests that this be further clarified. Among other things, the Board should clarify whether a party that is the source of a drug shipment would have liability where the recipient failed to comply with the requirements of the inference regulations, without the source’s knowledge. The “Additional Concepts” statement also seems inconsistent with section 5(g) of the “Inference” provisions, which would require the parties to have an agreement that would specify apportionment of liability for discrepancies discovered in electronic pedigree data.

Section (b) of the “Inference” provisions, in defining “infer,” refers to pedigrees providing “hierarchical relationships between those unique identifiers affixed to the smallest package or immediate containers and those unique identifies affixed to the aggregate containers [].” The phrase “hierarchical relationships” appears in several other instances throughout the “Inference” provisions. PhRMA requests that the Board explain what is meant by the phrase “hierarchical relationships” in this context.

PhRMA also requests clarification of section (c)(2) of the “Inference” provisions. In particular, PhRMA requests that the Board clarify what is meant by a “secured electronic transmission.” PhRMA further requests that the Board also clarify what it means for a digital signature to “prevent any alteration, tampering, or other change to the pedigree” and to “guarantee[]” that the data is “immutable and non-repudiable,” and again notes that these terms are not included in the Code, and thus, exceed the Board’s authority in our view.

Section (c)(3) of the draft inference regulations also refers to “Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened....” This language implies that manufactures are expected to apply tamper evident (TE) features when sealing a case for the express purpose to provide evidence that the case seal has not been tampered with or opened in order for inference to be permissible. Tamper evident tape is, however, different from ordinary packing tape in that special features are added to the TE tape to detect physical removal for corrugate, over taping or cutting. Thus, PhRMA requests clarification from the Board regarding exactly what is meant.

⁸ See Code § 4163.3(e).

Regular packing tape that seals a case closed and clearly has not been opened should be sufficient.

The “Additional Concepts” section states that “[a]ny discrepancies discovered in data or products must be remedied within 48 hours [].” PhRMA requests that the Board clarify (a) when the 48 hours would begin, and (b) in what way the discrepancy must be “remedied.”

Finally, the “Additional Concepts” section also states: “Sampling/audits must be at least at the level of ANSI/ASQZ1.4-2008, Special Level S-1 and the single sampling plan for normal inspections.” The accuracy of statistical sampling, which comes back to the level of acceptable risk, is not defined. Key when developing a sampling plan using this methodology requires understanding confidence limits, acceptable quality levels, lot size and sampling locations. From a manufacturers' perspective, each packaging line would represent a different process having its own unique operating curves. An important question for the Board's consideration is what if a lot fails statistical evaluation? Is that product acceptable for sale? How will that be managed? Would it put into question other packages within that lot? How are confidence limits and acceptable quality limits held consistent between the different supply chain partners and manufacturers?

Lastly, it is unclear whether the “Additional Concepts” will be codified in any final regulations.

III. Inspection

PhRMA believes that the “Inspection” provisions of the draft language exceed the Board's statutory authority under the Code, and in some respects are inconsistent with the Code itself. The Legislature has provided no specific authorization for the Board to impose recordkeeping and inspection requirements for electronic pedigree records, and the existing, relevant provisions of the Code already apply to records maintained in electronic form (for example, Code section 4105 discusses certain requirements applicable to “[a]ny records that are maintained electronically[.]”).

One example of potential inconsistency is that, whereas section (a) of the “Inspection” provisions would require that electronic pedigree files be maintained on the licensed premises (as described in Code section 4105(a)), the draft language omits the relevant exceptions to such a requirement that are described in Code sections 4105(b) and (e).

Also of concern to PhRMA, section (c) of the Inspection provisions would require that electronic records be made “immediately available” upon request by an authorized officer or representative of the Board. This is inconsistent with Code section 4015(f), which states that requested records must be provided “*within three business days* of the time the request was made.” (emphasis added).

Section (d) of the “Inspection” provisions would require that each premises maintain a “scanner and terminal” to be used by authorized officers and representatives of the Board. PhRMA believes that this requirement is outside the scope of the Board's authority.

Ms. Virginia Herold
June 21, 2013
Page 6

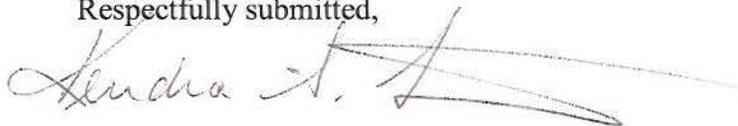
In addition, section (b) includes a reference to a “veterinary food-animal drug retailer or wholesaler.”⁹ The reference should be deleted from the draft language, as the Code provisions clearly exclude products “for veterinary use only.”¹⁰

PhRMA believes that electronic pedigree records should simply be subject to the existing requirements of the Code with respect to records and other documentation or disposition of dangerous drugs. Imposition of additional or different requirements for electronic pedigree records is unnecessary and would give rise to confusion.

* * *

Thank you for the opportunity to comment on the draft regulatory language on inference, certification and inspection. We look forward to a continued dialogue with California Board of Pharmacy about the important issues that the draft electronic pedigree regulations raise.

Respectfully submitted,



Kendra A. Martello, JD
Deputy Vice President, State Advocacy

⁹ This appears to be based on the recordkeeping provisions of section 4105(d) of the Code, which applies to (among other entities) veterinary food-animal drug retailers.

¹⁰ Ca. Bus. & Prof. Code 4034(g)(5).

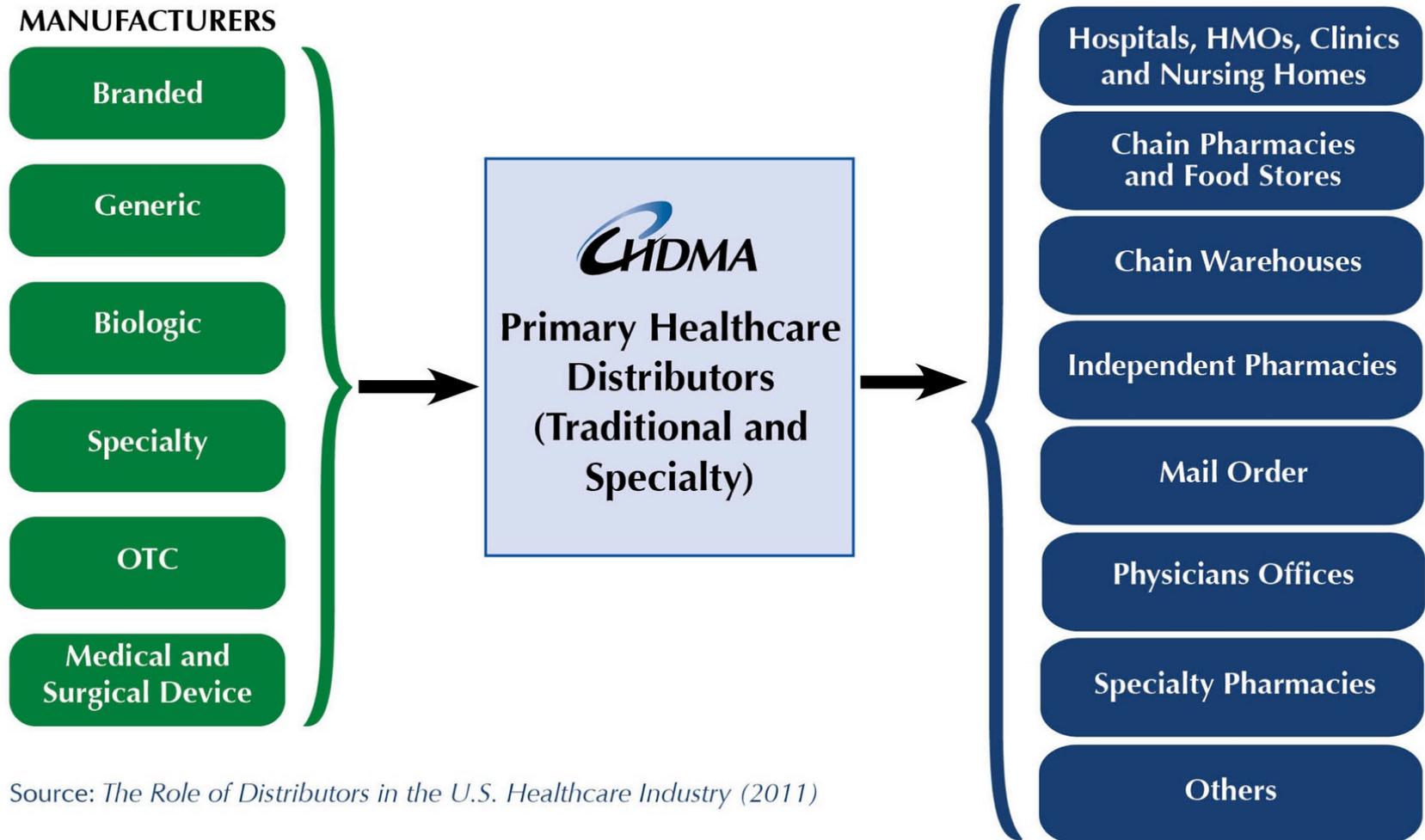
Inference: Key to CA Pedigree Implementation

California Board of Pharmacy
Enforcement Committee Meeting
September 11, 2012
Burlingame, CA

HDMA – Who We Represent

- Active members include 33 primary healthcare distributors – national, regional and specialty.
- HDMA's members offer value-added services that help ensure safe and timely delivery of nearly 9 million healthcare products to over 200,000 pharmacy and healthcare settings nationwide.
- Nearly 90 percent of all U.S. pharmaceutical sales go through HDMA distributors.

The Vital Link in a Sophisticated Supply Chain



Source: *The Role of Distributors in the U.S. Healthcare Industry (2011)*

Healthcare Distributors

Typical companies inventory more than nearly 56,000 healthcare products from an average of 1,100 different manufacturers.

The average distribution center picks more than 95,000 items each day to fulfill nearly 2,000 customer orders.



Distributors deliver consolidated products on a next-day basis in low units of measure.

The typical distribution center serves nearly 1,200 customers and nearly 1,300 ship-to locations.

HDMA in California

- California Customers: HDMA members deliver lifesaving medicines to approximately **32,000 customer locations** in California.
- Jobs in California: HDMA member companies directly **employ more than 6,600** California residents and contract for transportation and other services that support hundreds of additional jobs.

HDMA in California

- **AmerisourceBergen Corporation**
 - Corona, Orange, Sacramento, San Bruno, Valencia
- **Cardinal Health, Inc.**
 - Elk Grove, Valencia
- **H. D. Smith**
 - Carson
- **McKesson Corporation**
 - City of Industry, Ontario, San Francisco, Santa Fe Springs, West Sacramento, Visalia
- **Valley Wholesale Drug Company**
 - Stockton

Inference - Background

- First emerged during development of the California pedigree law.
- The concept of unit level track-and-trace was based originally on the capabilities of RFID technologies.
- In 2007 or 2008, it became clear that manufacturers overwhelmingly believed that unit level serialization was more practical and economically feasible through the use of two dimensional (2D) data matrix bar codes. This was confirmed through HDMA's 2010 track and trace survey.
- 2D bar codes utilize “line of sight” technology, thus, an individual must scan each bar code in order to *directly* capture product information.

Inbound Cases & Pallets



Inbound Cases & Pallets



Inbound Cases & Pallets



Case Level Bar Code Label



Distributor Volume

- On an average day, a typical HDMA member distribution center handles almost 2,000 customer orders, and picks (or processes) an average of 95,000 product units. Receipts come in from @ 1100+ mfrs.
- Scanning individual units on receipt is not practical or economically feasible.
- The Legislature understood the need for supply chain members to avoid having to unnecessarily open every single case of product

Distributor Volume - Receiving



Distributor Volume - Receiving



Inference Example

- Wholesale Distributor XYZ orders and receives ten individual units in a sealed case (A) from the manufacturer of a product, along with a communication stating that these ten units were numbered 1 through 10 in case A. Because the manufacturer provided this information, and the same manufacturer sent Wholesale Distributor XYZ the case, XYZ can *infer* that what the manufacturer sent to it is what was stated by the manufacturer – without requiring Wholesale Distributor XYZ to open the case to confirm.

Handheld Scanner



Product Cases



Product Cases



Open Product Case



Individual bottles in case



Major Changes in Operations

- The ability of HDMA primary distributor members to comply with the California law is heavily dependent upon manufacturer compliance beginning in January 2016.
- A future that includes serialized product, use of track-and-trace technologies, and electronic pedigree data exchange is one that has been contemplated, but we cannot yet fully understand or anticipate how such changes will require modifications to our members' operational and logistics functions.

Use of Inference When . . .

- Recipient places an order for product with the shipper, with whom the recipient has a business relationship; and
- A sealed homogenous (same lot, same product) case is sent by the shipper directly to the recipient; and
- The shipper and recipient have technology solutions to provide electronic business-to-business transactional security;

. . . all of these factors are present.

- And, the shipper sends – in advance of, or in conjunction with shipment – information about the items/contents of such case, including the items' serial numbers and pedigree information related to each specific case; and
- The recipient receives the case and the product information from the shipper.

Inference is Necessary

- Allowing inference by distributors is necessary to help facilitate implementation of California's pedigree law.
- Allowance of inference is consistent with the spirit and the **intent** of the law – to employ technology and processes in the supply chain to permit electronic track-and-trace for the first time.
- **Without inference**, such technologies and processes will be difficult or impossible to successfully deploy.

Safety, Efficiency and Access

- Inference will help to ensure that California providers and patients have continued access to life saving medicines.
- Inference will actually help ensure increased security of the supply chain by
 - Limiting open cases in a warehouse receiving area;
 - Limiting personnel handling items; and
 - Limiting opportunities for diversion, theft or contamination.
- Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain.

Inference: Key to CA Implementation

- Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain.
- **Without inference**, such technologies and processes will be difficult or impossible to successfully deploy.

This is Big.



Thank You

Elizabeth A. Gallenagh
Vice President, Government Affairs and
General Counsel
HDMA

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703-885-0234

ATTACHMENT 5

Proposed Draft to Enforcement and E-Pedigree Committee

March 2013

Certification

(a) For the purposes of Business and Professions Code section 4034, and the delivery and receipt of electronic pedigrees, "certification" shall refer to the process by which each participant in the supply chain confirms and attests to the accuracy of electronic pedigrees transmitted or received in conjunction with delivery, transfer, receipt, or acceptance of corresponding dangerous drugs.

(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the delivering or transferring party (hereinafter, the "source") shall transmit to the buying, receiving, or accepting party (hereinafter, the "recipient") via a secured electronic transmission, the electronic pedigree corresponding to the dangerous drug being delivered or transferred, including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d). The electronic pedigree transmitted by the source to the recipient shall include, as to each such individual unit, at least the following:

- (1) The name and principal address of the source, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.
- (2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
- (3) For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address, and federal or state registration and/or license number(s) permitting sale or transfer, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- (4) A certification under penalty of perjury from a responsible party of the source that the information contained in the pedigree is true and accurate.
- (5) The unique identification number affixed to the smallest package or immediate container.

The electronic pedigree provided by the source to the recipient shall include a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree, and that guarantees that the data is immutable and non-repudiable by the source.

The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine, the information contained in the pedigree is true and accurate. By so attesting, the responsible party confirms that the source has verified the prior transaction history and corresponding certifications for the dangerous drug

to the best of its ability, that there is nothing in the prior transaction history that raises suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

(c) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of an electronic pedigree, the recipient shall receive an electronic pedigree from the source that corresponds to the dangerous drug being delivered or transferred. The recipient shall certify receipt of the dangerous drug by verifying the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, confirming there is nothing in the transaction history that raises suspicion, verifying correspondence between the pedigree data and the dangerous drug received, and by including in the pedigree a digital signature by a responsible party for the recipient that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the recipient.

DRAFT

Proposed Draft to Enforcement and E-Pedigree Committee

March 2013

Inspection

(a) Pursuant to Business and Professions Code sections 4081 and 4105, electronic pedigree records are among the records of manufacture, sale, acquisition, or disposition of dangerous drugs that shall be at all times during business hours open to inspection by authorized officers of the law, that shall be preserved for at least three years from the date of making, and that shall be at all times retained on the licensed premises in a readily retrievable form.

(b) Electronic pedigree records shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of the electronic pedigree records.

(c) Upon request by an authorized officer of the law or by an authorized representative of the board, the electronic records shall be made immediately available in electronic format for duplication or download, duplicated or printed into a paper format, or both, as directed.

(d) Each licensed premises shall have available a scanner and terminal that may be used by an authorized officer of the law or by an authorized representative of the board to access electronic pedigree record information regarding the smallest package or immediate container for any dangerous drug by, among other things, scanning the unique identification number affixed to the smallest package or immediate container and accessing the corresponding pedigree.

ATTACHMENT 6

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June 14, 2013

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VIA E-MAIL AND U.S. MAIL

Ms. Virginia Herold
California Board of Pharmacy
1625 North Market Street, Suite N219
Sacramento, CA 95834

**Re: Submission of Information Necessary for Board Rulemaking on “Drop Shipment”
and Certification of Individual Package Units Drug Pedigree Law**

Dear Ms. Herold:

On behalf of one of our pharmaceutical manufacturing clients, the purpose of this letter is to submit general information and background on their “direct ship” model, and a draft regulatory template for your consideration. We are pleased to see that the California Board of Pharmacy’s (the “Board”) Enforcement Committee will be undertaking the review of information necessary to initiate future regulatory proceedings on this topic, as authorized by Section 4163.1 of the California Business and Professions Code. Our client, respectfully, wishes to provide regulatory language for Board consideration, stakeholder reaction, and, ultimately, formal rulemaking proceedings that address a very unique business model in the prescription drug distribution supply chain.

As detailed in Exhibits “A” and “B,” below, our client utilizes a “drop-ship” distribution model that provides treating physicians and their patients with timely and efficient access to patients with certain critical, and treatment time-sensitive disease states. Our client has been using the “drop-ship” model for a period approaching a decade, and knows that other companies have used comparable models for greater and shorter periods of time. This model allows our client to facilitate the direct shipment of medications to a healthcare provider’s office, and ultimately to the patient, within a day of placing an order.

In this model, wholesalers place orders for the product and consequently take title to the ordered product, but never take possession or physical control of the product. The role of the wholesaler in this model is thus limited to facilitating product distribution by providing administrative services, such as the processing of orders and payments.

Ms. Virginia Herold
California Board of Pharmacy
June 14, 2013
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Section 4163.1(b) of the California Business and Professions Code permits the Board to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in California law is to provide the capability to track and trace drug shipments. As a result, only those stakeholders that actually take possession or physical control of the drugs are best positioned to satisfy the objectives of the law's pedigree requirements.

In the context of a drop shipment distribution model, pedigree information ought to include records of any shipments from manufacturers to dispensers, as well as any returns. However, we respectfully submit that the pedigree requirements should not apply to wholesale distributors who take only legal title of the drug product but do not take possession or physical control. Ensuring that entities that never physically handle the product are not subject to the reporting requirements will allow companies, such as our client, to maintain important efficiencies in its distribution system, without subjecting its wholesalers to unnecessary regulation, while continuing to provide accurate tracking of pharmaceutical products throughout the chain of physical custody. Recent federal legislative efforts in this area also recognized this distinction between a "drop-ship" model and more traditional distribution models.

Thank you for your consideration in this regard. As you may require any additional information, please don't hesitate to contact me at (916) 441-2430.

Respectfully submitted,



JOHN R. VALENCIA

JRV:mab

Enclosures: Exhibits "A" & "B"

Exhibit "A"

"Drop-ship" Distribution Process

Some manufacturers use a "drop-ship" distribution model that provides treating physicians and their patients with timely and efficient access to drugs. By using a drop-ship model, the manufacturer can facilitate a direct shipment of its drug to a healthcare provider's office. In this model, wholesalers place orders with the manufacturer or a designated distributor for the product and consequently take title to the ordered product, but never take possession or physical control of the product. Instead, the manufacturer or designated distributor ships directly to the physician upon receipt of the order. The role of the wholesaler in this model is thus limited to facilitating drug distribution by providing administrative services, such as the processing of orders and payments.

Section 4163.1(b) of the California Business and Professions Code (BPC) permits the California Board of Pharmacy to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in the California BPC is to provide the capability to track and trace drug shipments. Manufacturers are the first step in the pedigree chain. Pedigree information should be passed from each entity who takes physical possession onto the next physical owner within the drug distribution system. In the context of the drop shipment distribution model described above, pedigree information ought to include records of any shipments from manufacturers to dispensers, as well as any returns. However, the pedigree requirements should not apply to wholesale distributors who take legal title of the drug product but do not take possession or physical control. The recent federal legislative efforts in this area also recognized this distinction between a "drop-ship" model and a more traditional distribution model.

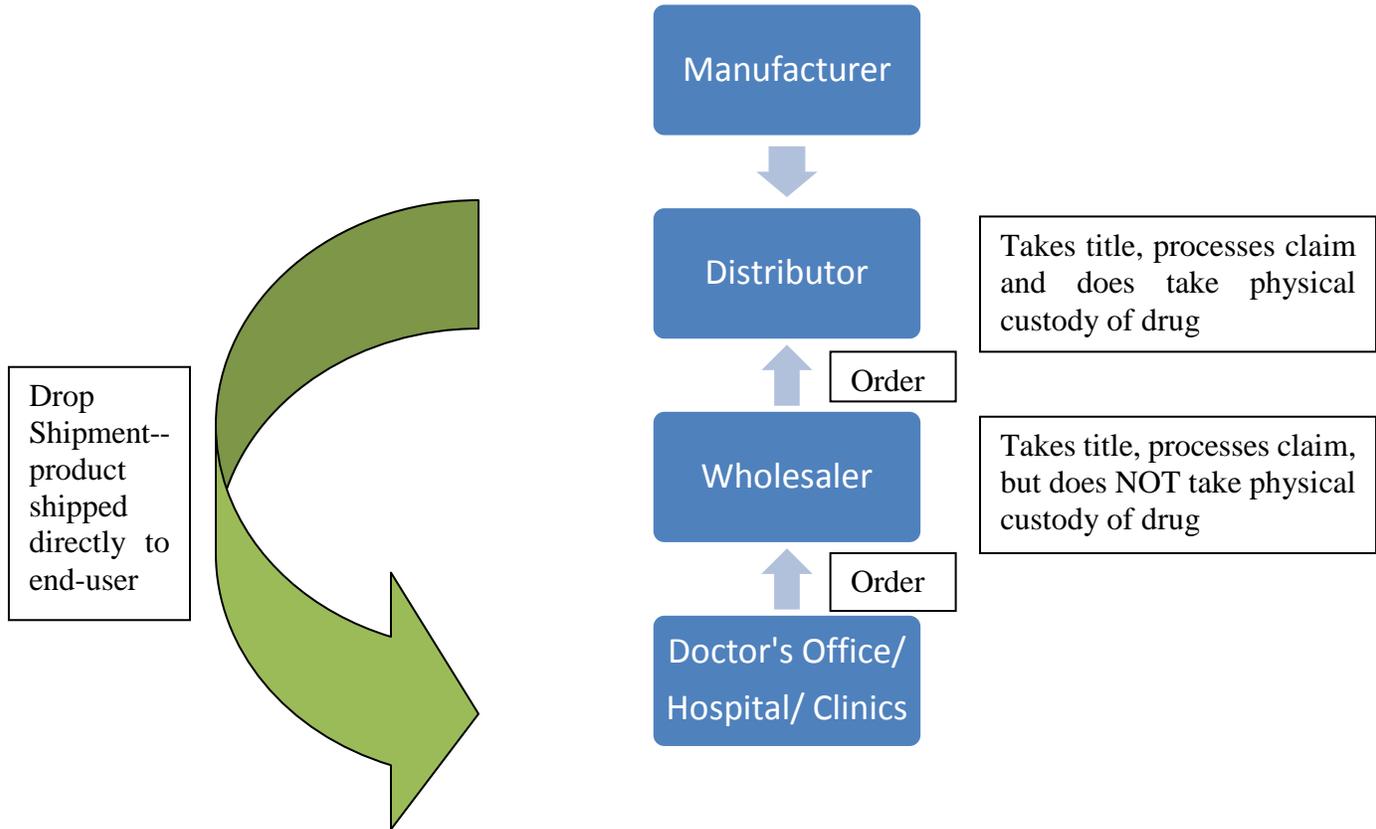
Any potential regulations should ensure that entities who never physically handle the product are not subject to the reporting requirements. This will allow manufacturers to maintain important efficiencies in their distribution system, without subjecting the wholesaler to unnecessary regulation, while continuing to provide accurate tracking of pharmaceutical products throughout the chain of physical custody. The "drop-ship" model also significantly benefits patients by allowing for quicker access to treatments via a just in time delivery system-often the drug is delivered within 24 hours of placing an order. This model obviates the need for physicians to keep a large stockpile of drugs in their inventory, thus ensuring patients have safe and quicker access to life extending drugs. The following draft language is submitted for your consideration as you develop regulations to implement the law.

Ms. Virginia Herold
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Proposed Draft: Limitation on Reach of Drug E-Pedigree Requirements in the Instance of “Drop Shipment” Sales of Dangerous Drug Products in California (Authority: Bus. & Prof. Code Sec. 4163.1)

“_____ . For the purposes of Business and Professions Code Section 4163.1, when a manufacturer utilizes the “drop shipment” means of sale for a dangerous drug product as defined by that section, only those entities involved in the physical handling, distribution, or storage of a dangerous drug product, are required to provide or receive the “pedigree” required by Section 4034. Any entity, including but not limited to a wholesale distributor, that is not involved in the physical handling, distribution, or storage of the dangerous drug product sold by means of “drop shipment,” is not required to provide or receive a pedigree for that dangerous drug product, [even if such entity holds legal title to the dangerous drug product]. For purposes of this section, facilitating the distribution of a product by providing various administrative services, including processing of orders and payments, [even if holding title,] shall not, by itself, be construed as being involved in the physical handling, distribution, or storage of a product.”

Exhibit "B"
A 'DROP-SHIP' DISTRIBUTION MODEL



Summary of Minutes from the March 14, 2013 Enforcement and E-Pedigree

c. Discussion on the Use of Drop Shipments in an E-Pedigree System

Discussion:

The committee was advised that board staff released a solicitation request through the board's email notification system that the board was seeking information on drop shipments from members of the supply chain.

The committee heard comments from John Valencia, representing a number of clients. Mr. Valencia indicated that a number of the clients he represents need guidance for drop shipments. Mr. Valencia spoke about a drop ship model that is used for some specialty products. He referenced comments submitted and detailed some changes between the HDMA model discussed earlier in the meeting and the proposed solution being offered by his clients. Mr. Valencia urged the committee to discuss the issue and move forward the language for discussion as it will solve a real dilemma for a small but specialized area.

Mr. Room clarified that the proposal appears to specify that there would be a direct connection between the manufacturer and the physician's office or clinic. Mr. Room noted that the proposed solution would work for their business model, but not for all.

Mr. Valencia indicated that his clients need to be in some place of certainty to ensure businesses know how to move forward as the implementation date moves closer. Mr. Valencia reminded the committee that the billing relationship is not what is important in tracking a pedigree.

Mr. Room indicated that he did not have any concerns from a legal perspective with the draft language.

Ms. Herold again requested information from industry to ensure that the board has the necessary information to ensure the development of the language is appropriate.

Drop Shipments and the California Pedigree Law

Liz Gallenagh & John Howells
HDMA

California BOP Enforcement Committee
March 14, 2013

Overview

- Drop shipments defined in the statute
 - Legislature contemplated this type of transaction and the need to provide for an alternative to the “typical” pedigree requirements.
- The product goes directly from the manufacturer to the pharmacy
 - Exception: when there are exclusive distribution arrangements and a manufacturer designee is performing the drop shipment.
- One of the most secure transactions in the supply chain.

Statutory Definition

- 4163.1. (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:
 - (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.
 - (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.
 - (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.
- (b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

Why Do Drop Shipments Occur?

- Type of product – predominantly Specialty Rx
 - Special handling, cold chain, etc.
 - Special administration/delivery to patient (IV, oncologics, etc.)
 - Out of stock/low stock.
- Emergencies.
- Critical Patient Need.

Drop Shipment Manufacturer to Pharmacy

Manufacturer

Distributor

Invoice matching & exception
processing

Pharmacy

Processing & reconciliation

Typical time is 3 – 7 days *

Data

Data

Product Shipment 1 – 2 days

The product is likely
to be dispensed
on the day of receipt
or the next day.

Manufacturer Designee Drop Ship

Manufacturer

Manufacturer
Designee

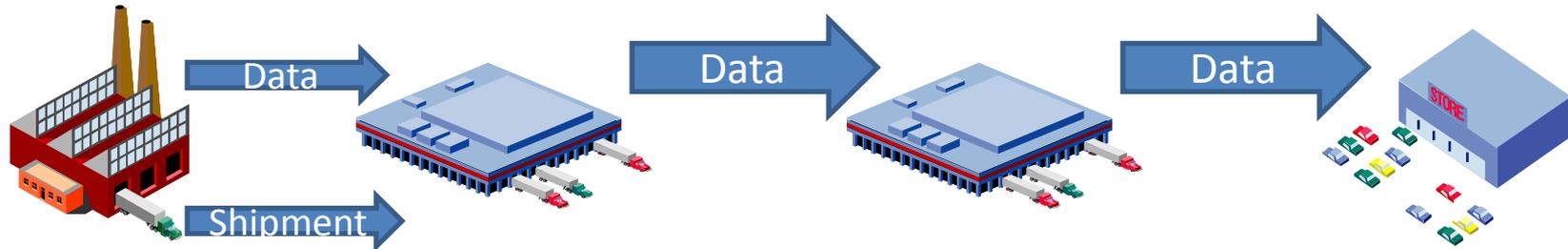
Distributor

Invoice matching & exception
processing

Pharmacy

Processing & reconciliation

Typical time is 3 – 7 days *



Product shipment takes 1 – 2 days

The product is likely
to be dispensed
on the day of receipt
or the next day.

Reasons why drop shipments warrant consideration of an alternative

- In cases of critical patient need, do not want to delay dispensing of the product.
- In most drop ship cases, the drug has been administered before the wholesaler has been notified.
- This is an invoice / financial transaction. Invoice systems do not contain pedigree data.
- Pedigree and invoice systems are separate.
- Emergencies/exceptions can cause major delays in data processing.

Pedigree alternative for drop ship

- The financial “owner” of the product will not have custody of the product, and therefore, is not able to vouch for the pedigree associated with the product.
- In lieu of a pedigree, the manufacturer performing the drop shipment should indicate it is a drop shipment – either on the invoice (or via some other standard communication).
- The distributor in the center of the transaction (owns the product from a financial standpoint but does not have possession of the product) also indicates on its invoice that the product was drop shipped to the customer.
- Drop shipments by distributors also occur, particularly when there is an exclusive distributor relationship with the manufacturer or a product launch. The process for an exclusive distributor drop shipment should follow the same rules as a manufacturer drop shipment, as described above.



Questions?

ATTACHMENT 7



California State Board of Pharmacy

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www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
E-PEDIGREE COMMITTEE MEETING
MINUTES**

DATE: June 24, 2013

LOCATION: Department of Consumer Affairs
First Floor Public Hearing Room
1625 N. Market Boulevard,
Sacramento, CA 95834

**COMMITTEE MEMBERS
PRESENT:** Randy Kajioka, PharmD
Rosalyn Hackworth, Public Member
Stanley C. Weisser, Rph

**COMMITTEE MEMBERS
NOT PRESENT:** Ryan Brooks, Public Member
Tappan Zee, Public Member
Amy Gutierrez, PharmD
Shirley Wheat, Public Member
Deborah Veale, Rph

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Judi Nurse, Supervising Inspector
Joshua Room, Supervising Deputy Attorney General
Desiree Kellogg, Deputy Attorney General
Carolyn Klein, Staff Manager
Laura Hendricks, Staff Analyst

Note: The webcast for this meeting is available at:
<http://www.pharmacy.ca.gov/about/meetings.shtml>

Call to Order

Chair Randy Kajioka called the meeting to order at 9:36 a.m.

Chair Kajioka announced 2 hours of continuing education credit would be available for attending the entire meeting.

Chair Kajioka conducted a roll call. Committee members present: Dr. Randy Kajioka, Rosalyn Hackworth and Stan Weisser. Committee members not present: Dr. Amy Gutierrez, Shirley Wheat, Ryan Brooks, Deborah Veale and Tappan Zee.

Note: Mr. Weisser temporarily appointed himself to the committee.

I. Next Scheduled Meetings of the E-Pedigree Committee for 2013

Chairperson Kajioka announced the remaining e-Pedigree Committee dates for 2013.

- September 26: Southern California
- December 10: Likely San Francisco

II. Presentation by TechN'Arts

On January 1, 2010 Turkey implemented a unit serialization e-tracking system for prescription drugs, somewhat similar to California's requirements. Mr. Taha Yayci provided a presentation via Skype on an overview of the requirements of Turkey's system, and how the system has operated since implementation. The presentation is available on the Board's website:

www.pharmacy.ca.gov/meetings/agendas/2013/13_jun_e_ped_presentation.ppt

Discussion

Mr. Yayci stated that from 2005 to 2009 a group worked to convince Turkey's politicians of the country's drug supply problems and to get the required legislation in place. It then took one year to get the technology in place - the system implementation took place in January 2010. The system has been fully functioning for three years.

The committee asked if inference was used in Turkey's system.

Mr. Yayci answered that solving the problem of inference was one of the biggest problems in implementing the system. Their solution was the creation of "Package Transfer Service (PTS)" which is a centralized file sharing platform that contains hierarchal data of which container holds each sellable unit and can be shared between each stakeholder in the system.

Mr. Yayci noted that wholesalers rate manufacturers based on their reliability and quality of service. If a manufacturer has a high rating then a wholesaler will not need to open a packager to scan each sellable unit inside. However, if they have a low rating, than a wholesaler will open each package and scan each sellable unit to ensure that the inference is correct.

Chair Kajioka noted that this is similar to the board's "trusted relationship."

Chair Kajioka asked Mr. Yayci to present at the July 2013 Board Meeting.

Mr. Yayci responded that he would like to attend the meeting in person. The board will work with him to coordinate presenting either in person or via Skype.

The committee asked if there were complaints from the industry about an increase in workload.

Mr. Yayci answered at first there was a lot of push back from the industry. To address this multiple workshops were held to discuss problems and concerns. However once the system was in place, the industry found it to be beneficial as it prevented diversion and counterfeits from entering the supply chain.

Ms. Herold asked if there were companies that could not sell drugs because they couldn't meet Turkey's deadlines.

Ms. Yayci answered that at the beginning of the project the required technology was not available for the system to work. It took six months from the January 2010 implementation date to get all of the technology in place, this resulted in the temporary slowdown of the healthcare system.

There were public comments.

III. Discussion Regarding Comments Submitted by the Board of Pharmacy in Response to Federal Legislation in April 2013

In April different versions of federal legislation to provide supply chain security were introduced in both the House of Representatives and the Senate. In May, the House passed its version. In the Senate, the Senate HELP Committee has passed its bill but the full Senate has not voted on this matter yet. If the Senate passes the bill pending there, the matter will go to a conference committee to resolve the differences between the two different approaches.

At the request of President Weisser, the board submitted comments on both versions of the legislation. These letters are provided in the meeting materials.

Discussion

Chair Kajioka asked if there were any updates on federal legislation in this area.

Mr. Room responded that the full Senate has not voted on the bill yet, but it is expected to be heard in the coming weeks.

Mr. Room noted that the letter to the House of Representatives was absent from the meeting materials. He added that the letter to the House expressed a general opposition to the House bill in preference to the Senate Bill. The letter has been added on the board's website.

Chair Kajioka provided a brief summary of the letter sent to the House of Representatives as follows.

- The House bill does not protect Californian's to the degree the board feels is necessary
- There is strong board support for having one standard for all 50 states to avoid variances
- The board strongly supports strengthening the supply chain to protect consumers on a national level

- The board is concerned that California’s law has an implementation date of 2015-2017, however the federal bill would push implementation out by 10 years

Mr. Room noted that another letter was sent to the House in November 2010 that was extremely detailed in outlining concerns that board had with the bill in its approach to supply chain security. The letter sent in April did not go into as much detail; however, it did reference the letter sent in November. Mr. Room added that another area of concern the board expressed in the letter was how counterfeit drug investigations by the regulatory agency would be accomplished.

Mr. Weisser encouraged the public to review the letter once it was provided on the website.

Mr. Room commented that some changes have been made to the bill in response to the board’s initial comments - including clarifying language on how counterfeit drugs would be provided to regulatory agencies for investigation.

Mr. John Valencia, representing a variety of manufacturers, asked if federal legislation would preempt California’s law and if the board would have the authority to take additional measures if the bill was passed.

Mr. Room answered that both the House and Senate bills have explicit preemptive language on certain subject areas, one of those being anything related to serialization and track and trace. The bills differ on national wholesale licensure standards. The House bill specifically preempts any additional state regulation of those entities, the Senate bill sets a floor but allows states to have additional requirements.

IV. Update on the Status of Pending CALIFORNIA Regulations on Requirements for the Serialized Numeric Identifier, Reporting the 50 Percent of Products Serialized by January 2015 and the Remaining 50 Percent by January 2016, and “Grandfathering” Parameters for Unserialized Products in the Supply Chain – 16 California Code of Regulations Section 1747. -1747.1

At the February Board Meeting, the board held a regulation hearing and approved regulation requirements for the following items. The specific language is provided in the meeting materials.

1. The serialized numeric identifier (section 1747)
2. The process for advising the board how a manufacturer will reach the 50 percent of its products that will be sold in California after January 1, 2015, and the remaining 50 percent by January 1, 2016 (section 1747.1)
3. How to designate unserialized product that may exist in the supply chain after the staggered implementation dates (section 1747.1).

Discussion

Chari Kajioaka noted that this subject has been discussed at multiple meetings and asked if the committee had any questions or comments.

Ms. Herold noted that the regulations have been undergoing review by the State and Consumer Services Agency since the beginning of April. She added that it has not yet gone to the Office of Administrative

Law (OAL) for review. Once received, OAL has the equivalent of 30 working days to either approve or deny it. The board hopes the process will be complete by September.

Mr. Room commented that both he and Ms. Herold have provided presentations to the industry on this subject, and they continue to receive questions on the application of these regulations and the general underlying requirement that manufacturers have 50% stock serialized by January 1, 2015. He added that as far as he is aware there have been no questions or comments provided that would prevent the regulation from continuing to be secured.

There was no public comment.

V. Discussion on GS1 Healthcare US's Implementation Guideline Applying GS1 Standards to US Pharmaceutical Supply Chain Business Processes, Release 1.0

At the board's last e-pedigree meeting, GS1 presented their new implementation written guideline. This guideline has been aigenized for this meeting to ensure interested parties are aware of its availability.

Although it takes about 100 pages to lay out the standards, Ms. Herold commented that the material is valuable in providing considerable background about tracking and tracing. The guidelines were provided for review in the meeting materials.

Discussion

There were no comments from the committee or the public

VI. Presentation by GS1 on Using EPCIS to Support E-Pedigree Requirements

Mr. Bob Celeste, senior director at GS1 Healthcare, provided a presentation to show how EPCIS can be used to support California pedigree requirements. The presentation has been attached at the back of these meeting minutes.

Discussion

Mr. Weisser asked Mr. Celeste what he thought of the presentation by Turkey earlier in the meeting.

Mr. Celeste answered that GS1 Global worked with Turkey on the successful implementation of their track and trace system. He added that it is important to work towards a standardized way of tacking products through the supply chain on a global scale.

Mr. Room asked if there are GS1 subscription costs.

Mr. Celeste answered that the cost for a manufacturer is about \$0.10 per product line (not per each). To get a Global Locator Number (GLN) it costs \$50. GS1 manages the system globally to ensure there are not repeated identifiers anywhere in the world.

Mr. Kajioka asked if there is an annual fee per product line.

Mr. Celeste answered that the annual fee is about \$0.01 per product line.

Mr. Room clarified that a Global Locator Number (GLN) identifies a geographic location. So a pharmacy would only need one GLN were a wholesaler may need multiple GLNs.

Mr. Celeste responded that a GLN can actually identify one geographic location or one entity. So a wholesaler might choose to only use one GLN despite having multiple geographic locations.

Chair Kajioka asked if there was a way to tell if a product unit code had already been used in the system. For example: If a pharmacist scanned a code then the next day another pharmacist scanned a different product that had the same code - would it be flagged as counterfeit?

Mr. Celeste answered that currently it would not, and it is a problem with pedigree.

Mr. Room commented that the board has always understood that all it can do is raise the barrier and create complications for those trying to compromise the supply chain. The immediate notification of a code being used twice requires a level of technology that is currently not available.

Mr. Celeste added that massive counterfeiting would be very difficult to do with the pedigree system.

Chair Kajioka asked if an inspector could go into a pharmacy and use the system to find were a specific bottle of medication had been in order to determine if there was fraud.

Mr. Celeste answered that the pharmacy should be able to access the system to immediately and verbally provide the inspector with the containers movement through the supply chain, though it could take some time to pull the full written report.

Mr. Room noted that looking at one bottle's information would not reveal to an inspector that there were no other bottles sitting on a different pharmacy's shelf with the same serial number. However, if the fraud was taking place in the pharmacy the inspector could do an inventory of the entire drug stock to see if they had duplicate serial numbers in their stock. Likewise, if the fraud was taking place at the wholesale level, it is possible to look at the history of all the products leaving the wholesaler to find duplicate serial numbers.

Mr. Weisser asked Mr. Celeste if decommissioning a serial number would help to flag fraud.

Mr. Celeste answered that if a serial number is decommissioned it essentially does not exist anymore. This makes moving a decommissioned item to be properly destructed difficult to do, even when it is being done for a completely legitimate reason.

Mr. Room added that what would be preferable to have certain "not to be dispensed again" codes rather than having the number be decommissioned entirely.

Mr. Room noted that when the board developed the language for the law in 2003, this type of system did not exist. The current language more closely meshes with a system where the entire supply chain history is provided with every transaction in the chain. In the system that Mr. Celeste described, each transaction only transmits the information from the immediate trading partner. The board needs to decide if this constitutes receipt of pedigree.

Chair Kajioka reiterated that the system allows for an entity to know exactly to whom they bought/sold an item to, although the entity cannot see further up or down the chain.

Chair Kajioka agreed it that it does not make sense to use language that was written 10 years ago and may have become outdated. He instructed board staff to identify end of life scenarios and proposals for the committee to vet-out.

Chair Kajioka commented that this has been a long process because the board's first goal is always consumer protection. However they did not want to create technological barriers for the industry that would prevent the dispensing of medications.

No public comment.

The committee recessed for lunch at 11:45 a.m. and resumed 1:03 p.m.

VII. Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

Time was set aside at this meeting to provide interested parties with the opportunity to provide information or presentations to the committee about implementation matters or simply to ask questions.

Discussion

A presentation on questions from the industry was provided by Mr. Bill Fletcher from PharmaLogic Solutions. The presentation has been provided following the meeting minutes.

Ms. Herold noted that many questions have been received on e-pedigree implementation and the board's staff is working on posting a Q+A section on the board's website.

Mr. Fletcher reported that many companies base their 50% serialization on projections of future sales. The industry would like to know what the ramifications would be if they do not meet their projections or if they exceed them.

Ms. Herold answered that the board is looking for long term compliance. If a company makes a good faith effort to be compliant and can show the board that their projections were solid, the board will be willing to work with the company to meet the 50% serialization requirement.

Mr. Kajioka added that the board was purposefully flexible in the definition of 50% calculation in the law.

Mr. Fletcher noted that the flexibility in defining 50% is what has lead to the confusion within the industry.

Ms. Herold responded that under the pending regulation requirements, prior to January 1, 2015 someone with the authority to bind the company must commit, under penalty of perjury, in the company's statement to the board how it will meet the 50% serialization requirement. If the board determines that the projection is totally unrealistic the board had the ability to reject it.

Mr. Fletcher asked what a manufacturer should do with a pedigree for a product they have produced with a serial number prior to wholesalers being required to accept pedigrees (July 1, 2016).

Mr. Room confirmed this.

Mr. Fletcher asked to clarify that starting in 2015 a manufacturer can produce products that have a pedigree even when there is no wholesaler ready to accept pedigrees.

Mr. Room answered while this is not ideal there is no legal problem. The intent behind the staggered implementation dates was to allow for testing of the system and prevent delays when the full implementation date is reached. Mr. Room added that the board views 2015 to July 1, 2016 as the "good faith" period during which manufacturers can establish their 50 percent threshold and being sending product through the supply chain so they can work out any problems in the system. During this time period the board will be most willing to work with manufacturers on issues rather than making it an enforcement issue.

Mr. Fletcher reported that in the fourth quarter of 2014 manufacturers will be producing products that will not actually leave their facilities until 2015 when the 50 percent requirement will take effect. The manufacturers would like to know if they will still be allowed to sell the products in California in 2015 if it was supposed to be part of the 50 percent but was not able to be serialized.

Mr. Room answered that he feels people are overly concerned about this provision, the board understands that manufacturing takes place over a period of time. The goal of this provision is to ensure that manufacturers have a plan in place to have all of their products fully serialized to be sold in California by 2016. It is important that they be as forthcoming with the board as possible and show that they are making a good faith effort to meet the requirements, given that some of the product was produced prior to January 1, 2015.

Mr. Fletcher added that this is a large undertaking and companies are seeing this provision as black and white. In the course of trying to plan for the 50%, the issue of what to do with their current inventory is a concern.

Mr. Room responded that in his opinion a company should perhaps target 60% serialization so that issues such as inventory would not be as big of a problem.

Chair Kajioka stated that the board wants to see forward progress and not have companies with only 2% of their products serialized by 2016.

Mr. Fletcher asked if SKU was an acceptable measure for the 50 percent requirement.

Mr. Room answered that the law allows for this.

Mr. Fletcher asked it was acceptable for a company to use product family as their 50 percent requirement.

Mr. Room answered that product family would be an acceptable way to measure the 50% serialization requirement.

Mr. Fletcher reported that some manufacturers are concerned that trade information will be going all the way down the supply chain if they create a pedigree for an entire pallet. So they have adopted a policy of creating an electronic pedigree per case so that when a wholesaler distributes that case, only the pedigree for the case would move to the next recipient.

Mr. Room commented that the law only requires tracking of the unit. Tracking above the unit is done for convenience and logistical reasons. Therefore the manufacturer could have pedigrees for each unit if they choose.

Mr. Fletcher asked the board to look at using a number higher than 48 for inference as proposed in a new pending regulation, as many companies package products in cases of 100 items or more. He also reported that inference on the pallet level is common practice in other industries and recommended that the board consider this.

Mr. Room responded that as written, the regulation would only apply inference to sealed, homogeneous cases. There is no inference applicable to pallets, however several comments received by the board have advocated for inference applied to pallets.

Mr. Fletcher reported that he receives many questions on inference in general. Particularly in regards to why the board gets so carried away with inference when a unit will always be scanned before it is dispensed - so any counterfeit drug would be caught before it reaches the consumer.

Mr. Room answered that this law was written based on the model created by the FDA as part of its counterfeit drug taskforce in 2003. California relied on the FDA's expertise to determine what the best model would be to prevent counterfeit and adulterated products from getting into the supply chain. The intent was to create a closed system where the participants in the supply chain have the ability to intervene at any point and prevent further transmission of counterfeit or adulterated drugs. The ability to intervene would not be there if the members of the supply chain were not scanning individual units, or at least inferring individual units, at every stop in the chain.

Mr. George Pennebaker, pharmacist, commented that he feels that the board has moved away from its original intent to prevent counterfeit drugs from reaching the consumers.

VIII. Discussion to Develop Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163

Since July 2012, the board has several times released written requests for specific comments needed to develop possible regulations to authorize inference. The board received only a few comments in response to these requests for information, and few of the comments received were appropriately responsive to the board's inquiries. The comments provided by the supply chain can be obtained from the December 4, 2012 Meeting Materials of the Enforcement Committee:

<http://www.pharmacy.ca.gov/about/meetings.shtml#enforce>

At the March Enforcement and E-Pedigree Meeting, draft language was released for discussion purposes to develop the regulation language for inference. A copy of this proposal was provided in the meeting materials.

Following the March meeting, the board received additional comments specific to the language released in March. These comments were also provided in the meeting materials.

Discussion

Chair Kajioka asked Mr. Room to provide the primary issues that have been raised in the comments received by the board.

Mr. Room provided that the board would need to make a decision in the near future about what kind of aggregate containers it is comfortable applying any sort of inference to. Each time an inference is implied it is requiring a little less than that law, in the sense that you are not scanning individual units. So each instance needs to be supported by data that shows the inference is enhancing, rather than harming the overall security of the supply chain.

Mr. Weisser asked if enough comments were received to determine if a large portion of the industry shares a similar opinion on inference.

Ms. Herold responded that they received comments from associations that represent players in the supply chain. The intent of allowing for comments at this time is to make the regulation more meaningful at the front end. Ms. Herold added that the board needs to make decisions on inference and certification; however, she did not feel the committee meeting was the best setting to do so. She offered to integrate the comments received into the regulation so it would be easy to see the comments on each point of the language.

Mr. Room added that the draft language was provided to encourage comments and was not intended to be the final regulatory proposal. The board still needs to make decisions on the concepts before it is ready to line edit.

Chair Kajioka directed board staff to prepare a document integrating the language and the comments received for review by the committee.

Mr. Weisser commented that if the document could be provided at the next E-Pedigree meeting in September, then a recommendation could be made to the board at the October Board Meeting.

Ms. Herold noted that it may be better to have part of the discussion at the July Board Meeting to get a general consensus on where the board would like to go. Otherwise it would almost certainly mean the committee recommendation could not be made to the board until its meeting in January 2014.

Mr. Room added that he recommends not re-writing the regulation based on the comments received, without the input of the full board.

Chair Kajioka offered that the language provided was a good starting point and some good comments were received. An integrated report would allow the committee to make a stronger recommendation to the board.

Ms. Herold and Mr. Room offered that the language and the comments could be combined in a report to the board.

Ms. Herold added that the general opinion seem so be that the industry wants inference- perhaps in a more board sense than the board feels comfortable with.

Mr. Kajioka commented that you need to be able to certify the integrity of the product at each step in the chain in order to validate that it is safe to dispense to the consumer and to determine where a problem may have occurred.

Mr. Room expressed his gratitude to those who took the time to submit detailed comments.

No public comment was recieved.

IX. Discussion Concerning Possible Regulation Requirements on the Certification Process Needed to Comply with California's E-Pedigree Law

At the March Enforcement and E-Pedigree Meeting, the board distributed possible regulation language for the certification of each sale and purchase into the e-pedigree record.

A copy of the certification proposal was provided in the meeting materials. Also included in this section is proposed language for a regulation to specify board access to e-pedigree information during inspections.

Written comments submitted following the March meeting that pertain to these proposals were made available as part of the comments provided in the meeting materials.

Discussion

Mr. Room commented that the largest issue that the board needs to resolve with this proposal is what the party is actually certifying. In other words, to what level of information are they verifying or confirming as true or correct for the next recipient of that product.

Mr. Room suggested that a document integrating all the comments received be created.

Chair Kajioka directed board staff to prepare a document integrating the language and the comments received for review by the board.

No public comment was submitted.

X. Discussion Concerning Possible Regulation Requirements on the Use of Drop Shipments in an E-Pedigree System

The board has also begun work on the process by which drop shipments will be addressed in the e-pedigree system. The reference in California's Business and Professions Code with respect to drop shipments is provided below.

4163.1. Drop Shipment by Manufacturer

- (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:
 - (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

- (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.
- (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.
- (b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

In February, the board released a request for comments on drop shipments. One comment was received before the March Enforcement Committee Meeting and was provided in the meeting materials.

During the March committee meeting, the committee saw a PowerPoint presentation about drop shipments prepared by HDMA. An excerpt of the minutes of this meeting and the HDMA PowerPoint were provided in the meeting materials.

Board staff has not drafted a regulation proposal. The proposal submitted by industry as part of the February request for comments is:

Proposed Draft: Limitation on Reach of Drug E-Pedigree Requirements in the Instance of “Drop Shipment” Sales of Dangerous Drug Products in California (Authority: Bus. & Prof. Code Sec. 4163.1)

“For the purposes of Business and Professions Code Section 4163.1, when a manufacturer utilizes the “drop shipment” means of sale for a dangerous drug product as defined by that section, only those entities involved in the physical handling, distribution, or storage of a dangerous drug product, are required to provide or receive the “pedigree” required by Section 4034. Any entity, including but not limited to a wholesale distributor, that is not involved in the physical handling, distribution, or storage of the dangerous drug product sold by means of “drop shipment,” is not required to provide or receive a pedigree for that dangerous drug product, [even if such entity holds legal title to the dangerous drug product]. For purposes of this section, facilitating the distribution of a product by providing various administrative services, including processing of orders and payments,[even if holding title,] shall not, by itself, be construed as being involved in the physical handling, distribution, or storage of a product.”

Discussion

Mr. Room commented thus far the board has struggled with the topic of drop shipment and has not reflected a high level of satisfaction of any of the presentations or answers it has received on the subject.

Mr. Room reported that there are three main ways of approaching drop shipment as follows:

1. Not treat them any differently, and require that you have full pedigrees for all drop shipments.
2. Still require pedigrees to be reflective of all owners of a drug for a drop shipment, but somehow allow for either time tolerances or paperwork tolerances that would better accommodate pedigree requirements to the logistics of how drop shipments are actually handled in the supply chain.
3. Anyone who is not involved in the actual handling of a drug being dropped shipped would not have pedigree appending requirements for a wholesaler who does not have to certify their participation in the pedigree transaction.

The comments provided by John Valencia on behalf of his clients reflect the third approach to drop shipments.

Mr. Room added that a drop shipment must have the three characteristics described in Business and Professions Code Section 4163.1, one of which is the shipment must be directly from a manufacturer to a pharmacy or other dispenser.

Mr. Weisser commented that the drop shipment system has been around for a long time and usually goes directly from the manufacturer to the pharmacy or practitioner for patient use.

Mr. Valencia, representing two specialty manufacturers, requested that the committee make a recommendation on the proposed language so that the full board can move forward with its approval.

Mr. Room commented that perhaps the language needs to be modified slightly.

Mr. Valencia expressed that his clients would be happy to review and comment on any edits the board made.

Ms. Hackworth provided that she feels language needs to be added to handle how the product will move back up the supply chain.

Angela Blanchard from HDMA commented that they support moving forward with the proposed language provided by Mr. Valencia and are open to working on fine tuning the language.

Mr. Room stated that he would make several modifications discussed by the committee and bring it to the board meeting.

XI. Additional General Discussion

Dr. David Holness, CEO of PharmaDocs, commented that authentication may be a way to fill the gaps that exist in the track and trace system. PharmaDocs has such a system.

XII. Closing Comments

Adjournment

2:28 p.m.



GS1 STANDARDS

THE ROLE OF GS1

GS1 is a not-for-profit organisation dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

- **109** member service organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world

GS1 IS BOTH GLOBAL & LOCAL



GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programs...not-for profit organization ...

GS1 Member Organizations

Local offices in 110 + countries around the globe, such as **GS1 US**

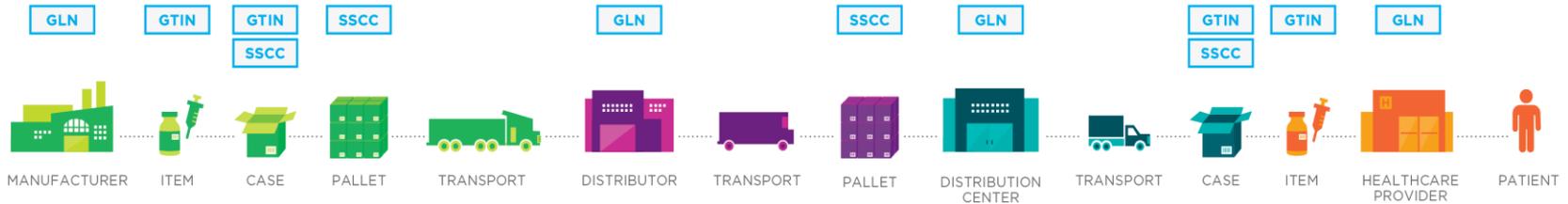
Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

GS1 STANDARDS IN HEALTHCARE



IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

GLN Global Location Number **GTIN*** Global Trade Item Number* **SSCC** Serial Shipping Container Code **EPC*** Electronic Product Code™



CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES

EAN/UPC



GS1-128



ITF-14



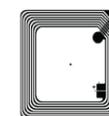
GS1 DataBar™



GS1 DataMatrix



EPC-ENABLED RFID TAGS



SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®) **TRANSACTIONAL DATA** eCom/EDI **PHYSICAL EVENT DATA** EPC Information Services



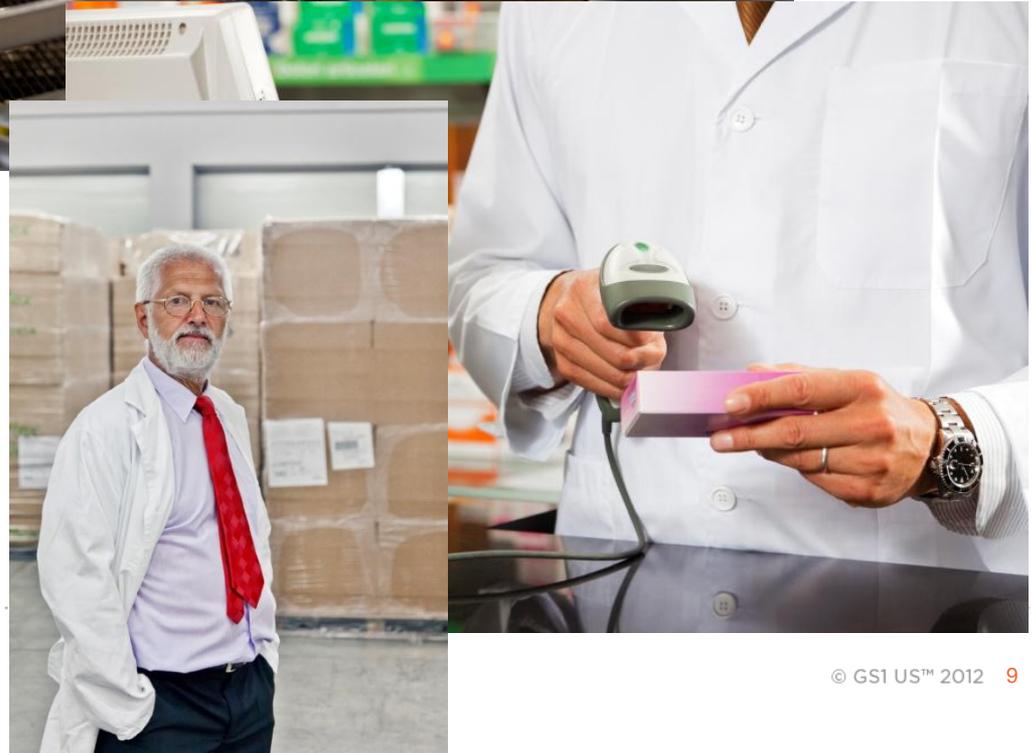
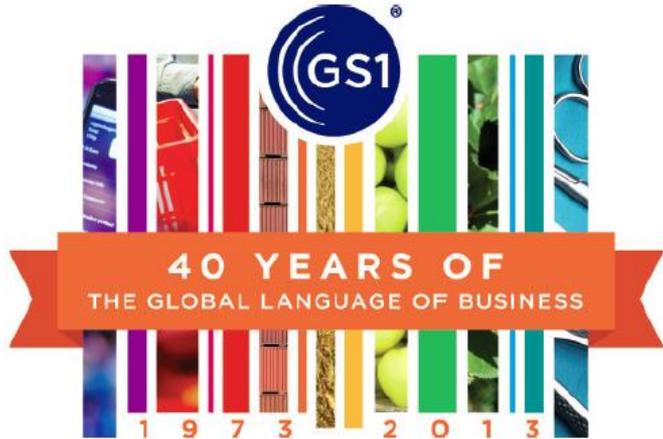
CONTENT

- Purpose
- The trouble with Pedigrees
- EPCIS based pedigree data
- Holding data vs having access to data
- A counterfeit in the middle of the supply chain
 - DPMS
 - EPCIS
- Massive counterfeiting
 - DPMS
 - EPCIS
- Pharmacist purchasing on grey market
- Inspection process considerations

PURPOSE

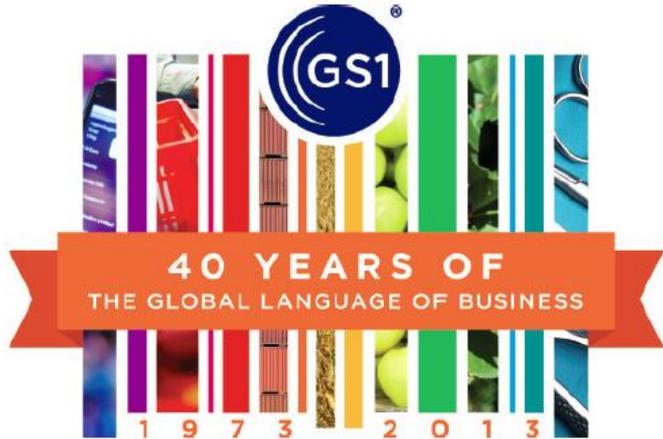
Companies in the industry are making significant investments in hardware and software, Initially, we would like a signal that an EPCIS based solution looks viable. In the short term, we would like (as we did with the Pedigree Messaging Standard) a statement that would indicate that pedigree data delivered via an EPCIS platform is acceptable for compliance.

THE TROUBLE WITH PEDIGREES



In Order for Pedigree to work,
we need a high level of
automation.

THE TROUBLE WITH PEDIGREES

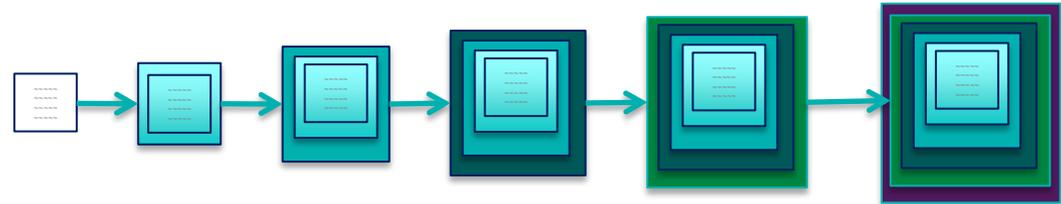


In regular transactions, products are ordered and information is transacted on the product ID rather than the full set of product data. This also applies to the company identifiers (Customer #, etc.).

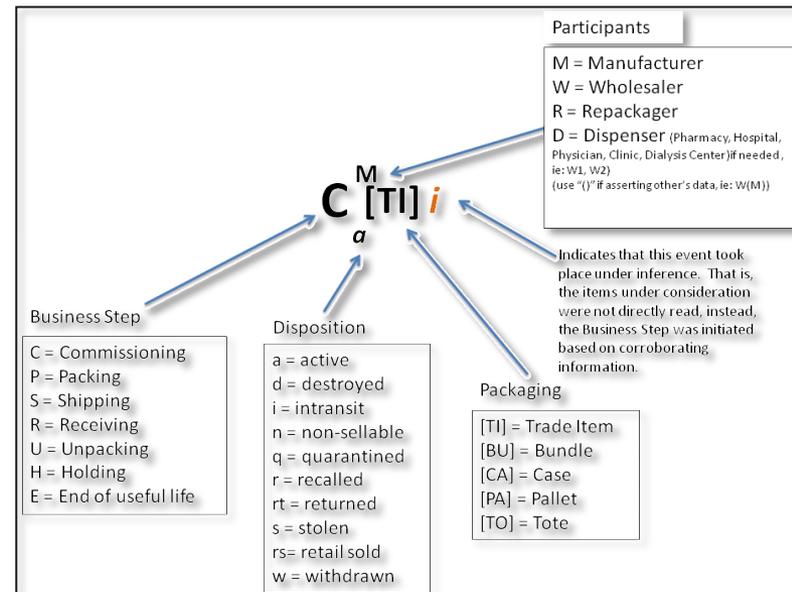


PEDIGREES VS EPCIS BASED PEDIGREE DATA

Pedigrees are document based. Where each trading partner adds their document to the last with no current mechanism for error corrections.



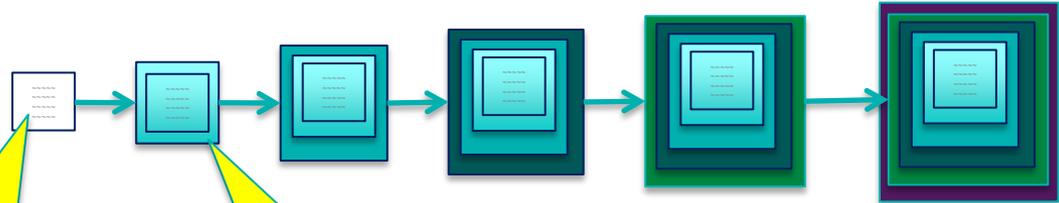
EPCIS is event based. Allowing more flexibility to describe what took place and allows error correction.



PEDIGREES VS EPCIS BASED PEDIGREE DATA

Pedigrees can contain data that is difficult to verify.

- By trading partners
- By inspectors



Manufacturer X's Pedigree:

Ship From: Manufacturer X,
123 Sunset Blvd, Sacramento
CA 95834

Ship to: Wholesaler Y, 562 El
Camino Real, Los Altos, CA
94022

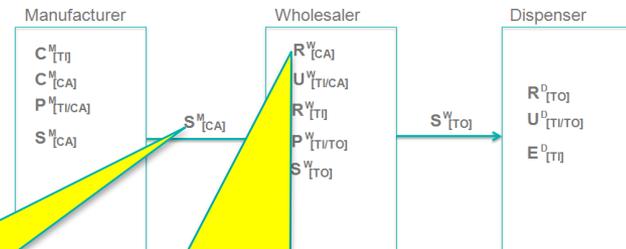
Wholesaler Y's Pedigree:

Ship From: Manufacturer X, 51
Main Street, Newark, DE, 19711

Ship to: Wholesaler Y, 562 El
Camino Real, Los Altos, CA
94022

PEDIGREES VS EPCIS BASED PEDIGREE DATA

EPCIS uses independently verifiable IDs



Manufacturer X's EPCIS data:

Transferred By ID:
GLN/0312345123459

Transferred To ID:
DEA/40695843

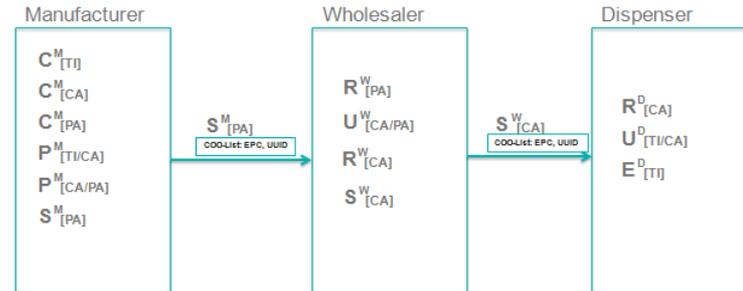
Wholesaler Y's EPCIS data:

Transferred By ID:
GLN/0312345123459

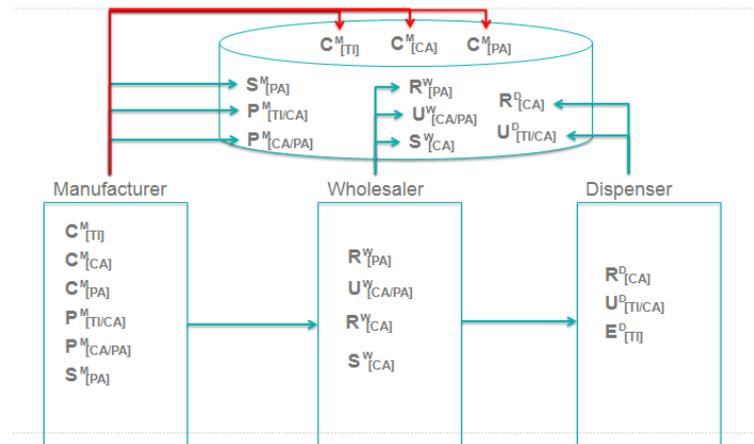
Transferred To ID:
DEA/40695843

EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



EPCIS can be used in a number of architectural settings.



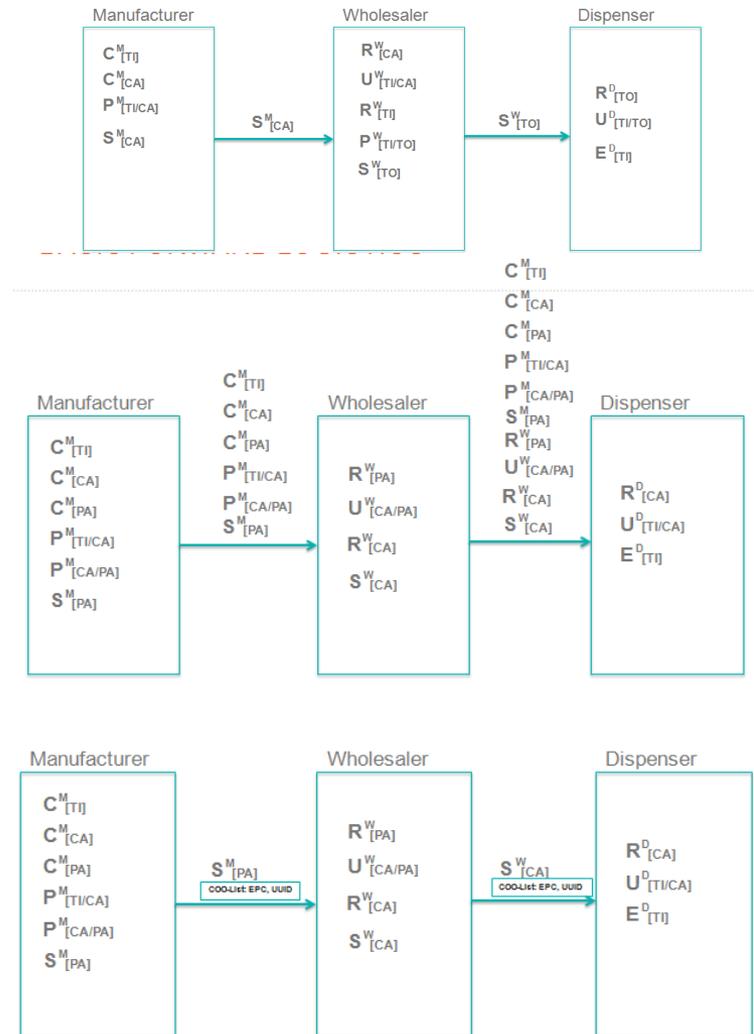
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA

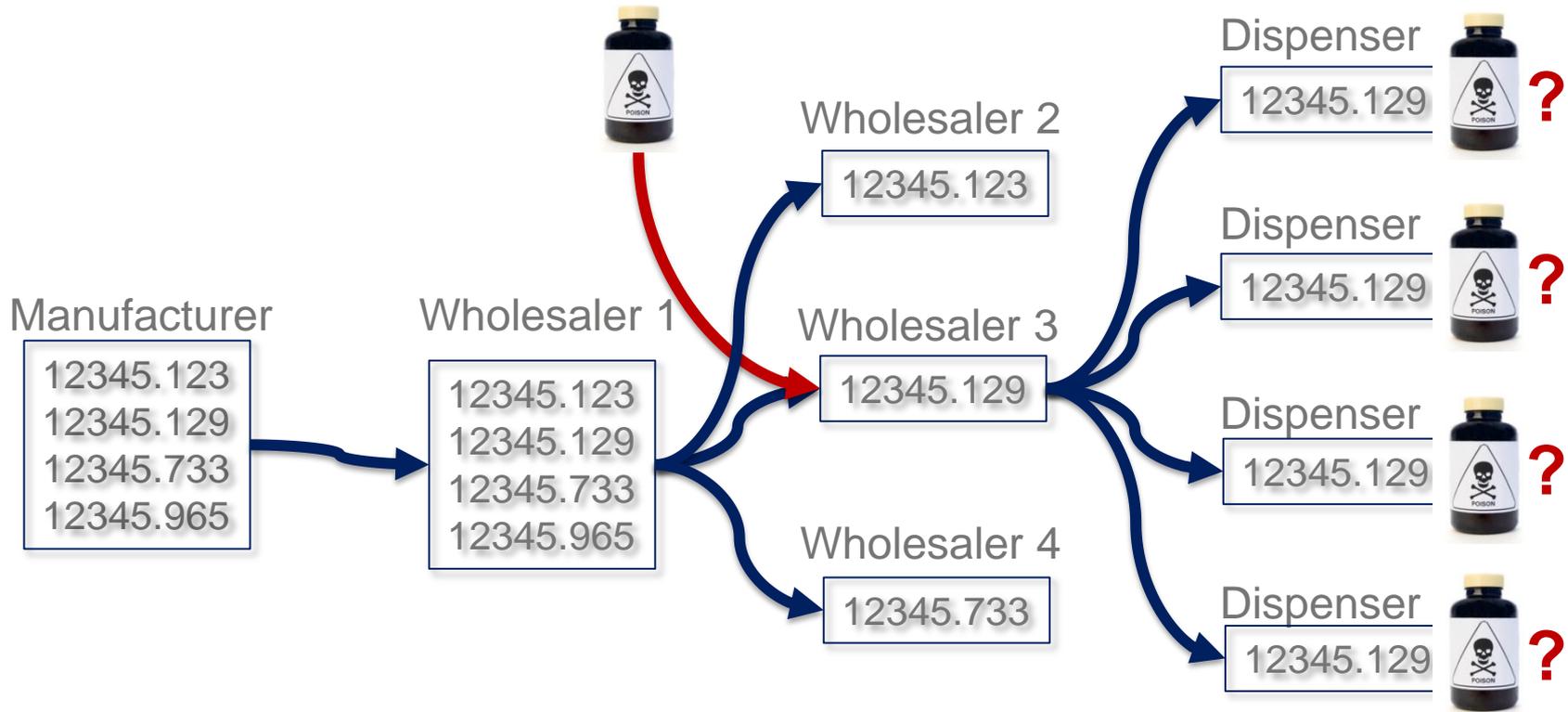
The Rx Guideline v1.0 describes how EPCIS can be used to share pedigree data via supply chain events in a 1 up / 1 down fashion.

We are trying to avoid entirely duplicating DPMS in EPCIS (passing all data redundantly).

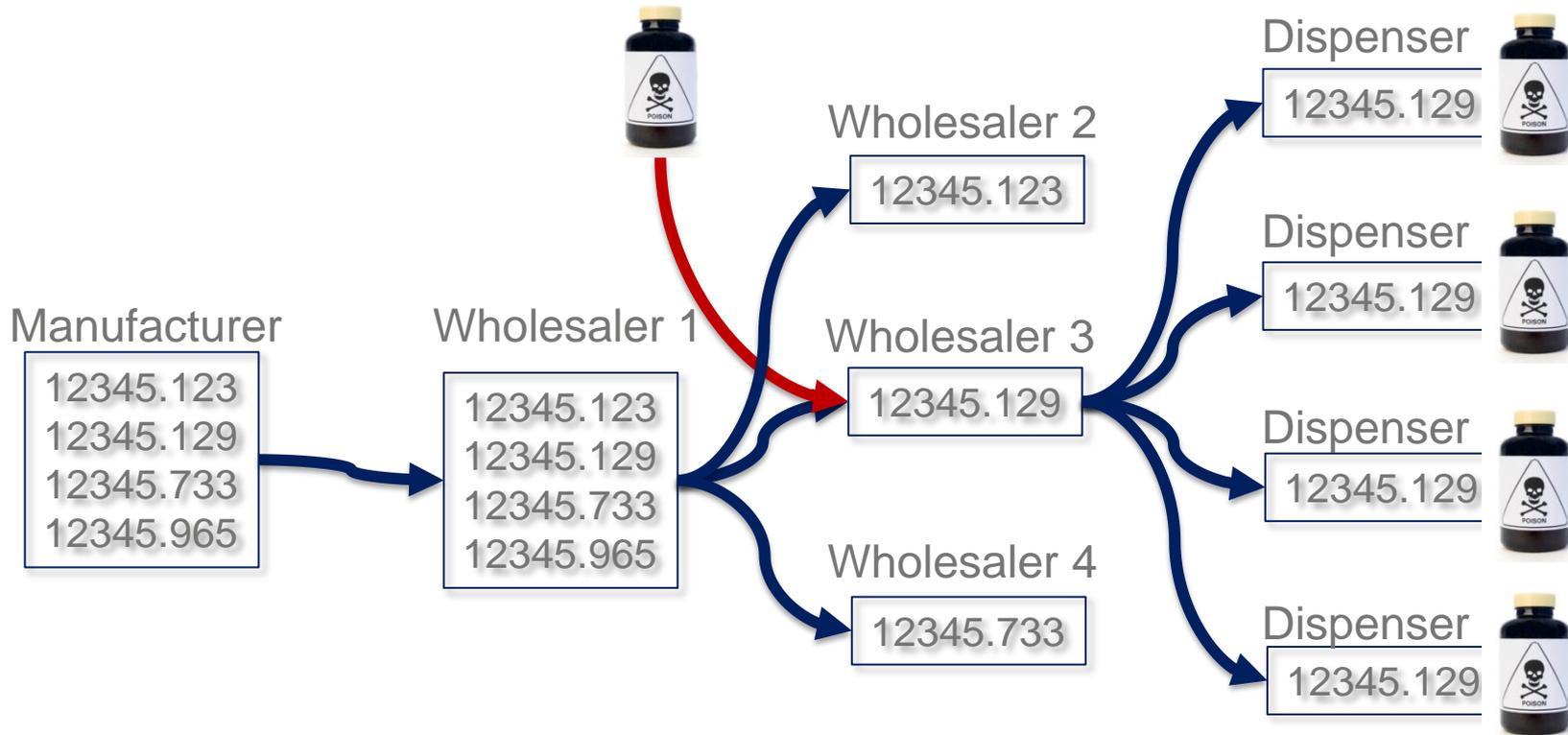
By including a “Breadcrumb trail” or Chain of Ownership list including a minimum set of data and provide the trail back to the manufacturer.



A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

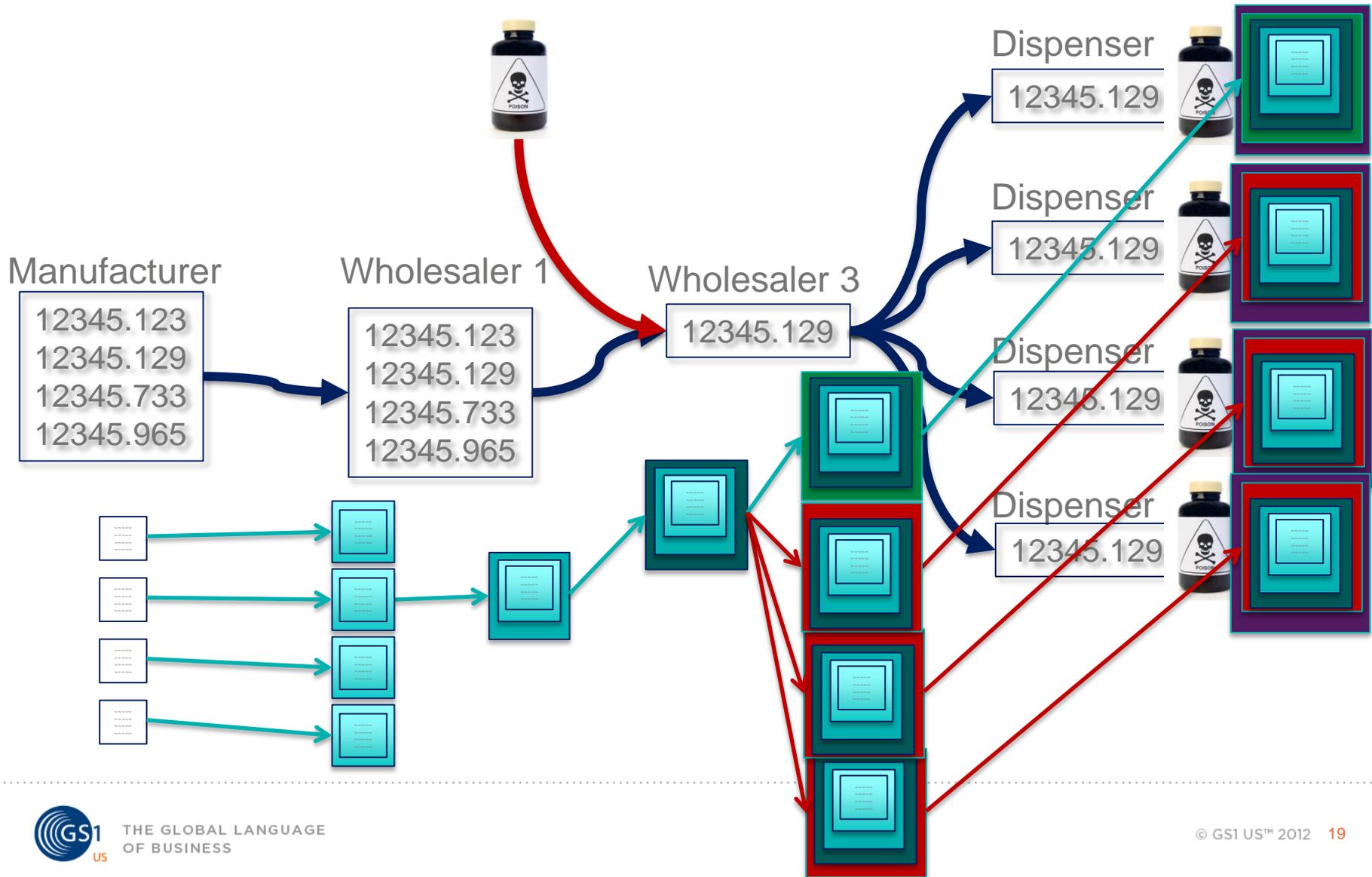


A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN



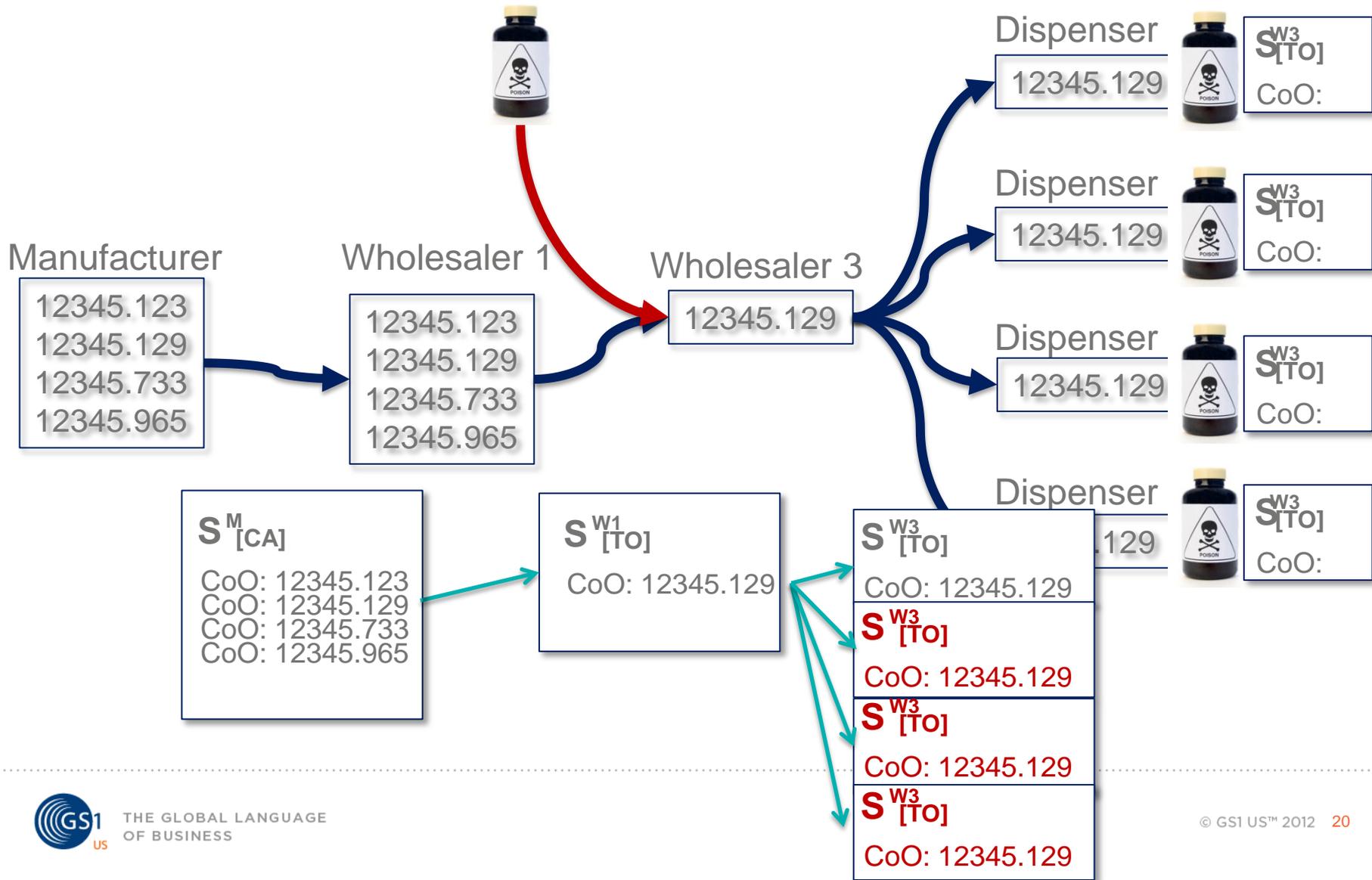
A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

DPMS



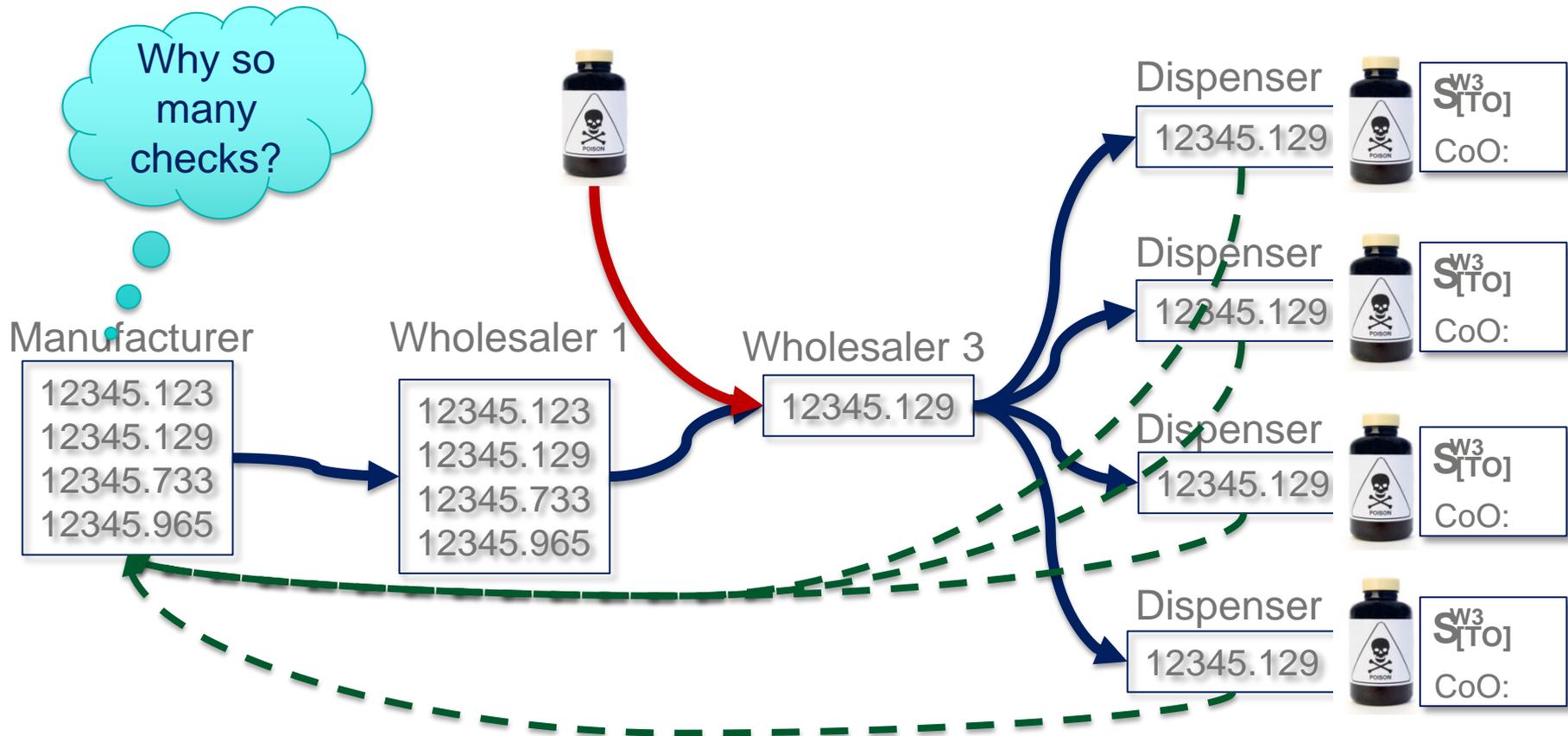
A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

EPCIS

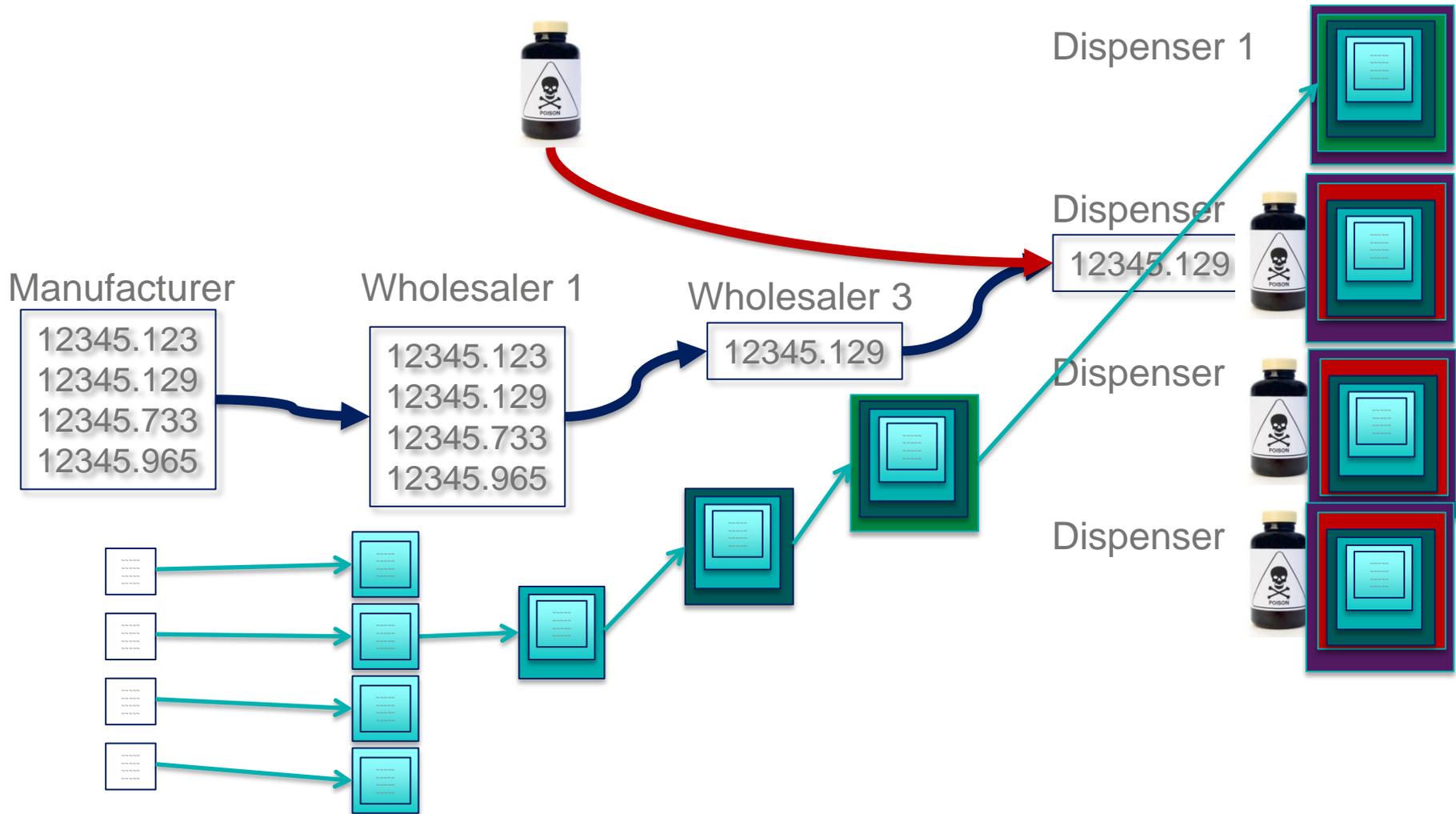


A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

EPCIS



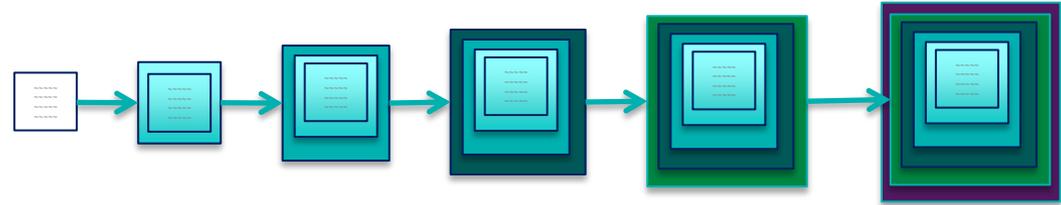
A PHARMACIST PURCHASING OFF THE GREY MARKET



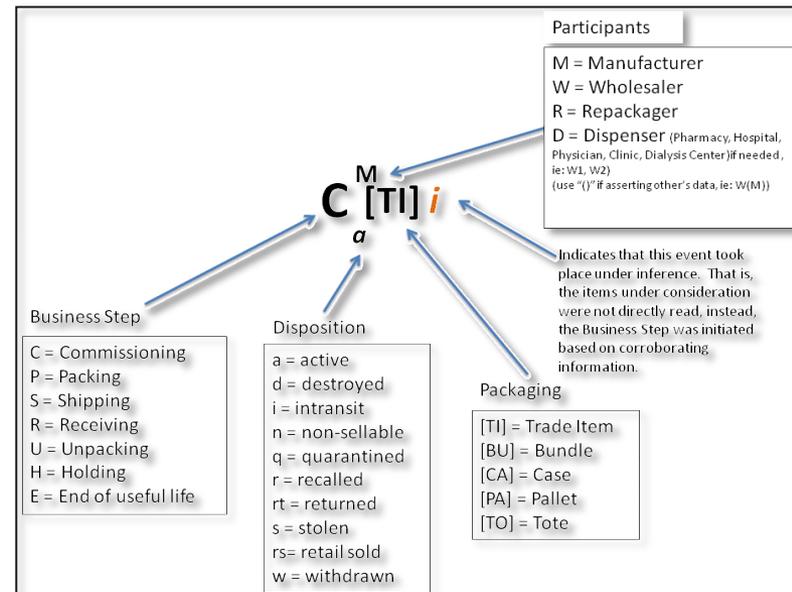
INSPECTION PROCESS

THE INSPECTOR WILL ENCOUNTER THE SAME ISSUES AS THE SUPPLY CHAIN

Pedigrees are document based. Where each trading partner adds their document to the last with no current mechanism for error corrections.



EPCIS is event based. Allowing more flexibility to describe what took place and allows error correction.

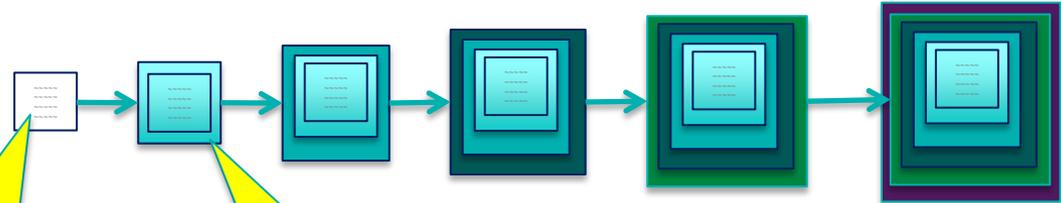


INSPECTION PROCESS

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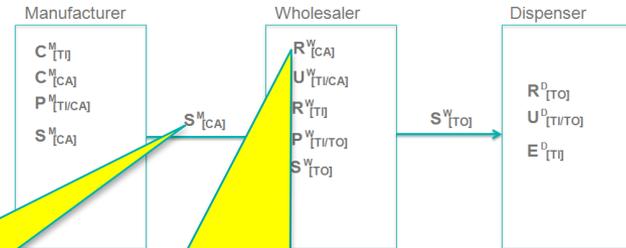
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Main Street, Newark, DE, 19711

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INSPECTION PROCESS

THE INSPECTOR WILL ENCOUNTER THE SAME ISSUES AS THE SUPPLY CHAIN

EPCIS uses independently verifiable IDs



Manufacturer X's EPCIS data:

Transferred By ID:
GLN/0312345123459

Transferred To ID:
DEA/40695843

Wholesaler Y's EPCIS data:

Transferred By ID:
GLN/0312345123459

Transferred To ID:
DEA/40695843

INSPECTION PROCESS

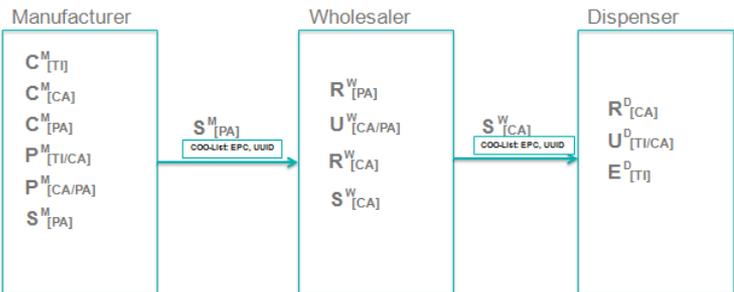
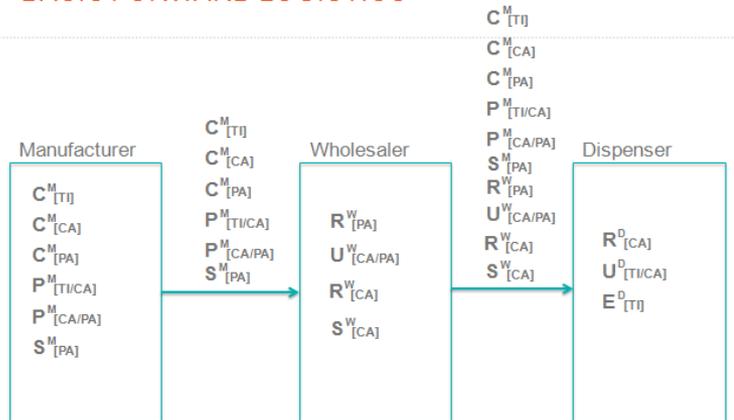
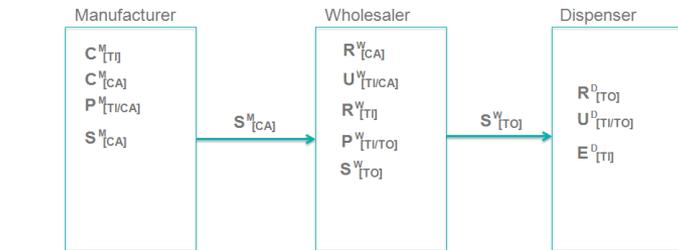
THE INSPECTOR WILL ENCOUNTER THE SAME ISSUES AS THE SUPPLY CHAIN

The Rx Guideline v1.0

describes how EPCIS can be used to share pedigree data via supply chain events in a 1 up / 1 down fashion.

We are trying to avoid entirely duplicating DPMS in EPCIS (passing all data redundantly).

By including a “Breadcrumb trail” or Chain of Ownership list including a minimum set of data and provide the trail back to the manufacturer.



SUMMARY OF EPCIS ADVANTAGES

- Provides comparable security to other business transactions
 - Orders, Invoices, Advance Ship Notices
 - Includes capability to manage exceptions
- Tested in pilots
 - Pfizer / McKesson
 - Abbott / McKesson / VA (via GHX)
- More effective than DPMS
 - Less master data errors
 - Provides auditable data
 - Better suited to supply chain use
- Flexible standard format
 - Valuable information is accessible for other business uses
 - Allows trading partners to expose data only about the actual products traded
 - Can support many architectures (Distributed/Central/Semi-Central)
 - Allows trading partners to choose the amount of data provided to them
 - Publishable set of standard messages and queries

CONTACT INFORMATION

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1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648 USA

T +1 609.947.2720

E rceleste@GS1US.org

www.GS1US.org

Connect with the GS1 US community on





THE GLOBAL LANGUAGE OF BUSINESS

EPCIS BASED PEDIGREE DATA



EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



A Pedigree currently calls for:

Trading partners to send full sets of data on the product, companies or locations, certifiers and production run (exp date and Lot#).

PRODUCT DATA

NDC OR GTIN REPRESENT THE FULL SET OF PRODUCT DATA

- NDC: 1234-5678-90
 - Name: Product FG, 100 ct 10MG Tablets
 - Desc: 100ct bottle of Product FG, 10MG Tablets
 - Strength: 10, UOM: MG
 - Dosage Form: Tablet
 - Container Size: 100, UOM: ct
- NDC: 1234-5678-90
 - Name: Product FG, 100 ct 10MG Tablets
 - Desc: 100tab bottle of Product FG, 10MG Tablets
 - Strength: 10, UOM: MG
 - Dosage Form: Tablet
 - Container Size: 100, UOM: ct
-

COMPANY DATA

GLN, SGLN, DEA, ETC.

Address Types:

- Business Location
- Transferred By
- Transferred To
- Ship From Location
- Ship To Location

Attributes:

- Name:
- Street Address:
- City:
- State:
- Zip:
- Country:

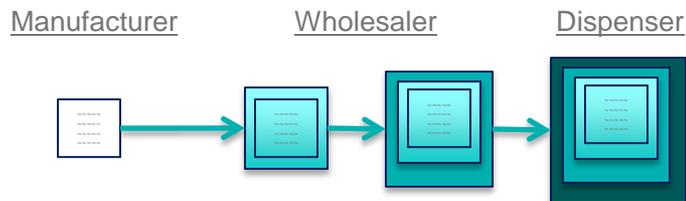
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A Pedigree currently calls for:

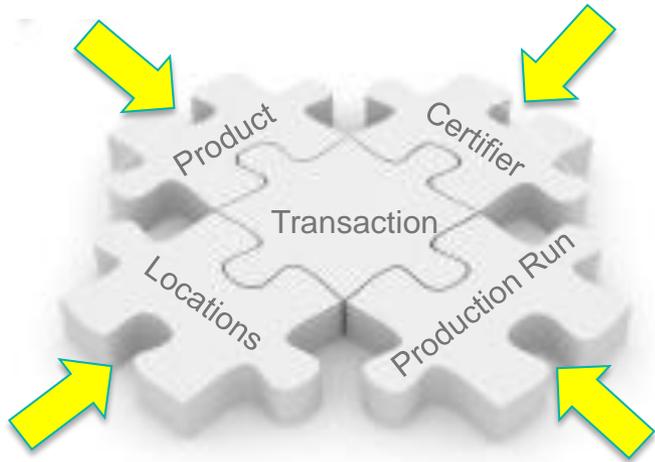
Trading partners to send full sets of data on the product, companies or locations, certifiers and production run (exp date and Lot#).



... and for each subsequent trading partner to append their own pedigree data.

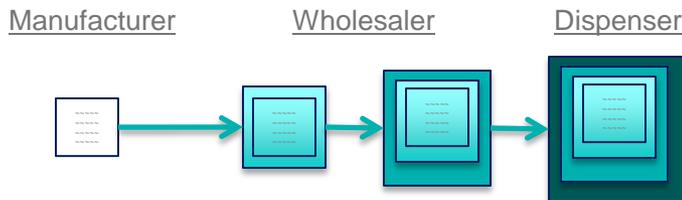
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



The result is that ...

The majority of data in a pedigree is repeated again and again, for each trade item in a shipment (ex: each bottle in a case or pallet).



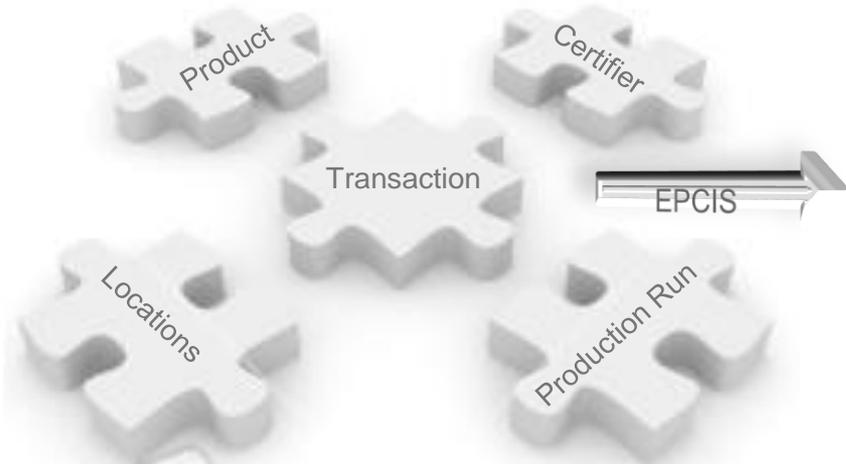
... this repetition is magnified as each trading partner adds their data to the pedigree.

Burdening the partners that are most likely least able to manage large amounts of data.

Challenging for inspection purposes.

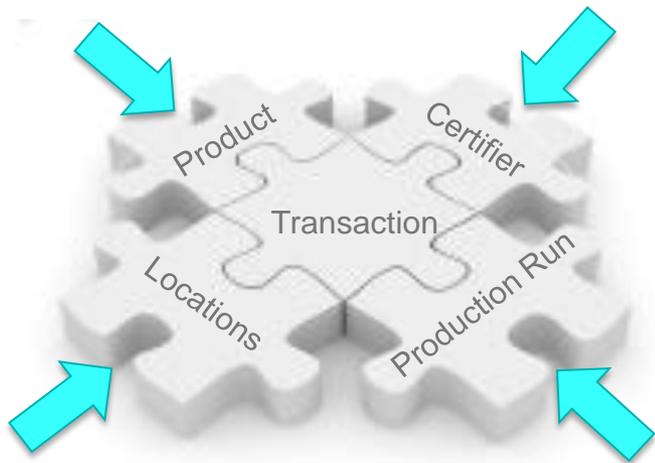
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



Using EPCIS,

The repeated data can be shared and managed separately ...



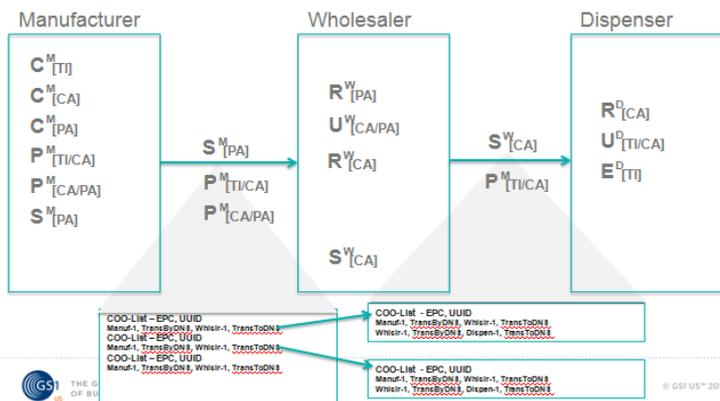
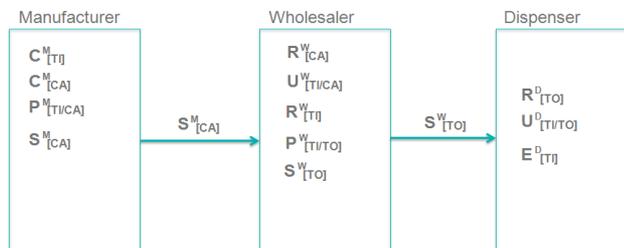
... and the associated data can be accessed when needed.

EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA

EPCIS events ...

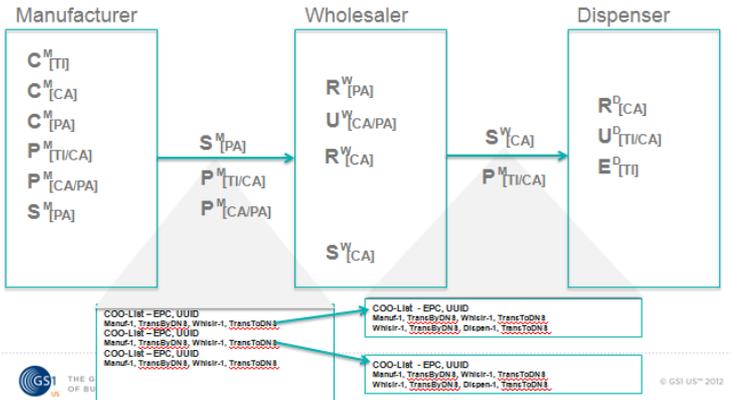
Can be used to collect pedigree data and share it with trading partners in a 1-up/1/down model



Can be extended to provide a Chain of Ownership List”.

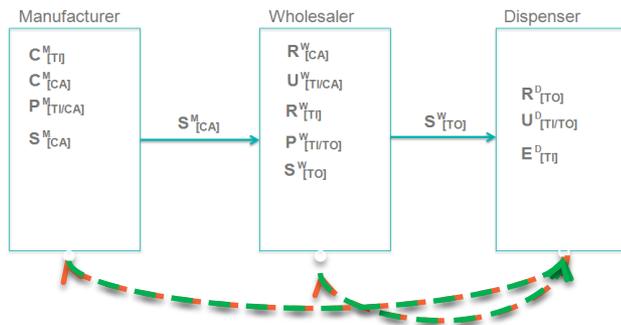
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



Using the Chain of Ownership List ...

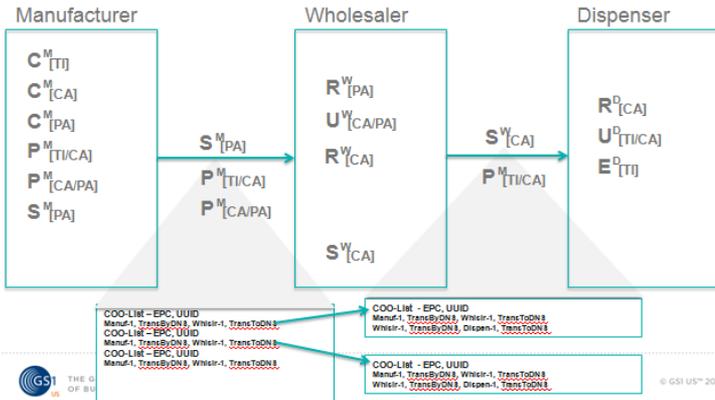
Companies have an immediate view into where an item has been in the supply chain.



... and, if needed, pull forward the full set of pedigree data.

EPCIS BASED PEDIGREE DATA

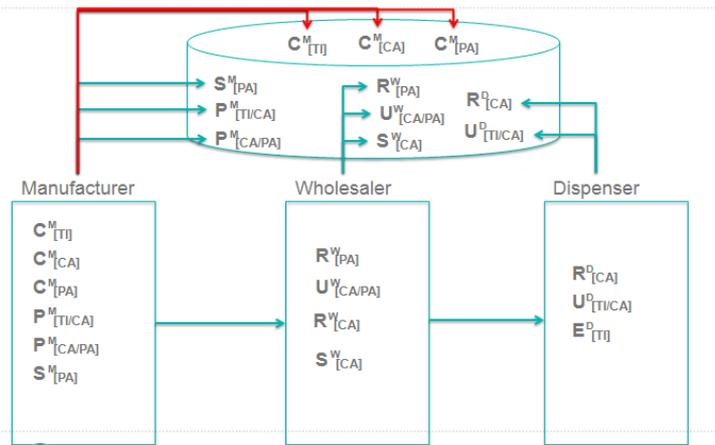
AVOIDING SENDING MASSIVE DUPLICATION OF DATA



EPCIS events can be used with ...

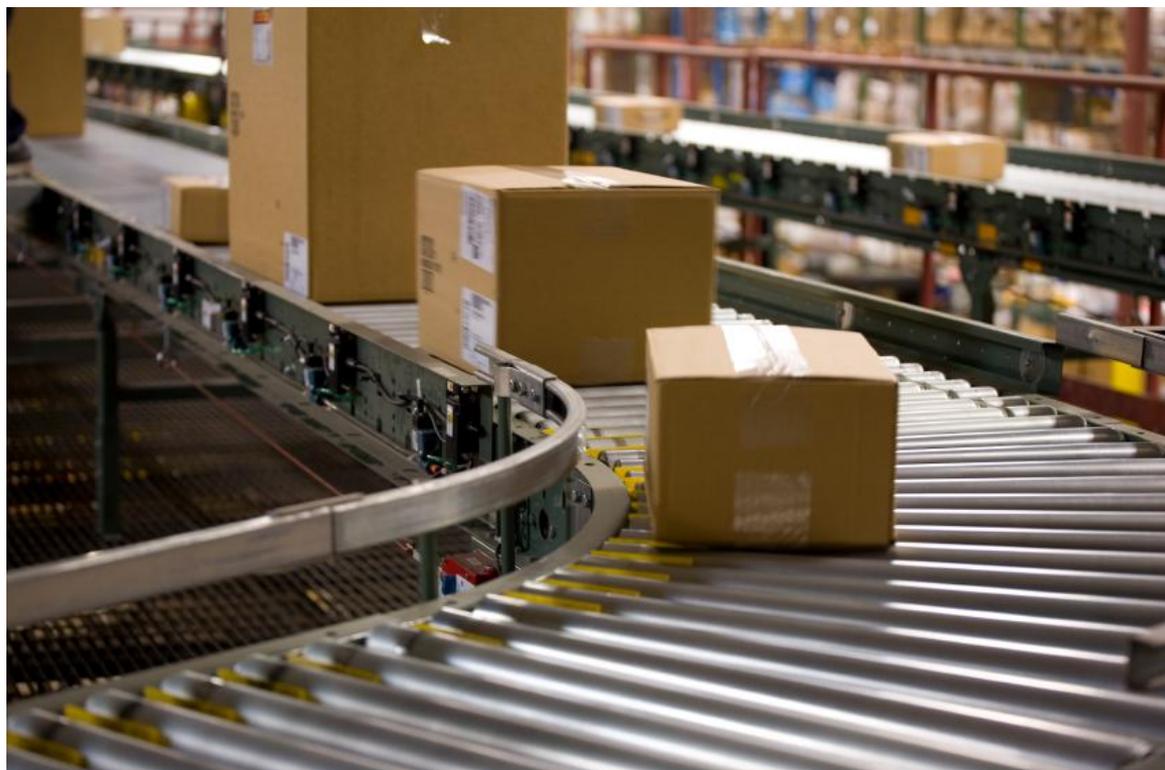
Distributed Architectures (each company holds their own data).

... and, Central and Semi-Central Architectures (each company contributes their data to one or more locations).

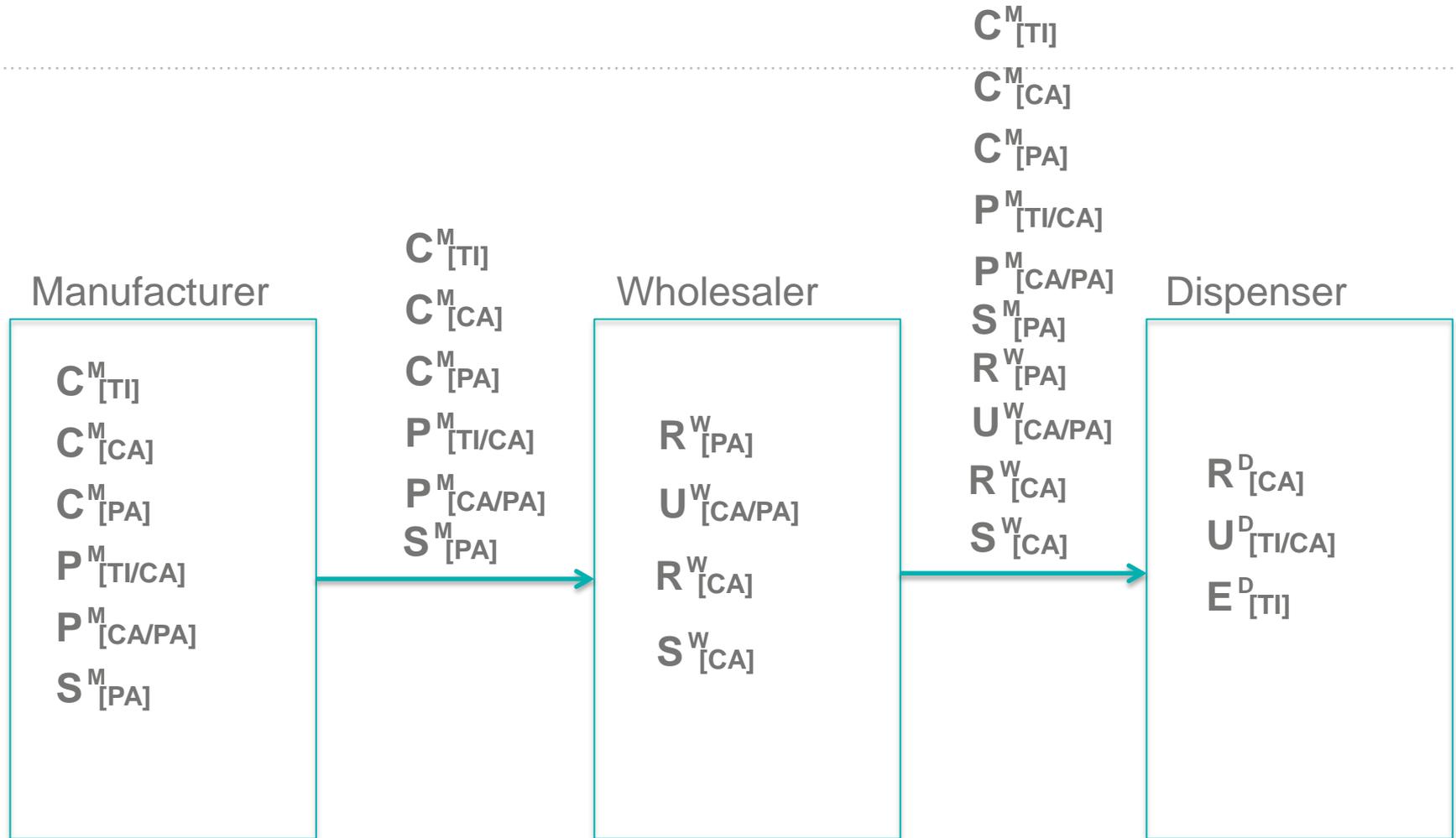


SERIALIZATION / TRACK & TRACE

THE CHALLENGE IS:

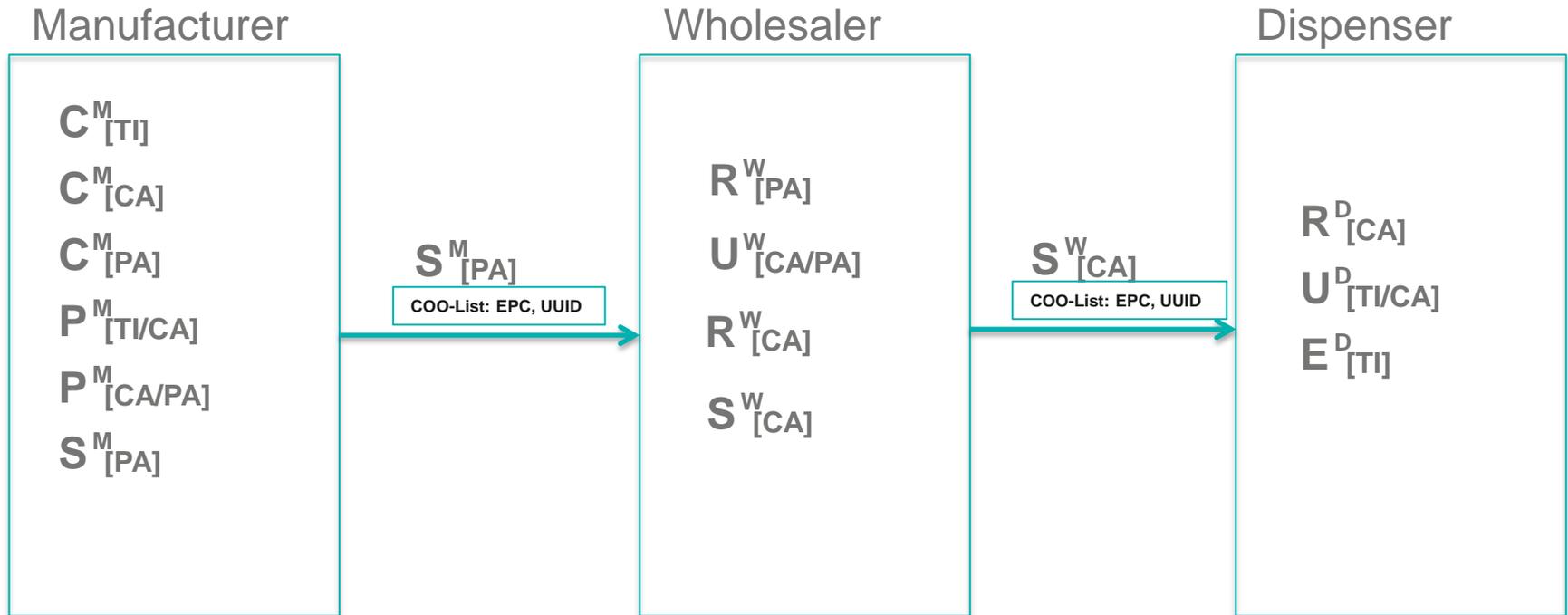


THE EQUIVALENT OF RECREATING DPMS IN EPCIS



EPCIS BASED PEDIGREE DATA

THE USE OF CHAIN OF OWNERSHIP LISTS



EXAMPLE:

CHAIN OF OWNERSHIP LIST DATA

COO-List: urn:epc:id:sgtin:030001.0012345.10000001003, urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6

•Key1

- **TransBy:GLN/** 0300011111116
- **TransByDNS:** www.Manuf-1.com
- **TransTo:DEA/** 12386549
- **TransToDNS:** www.Wholesaler-2.com

•Key2

- **TransBy:DEA/** 12386549
- **TransByDNS** www.Wholesaler-2.com
- **TransTo:GLN/** 0312311111114
- **TransToDNS:** www.Dispenser-1.com



CALIFORNIA STATE
BOARD OF PHARMACY

Scenarios for complying with California Board of Pharmacy (BoP) e-pedigree



Introduction

- Serialization/Traceability projects with 18 global life sciences companies.
 - Over 30 years of industry experience.
 - Plus dozens of projects with life sciences companies and validated systems spanning 20 years.
 - Over 10 years working with many of the world's largest companies on logistics and supply chain systems.
- Consultant specializing in solutions for global drug serialization, traceability and supply chain, including:
 - strategy,
 - requirements,
 - vendor selection,
 - pilots and
 - Implementation
- I don't sell hardware or software.
- Member GS1 US Healthcare.
- Certified GS1 Professional.





Today's Presentation

- Provide scenarios for selecting 50% of products for 2015 per 4163.5. (Pedigree Requirement Implementation Date).
- Discuss inference quantity of 48 items.
- The objective is to provide the basis for a future document from the State of California Board of Pharmacy (BoP) with scenarios to help avoid misunderstandings.





Unforeseen downturn

- The manufacturer submits its report in December 2014 in good faith.
- An unforeseen event prevents the company from meeting its commitment to California because products it thought would make up the 50% did not sell as well as expected.
- What is the ramification?





Pedigree goes nowhere

- The manufacturer produces serialized goods and ships them to wholesaler.
- Wholesaler is not yet required to accept pedigree.
- What does the manufacturer do with the pedigree before the wholesaler begins to accept pedigree?
- Will the BoP expect to observe a serialized item in California in 2015 and ask to see the manufacturer's pedigree?





Inventory

- Manufacturer produces products in early 2014 that may not be shipped from their warehouse until early 2015.
- If those items are among the 50% designated for serialization in 2015, can they still be shipped into California because they were packaged and in inventory at the manufacturer before 2015 even if not serialized.





Unit volume

- Specialty Manufacturer of high price low volume products selects to designate the 50% based on Unit volume.
- For all items shipped into California, 50% of the items sold in 2015 will be serialized and 50% will not be serialized.
- The company will ship all products as un-serialized for the first 6 months of 2015 and will ship serialized goods for the remainder of the year to ensure the total 2015 volume includes 50% serialized items.
 - May be applicable to specialty biologics.





Product package (SKU) type

- Company has 100 Stock-keeping Unit (SKU).
- It will designate 50 SKU for serialization
- The 50 SKU makeup 1% of sales into California?
---- OR ----
- The 50 SKU makeup 1% of volume?





Drug product family.

- The manufacturer has 10 Brands (Product Family)
- The company will designate 5 brands to be completely serialized before 2015.
- The 5 brands makeup 1% of sales into California?
---- OR ----
- The 5 brands makeup 1% of volume?





SKU Volume selection

- Manufacture identifies specific Stock-keeping Unit (SKU) that make up 50% of its annual unit projected volume into California.
 - They commit to serializing all of the defined SKU before January 1, 2015,
 - They report the SKUs to California in December 2014.
- Sales in 2015 are not what was expected and the actual sales into California for the SKUs was only 10% of annual volume.





Inventory of un-serialized goods

- Manufacture identifies specific Stock-keeping Unit (SKU) that make up 50% of its annual unit projected volume into California.
 - if they have inventory of un-serialized goods in the defined SKUs in inventory on December 31, 2014, can those un-serialized goods still be shipped into California.





Trade Information

- A manufacture ships 50 cases per pallet.
- When they ship to a wholesaler they will send 50 separate e-pedigree files, one for each case.
- This is done to avoid sending the information relating to the full pallet shipment through the supply chain.
 - Since the Drug Pedigree Messaging Standard (DPMS) pedigree is a nested file containing the original shipment.





Inference quantity

- Some companies package cases of 100 items or more.
- A more practical limit may be 200 items in a single sealed container.
- Although the vast majority of shipments of pallets of goods beyond the first recipient from a manufacturer are rare, the rule implies that pallets of cases can never be inferred, so wholesalers must always scan cases on pallets.





Inference

- Since all items will be scanned in their saleable unit form before dispensing,
 - Why not allow any size of container? If the items are not what are recorded on the pedigree, they will have to be returned and will not be dispensed.
 - How would a patient be harmed if all items are scanned before being dispensed?
 - How would the Board of Pharmacy (BoP) investigation be hindered if items in a sealed case do not match the pedigree? The provider of the items would be responsible and the items would not be dispensed until scanned into inventory and pedigree confirmed.





Feel free to contact us.

Questions? Need More Information?



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