



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

June 24, 2013

To: Members, E-Pedigree Committee

Subject: Subject Memorandum for the June Meeting

I. Next Scheduled Meetings of the E-Pedigree Committee for 2013

Mark your calendars:

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

II. Presentation by TechN'Arts

Turkey has implemented a unit serialization e-tracking system for prescription drugs, somewhat similar to California's requirements. At this meeting, Taha Yayci will provide an overview of the requirements of Turkey's system, and how the system has operated.

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

Attachment A

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.

At the request of President Weisser, the board submitted comments on both versions of the legislation. These letters are provided in **Attachment A**.

IV. 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 B

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 B**):

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 is currently undergoing review by the State and Consumer Services Agency. 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 this review process fully completed by September.

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

Attachment C

At the board's last e-pedigree meeting, GS1 presented their new implementation guideline. This guideline has been agendaized for this meeting to ensure interested parties are aware of its availability.

Although it takes about 100 pages to lay out the standards, the material is valuable in providing considerable background about tracking and tracing.

VI. Presentation by GS1 on Using EPCIS to Support E-Pedigree Requirements

During this part of the meeting, GS1 will provide a presentation to show how [EPCIS can be used to support Pedigree requirements](#).

VII. Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

Time has been 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.

VIII. Discussion to Develop Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163

Attachment D

At this meeting, the committee will hear comments and 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. 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 is provided as **Attachment D**.

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

At this meeting, the committee will work on this regulation proposal for inference.

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

Attachment E

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 E**. 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 D**.

The committee will discuss and refine these two draft proposals during the June meeting.

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

Attachment F

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 (see **Attachment F**).

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 F**.)

During this meeting, the committee needs to continue 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 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.”

XI. Additional General Discussion

XII. Closing Comments

Agenda Item III.

Attachment A



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.

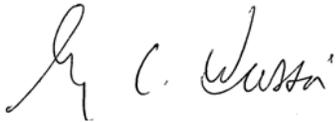
We also believe that the endpoint should be a national end-to-end track-and-trace system that is worthy of any additional delay, and adequate to replace the California model. We believe the necessary components of any such system include: participation by *all* industry partners; in passing and receiving 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

Agenda Item IV.

Attachment B

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.

Agenda Item V.

Attachment C

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.

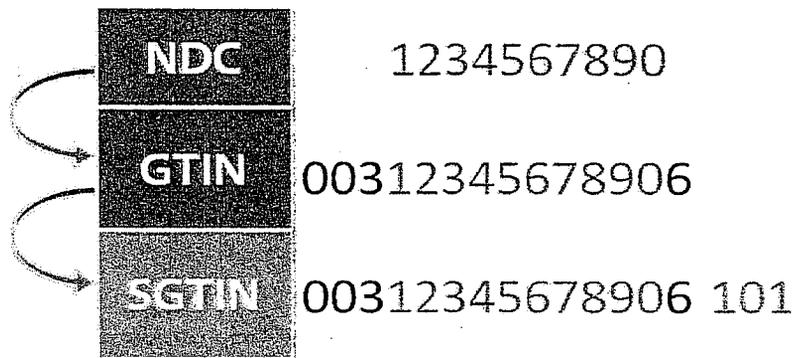


Figure 1: Relationship of the NDC, GTIN and SGTIN

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

① 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.

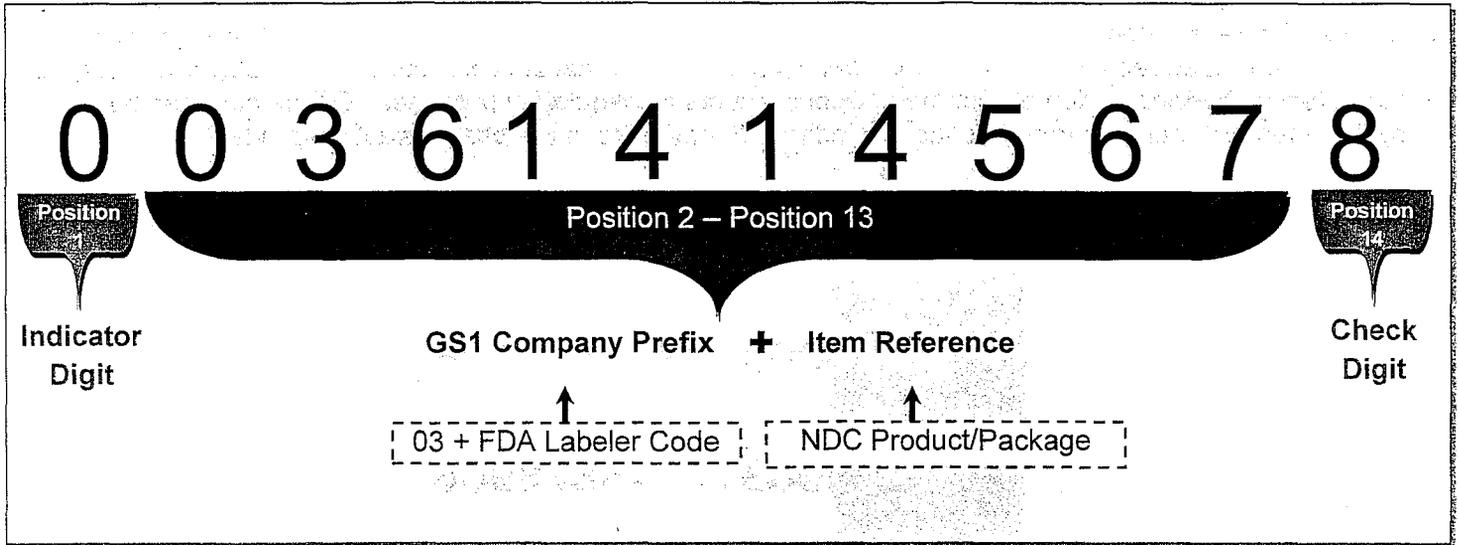


Figure 2: Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN “00361414567894”)

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 <u>or</u> 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**.)

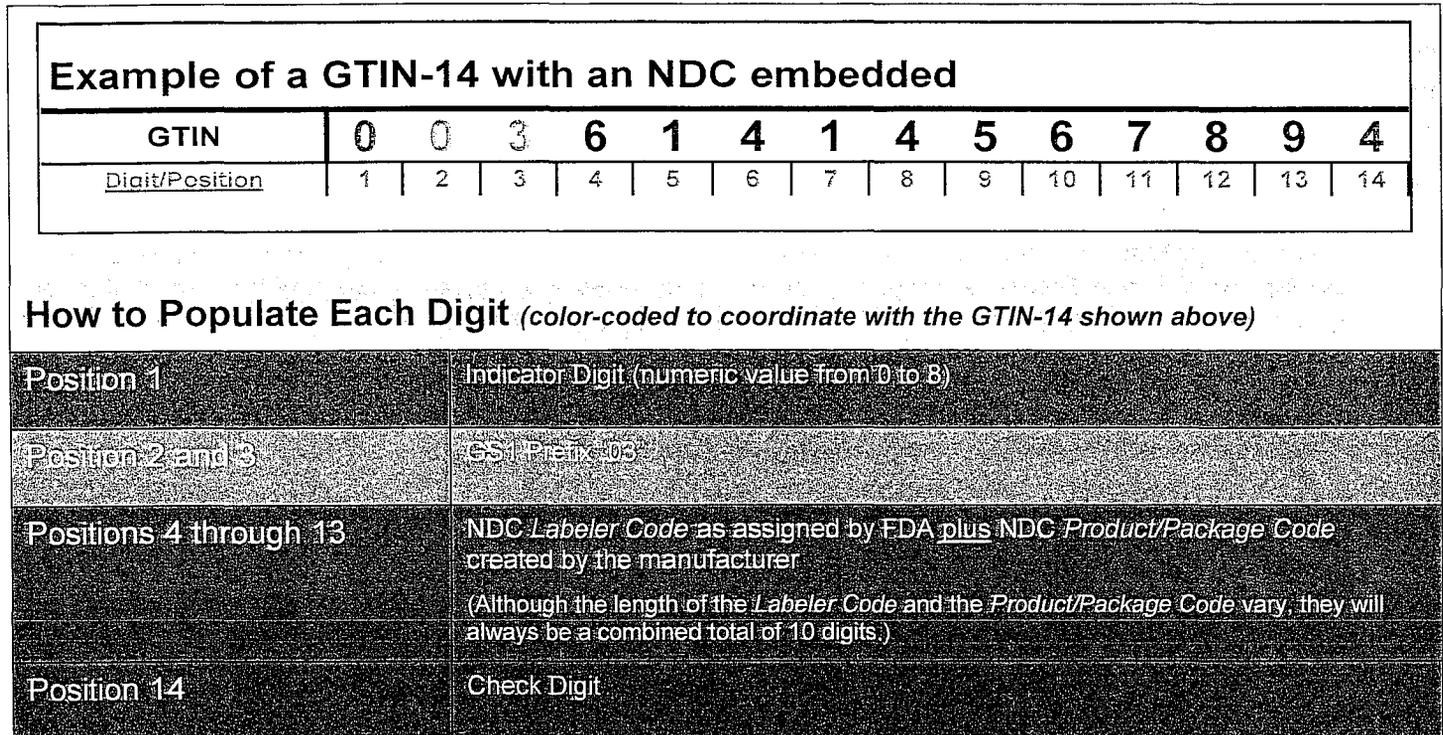


Figure 4: Populating the 14 digits of a GTIN-14 with an NDC embedded

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:

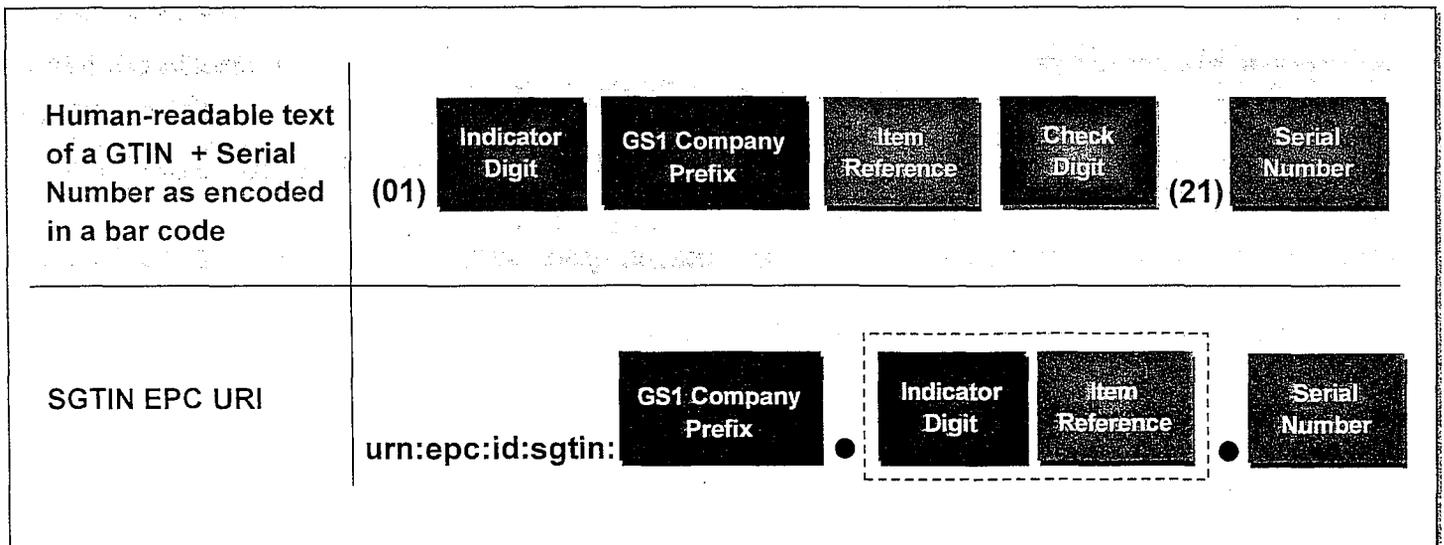


Figure 5: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format



- 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 (<i>color-coded to coordinate with the SSCC shown above</i>)	
Position 1	Extension Digit (numeric value from 0 to 9)
Positions 2 through 17	GS1 Company Prefix as assigned by GS1 US <u>plus</u> 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:

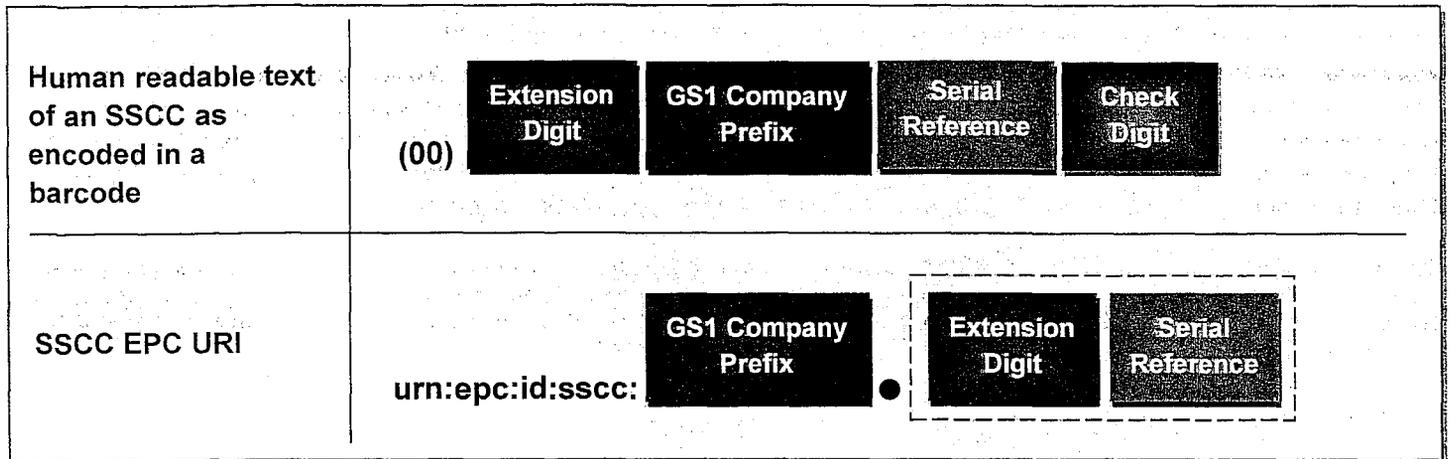


Figure 7: How the segments of an SSCC are represented in the SSCC EPC URI format

- 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.

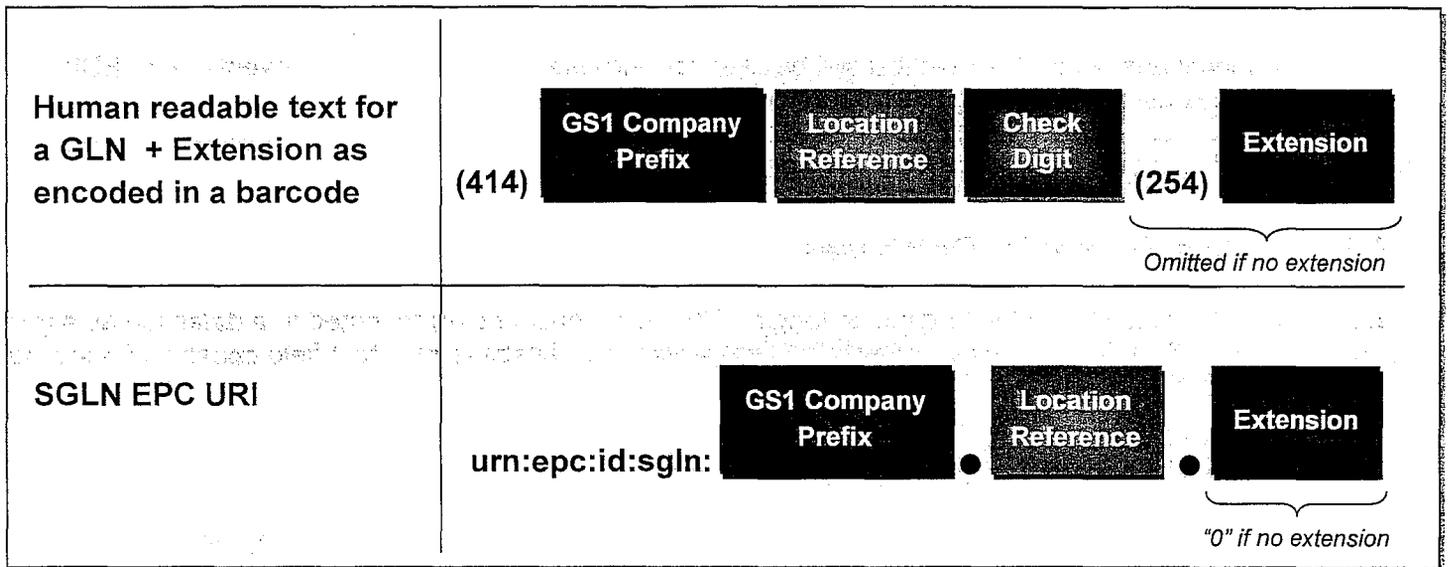


Figure 9: How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format

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 digitstext field (not numeric)
GLN Extension	<ul style="list-style-type: none">1-20 characterstext 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 extension2 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										
Encode the GS1 Identifier (GTIN or SSCC) first. Encode any optional data (such as batch/lot number, expiration date, serial number, etc.) following the identifier. NOTE: Although parentheses and spaces appear in the human readable text accompanying the barcode, these characters are not encoded in the barcode itself.	 <p>(01) 00314141999995 (10) 987654321GFEDCBA</p>										
For the most efficient encoding, ensure that fixed-length AIs precede variable-length AIs.	 <p>(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></p>										

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:

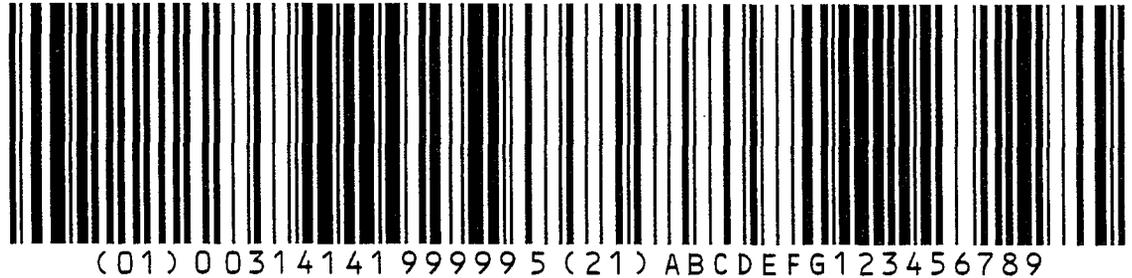
GTIN	<ul style="list-style-type: none"> Begin with the two-digit AI (01) to indicate GTIN. A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI. <ul style="list-style-type: none"> For GTIN-12: encode in 14-digit format using two leading zeros The data syntax for the 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

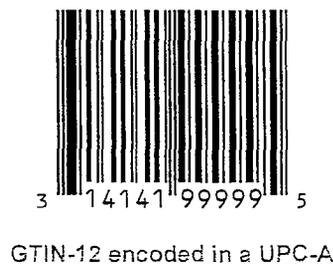


① Marking Products with Both UPC-A and GS1 DataMatrix

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).

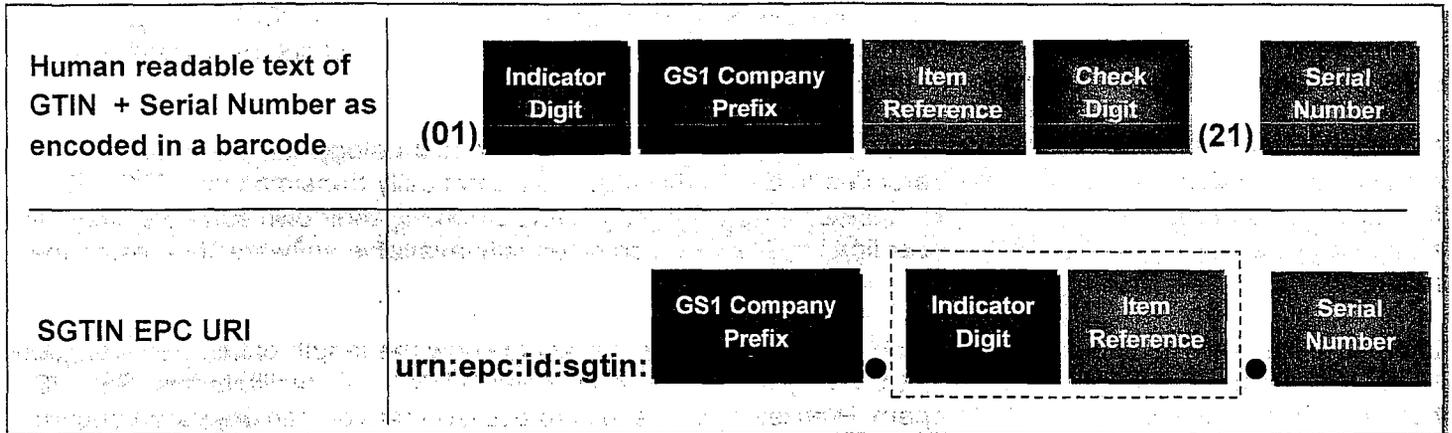


Figure 14: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format

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.

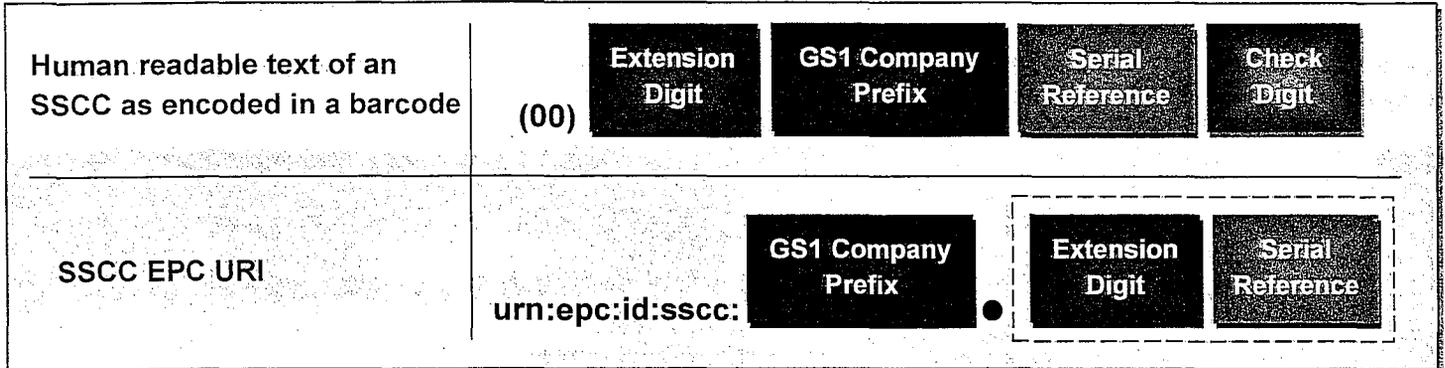


Figure 15: How the segments of an SSCC are represented in the SSCC EPC URI format

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*.

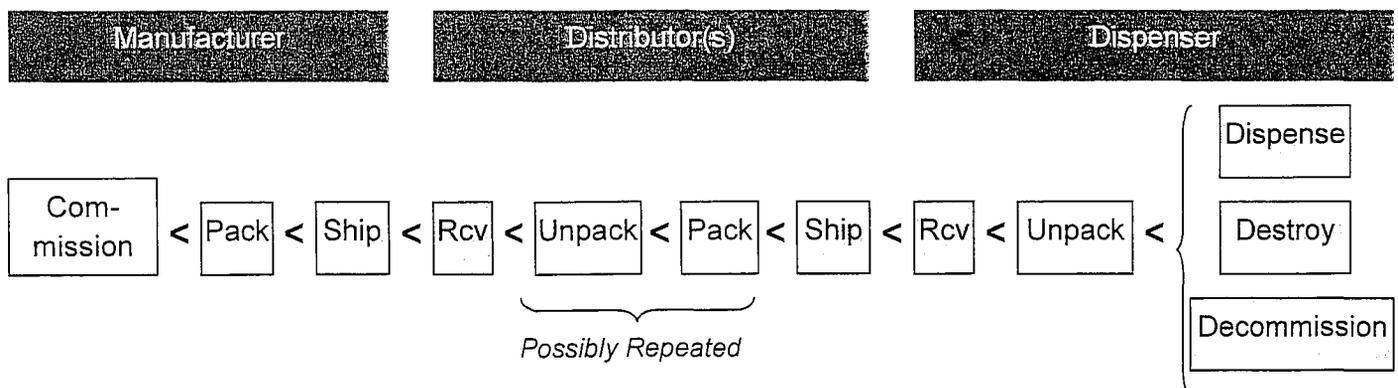


Figure 16: Event Time Relationships for Pedigree Purposes

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 **transferredById** or **transferredTold** extension to a shipping or receiving event (whichever party created the transaction). Namely, the *Business Transaction identifier* shall match the **transferredById** for an invoice, and the **transferredTold** for a purchase order. (See Section 17.3 for the definition of **transferredById** 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.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: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:030001111116: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">030001111116</gslushc:transferredById>
          <gslushc:shipFromLocationId type="GLN">030001111116</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:bt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction type="urn:epcglobal:cbv:bt: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.

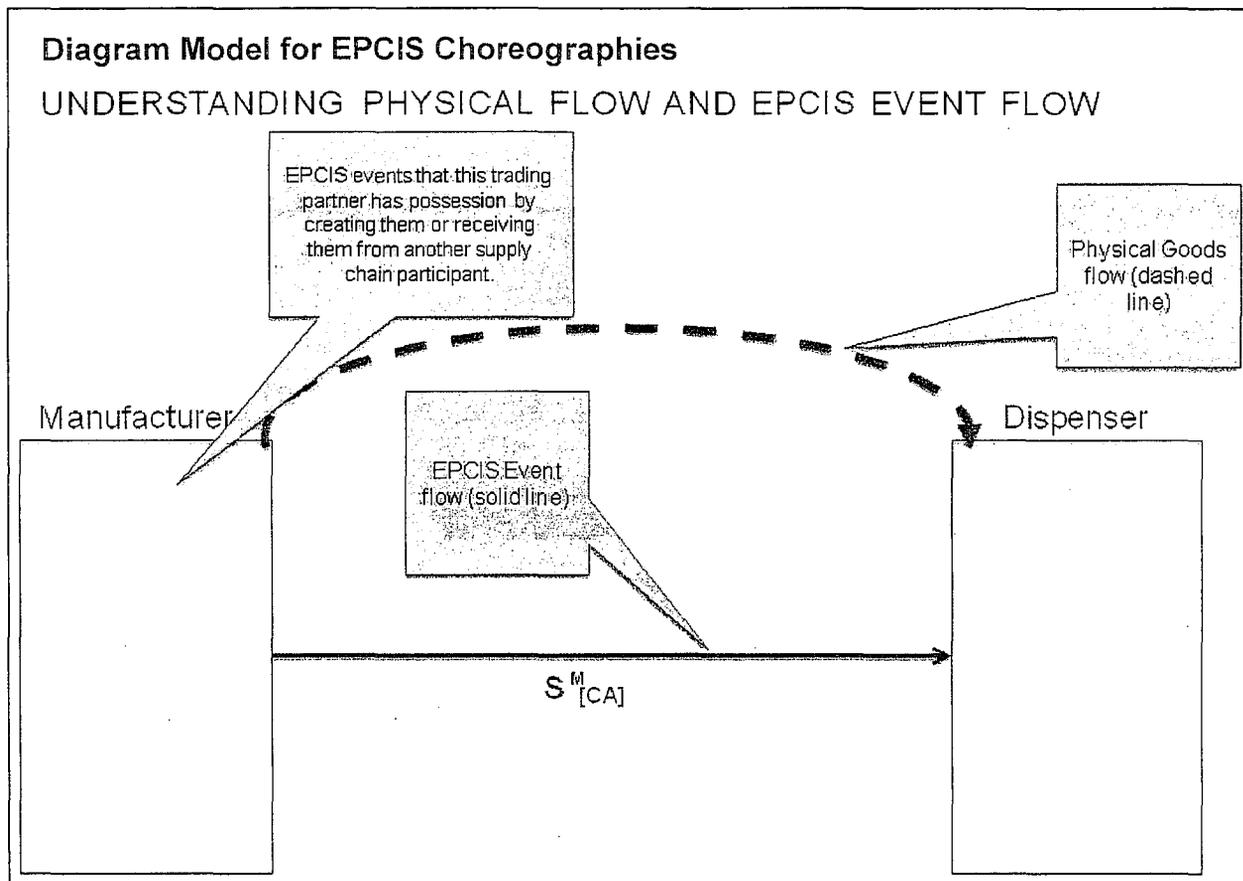


Figure 17: Model for EPCIS Choreography Diagrams

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.

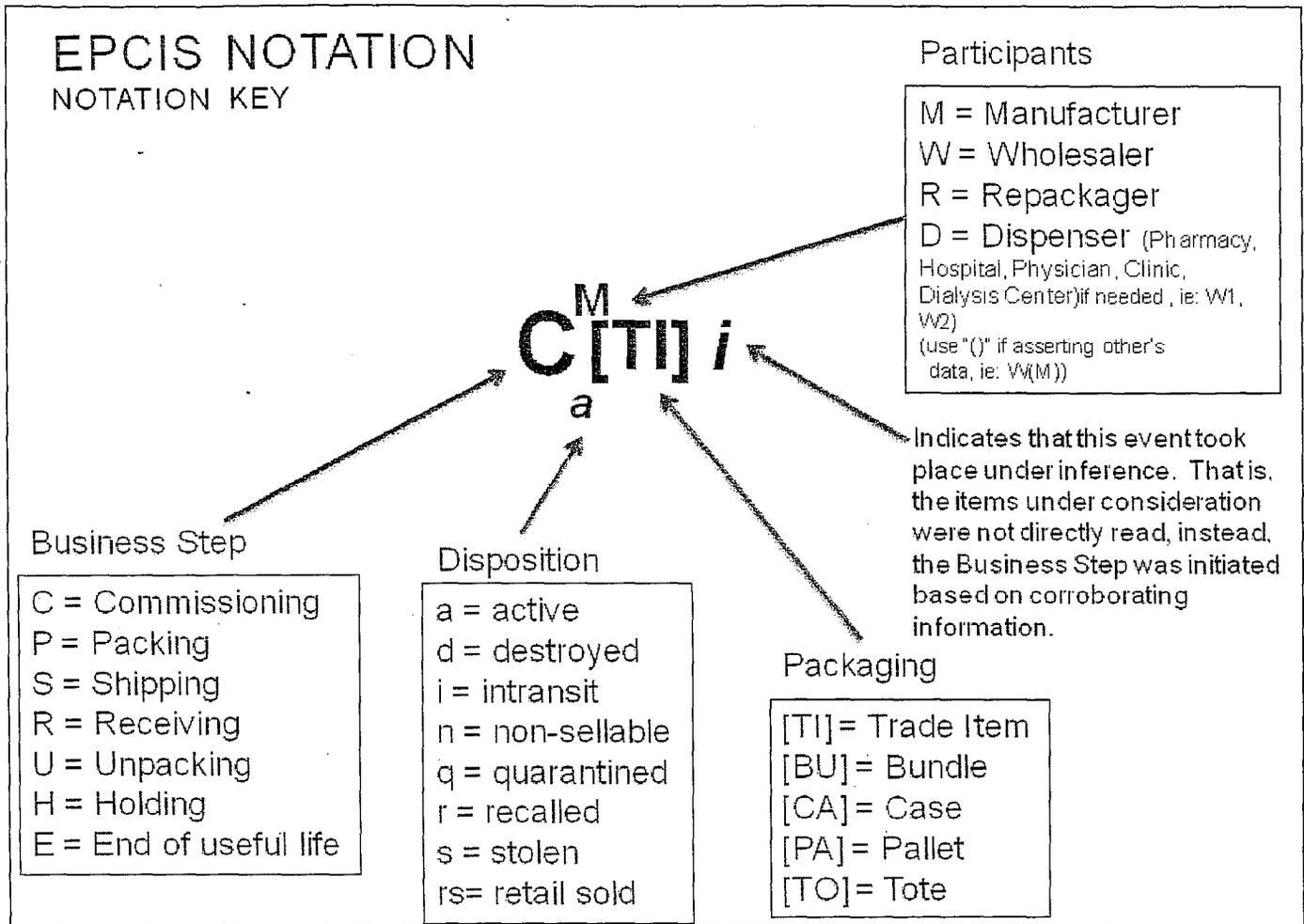


Figure 18: Shorthand Notation for Depicting EPCIS Events

ⓘ 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.)

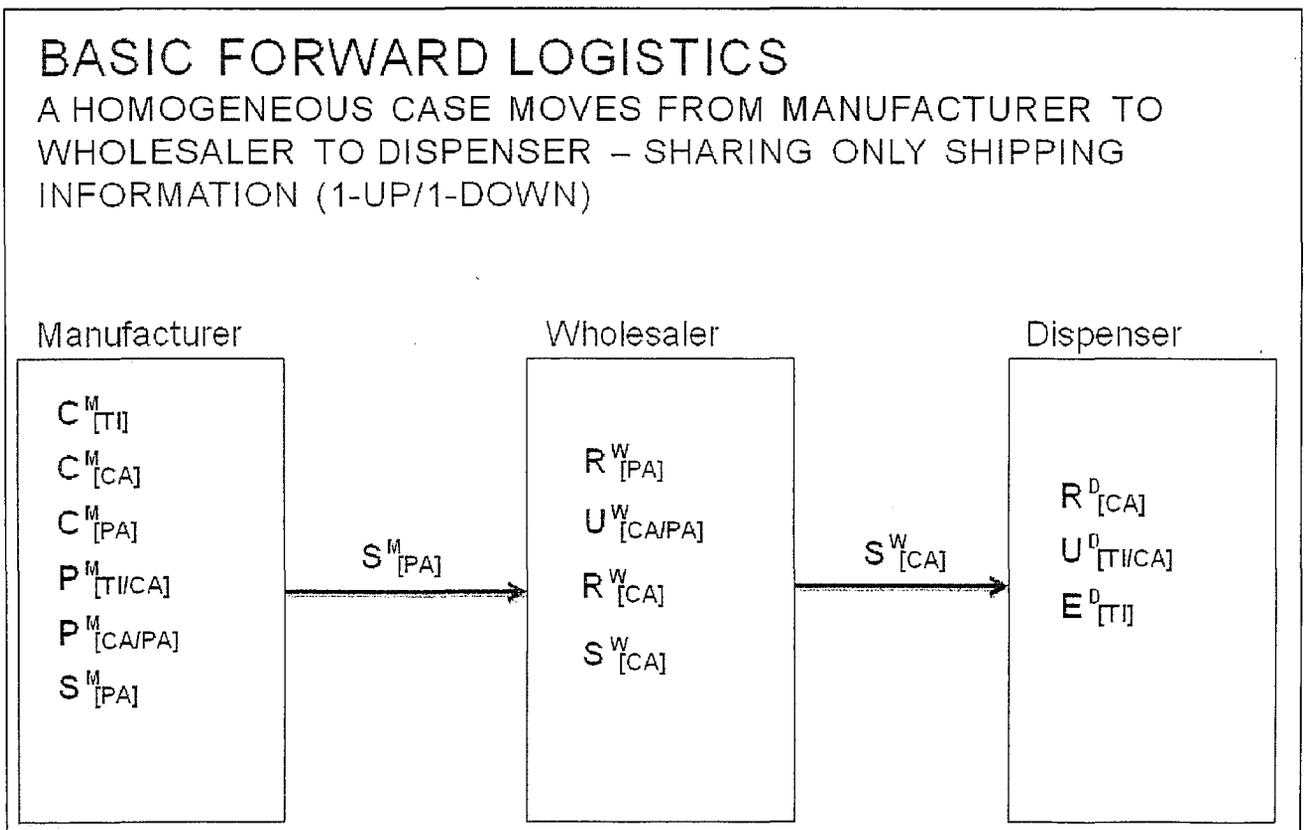


Figure 19: Ship full case through supply chain -- sharing *Shipping* events only

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.

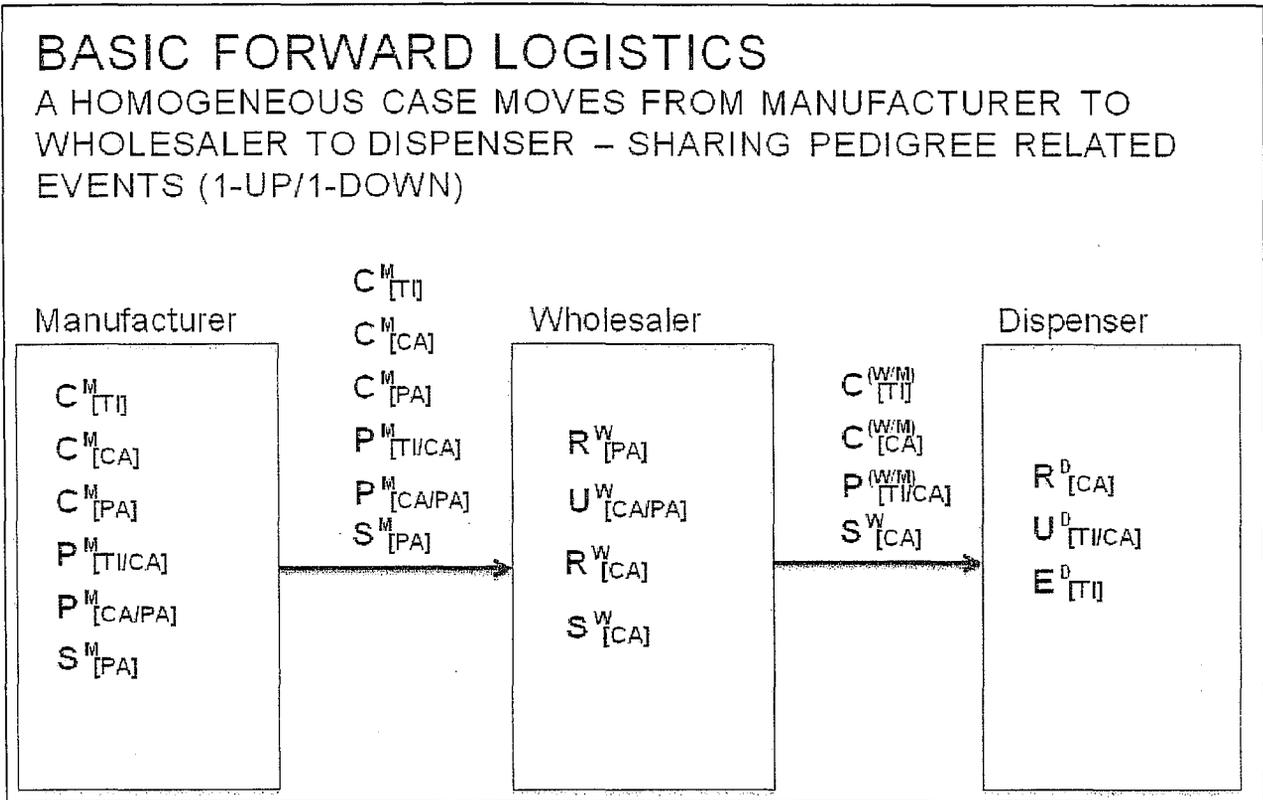


Figure 20: Ship full case through supply chain -- sharing *pedigree-related events*

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.)

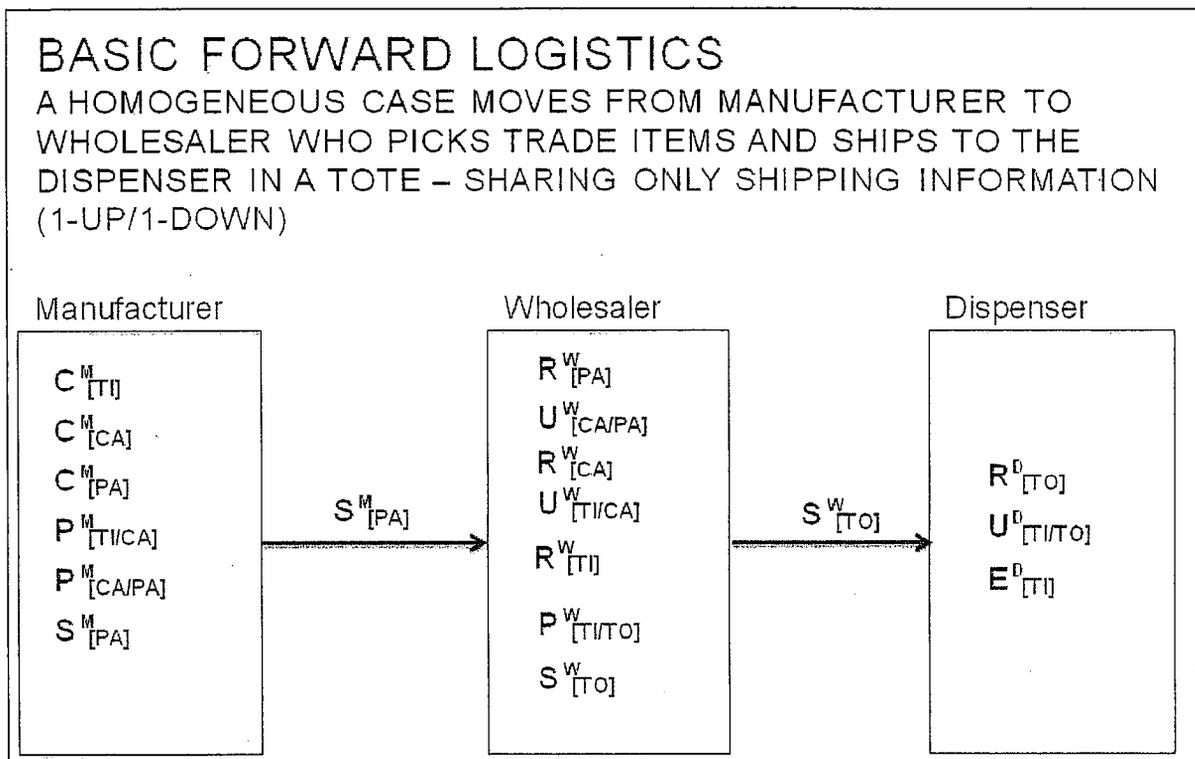


Figure 21: Ship pallet, break down to trade items, pack/ship totes -- sharing *Shipping* events only

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.

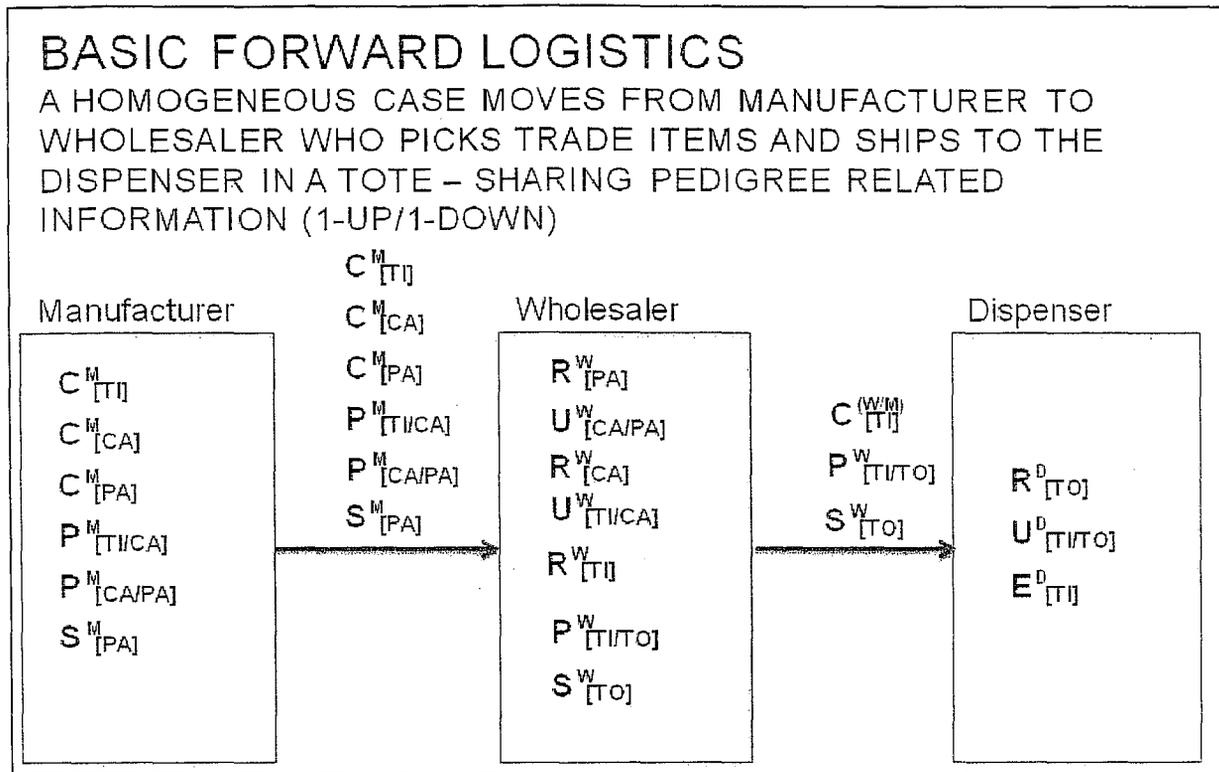


Figure 22: Ship pallet, break down to trade items, pack/ship totes -- sharing *pedigree-related* events

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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Agenda Item VIII.

Attachment D

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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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 ~~sean~~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 “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, 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 signaturecertification 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.
(847) 643-4249
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Whitehouse Station NJ 08889-0200

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,



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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,

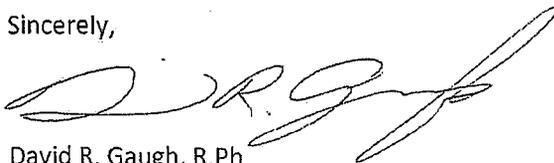
(D) The pedigree data must indicate that an inference was deployed for the certifications;

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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pharmacists
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:
- with which the recipient has an established relationship and existing contract;
 - 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;
 - 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;
 - 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;
 - ~~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;~~
 - ~~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~~
 - ~~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

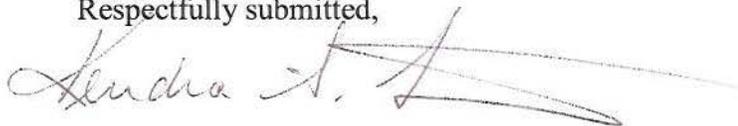
In addition, section (b) includes a reference to a “veterinary food-animal drug retailer or wholesaler.”⁹ The reference should be deleted from the draft language, as the Code provisions clearly exclude products “for veterinary use only.”¹⁰

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).

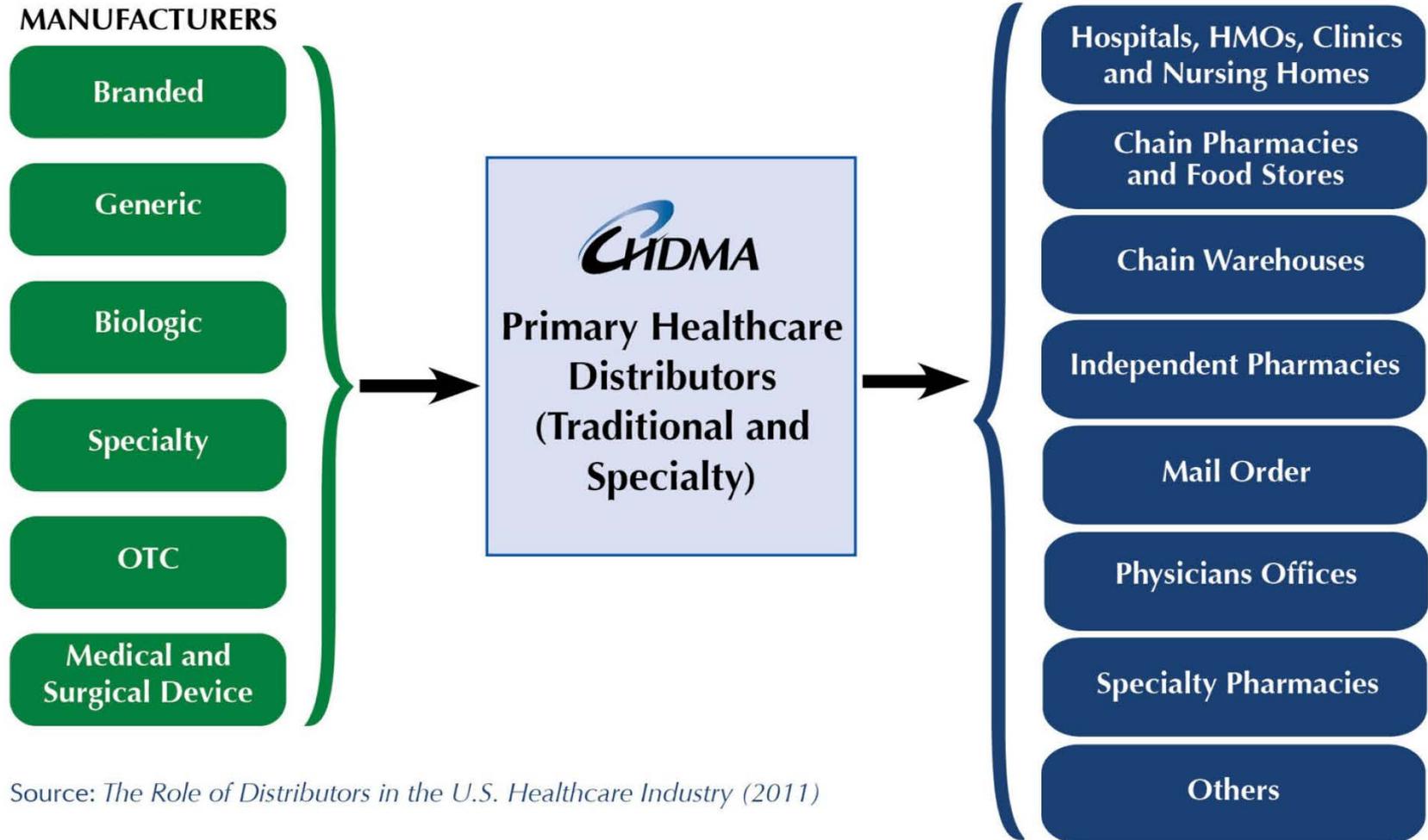
Inference: Key to CA Pedigree Implementation

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

Agenda Item IX.

Attachment E

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.

Agenda Item X.

Attachment F

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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.

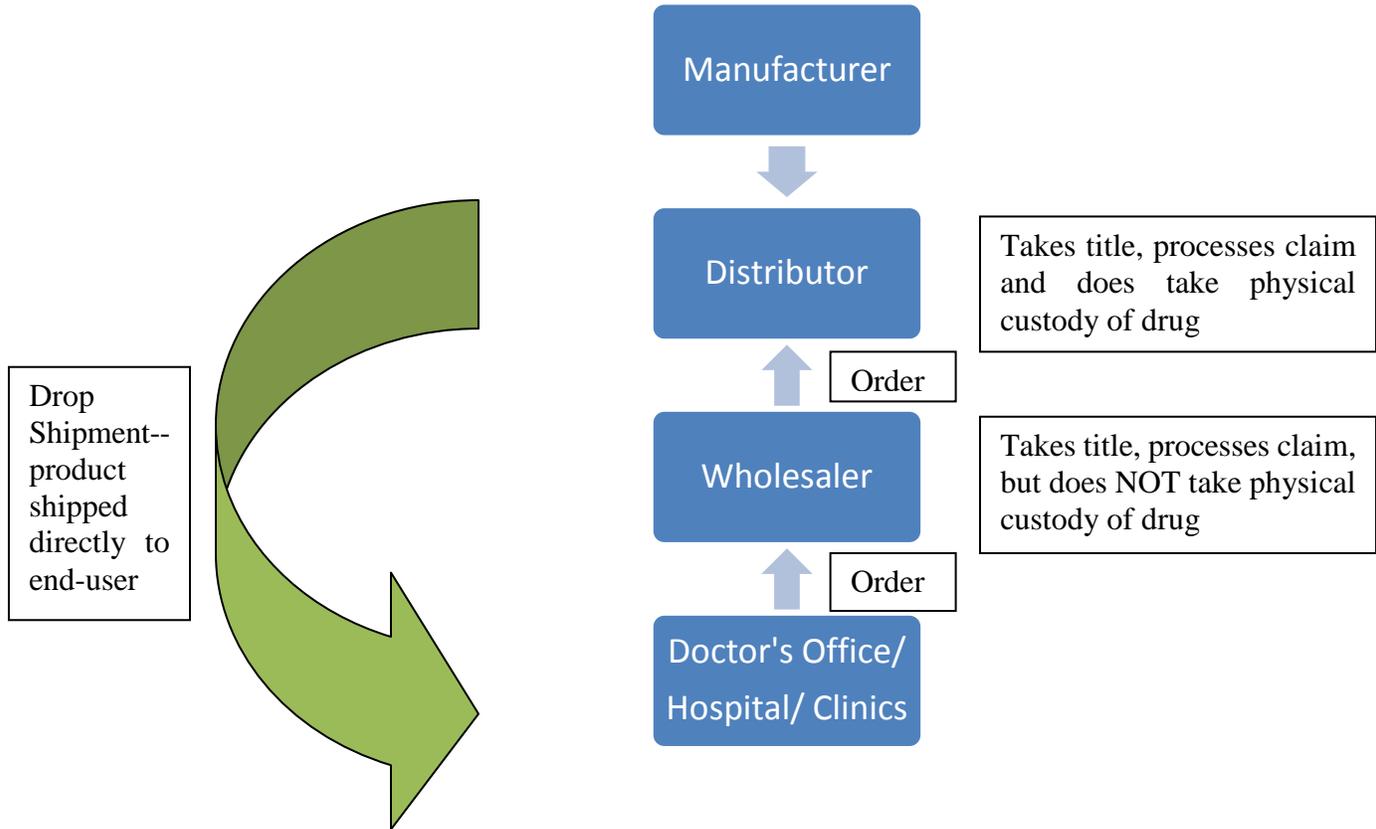
Any potential regulations should ensure that entities who never physically handle the product are not subject to the reporting requirements. This will allow manufacturers to maintain important efficiencies in their distribution system, without subjecting the wholesaler to unnecessary regulation, while 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
California Board of Pharmacy
June 14, 2013
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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

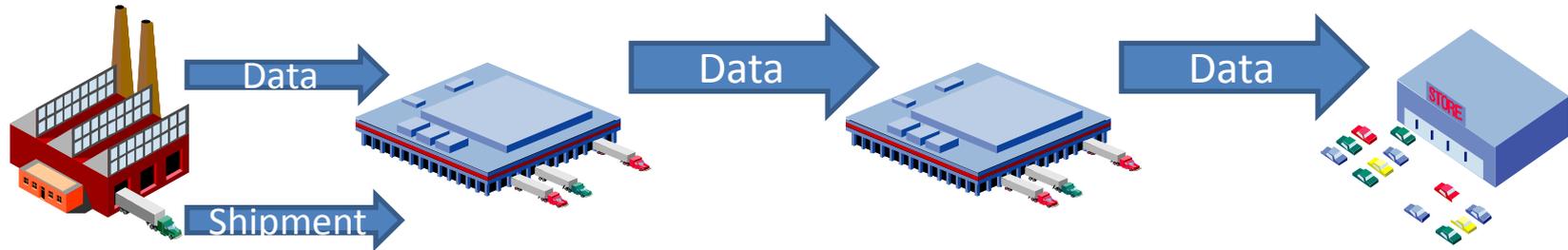
Manufacturer

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?