

# SupplyScape

## **Combining EPCIS with the Drug Pedigree Messaging Standard**

**Submitted to GS1 Healthcare US  
Pedigree / EPCIS Assessment Task Force**

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## 1 Introduction

In 2008 the GS1 Healthcare US Pedigree / EPCIS Assessment Task Force will select, refine and document an approach for combining the Drug Pedigree Messaging Standard with the Electronic Product Code Information Services (EPCIS) standard to produce a pharmaceutical track and trace system suitable for regulatory compliance and the maintenance and sharing of serialization data within the supply chain. This paper presents a proposal (Section 3.4) that SupplyScape is submitting for consideration, with a discussion of its merits. The discussion includes an analysis of alternative approaches and examines why they are deficient.

The companies who participate in the pharmaceutical supply chain need a pedigree approach that will allow them to comply with multiple state and federal pedigree laws that have different requirements. Due to the nature of the modern US drug supply chain, it is impossible to predict where a drug entering the supply chain will ultimately exit the chain and which pedigree laws it must comply with along the way. The movement of drugs through the legitimate supply chain can occur in complex and varied patterns when viewed through the requirements of pedigree laws. For these reasons, interoperability and flexibility to accommodate the varying laws is essential in a pedigree approach. Further, interoperability dictates that all members of the supply chain use the same standard for carrying the pedigree information between trading partners. This is exactly why EPCglobal developed the Drug Pedigree Messaging Standard.

But companies who participate in the pharmaceutical supply chain also want to be able to selectively share serial number visibility data about the serialized products that pass through the supply chain. The reading of serial numbers on items produces a huge volume of fine-grained data. Finding information about a given item could be like finding a needle in a haystack. This is why EPCglobal developed the EPCIS standard.

By linking systems that implement the Drug Pedigree Messaging Standard and EPCIS *in a standard way*, pedigree data visibility and accessibility will be enhanced and new applications can emerge that make use of data contained in systems that follow both standards.

In short, the approach proposed in this paper works by using Drug Pedigree Messaging Standard-based systems to hold pedigree data and EPCIS-based systems to hold serial number visibility data, with links provided so that pedigree data can be located and shared using EPCIS-based applications. This is a fundamentally different approach than in proposals made by others that seek to embed pedigree data directly within EPCIS events. We believe our approach offers the following benefits to the pharmaceutical supply chain:

- 1) The proposed approach is based on the ratified GS1 EPCglobal EPCIS and Drug Pedigree Messaging standards that are gaining wide acceptance and initial adoption within the pharmaceutical supply chain. The industry may choose from a list of certified vendors of systems that conform to each standard.
- 2) Pedigree message exchange is backward and forward compatible with existing certified Drug Pedigree Messaging Standard messages and systems. Companies are not forced to deploy the proposed approach. Companies that have already invested in the Drug Pedigree Messaging Standard can evolve by deploying EPCIS-based applications when they are ready. This approach allows an evolutionary transition by each supply chain member from compliance and trace to being able to eventually participate in full supply chain track and trace without jeopardizing interoperability along the way.
- 3) Companies who adopt the proposed approach can exchange standard drug pedigree messages outside of their EPCIS-based application whether or not products are serialized at the item level. This is essential for companies who need to comply with pedigree regulations outside of California, currently the only jurisdiction that requires serialization.

- 4) The proposed approach successfully binds ePedigrees with serialization event visibility data without radical modification to either the Drug Pedigree Messaging or EPCIS standards, thus retaining a clear separation of concerns and allowing each standard to serve its original purpose with all of the corresponding original benefits and features.
- 5) The proposed approach successfully avoids the “initial conditions” pitfall that would require *every member* of the supply chain to deploy an EPCIS-based application before *any one* supply chain member can be compliant with the pedigree laws. The timing of investments is left up to each company. Supply chain members who choose compliance at a minimum can later add EPCIS without throwing away the prior investment in systems based on the Drug Pedigree Messaging Standard.
- 6) The proposed approach establishes a generalized technique for linking EPCIS serial number visibility events to external transactional information that can be reused with other data types not related to pedigrees or regulatory compliance.

## 2 Nationwide Compliance and Interoperability

Pedigree requirements vary from state to state, where they exist. While there is a US federal pedigree law, the PDMA (Prescription Drug Marketing Act) does not override the state pedigree laws so the federal requirement is generally regarded as specifying the minimum requirements that must be met in states that do not already have a law. Several state laws exceed the PDMA in multiple key requirements.

*Nationwide compliance* is the condition that allows trading partners to sell pharmaceuticals anywhere in the US without concern with variations in local pedigree laws. It enables trading partners to pass pedigrees that comply with the strictest provisions of each existing US state or federal pedigree law. Avoiding a state-by-state compliance approach is essential because the modern pharmaceutical supply chain operates on a nationwide basis. In the absence of an overriding federal pedigree law the industry needs to comply with a super-set of the various state pedigree laws. This is the only way to accomplish true nationwide compliance.

*Interoperability* is the condition that allows the pedigree systems installed by each trading partner to recognize and properly process the pedigrees sent and received by them. Pedigrees are a collection of information contributed by multiple parties. To be coherent and understandable, each contribution must conform to the same standard.

Any proposal that will be considered for adoption by the industry for use as a pedigree system must demonstrate how it will accomplish nationwide compliance *and* interoperability, achieving an uninterrupted supply and uninterrupted distribution of medicines. Our proposal relies on the GS1 EPCglobal Drug Pedigree Messaging Standard which was developed by participating members of the pharmaceutical supply chain specifically to provide nationwide compliance and interoperability.

### 2.1 Summary of Key Pedigree Requirements

Nationwide compliance can be accomplished only when supply chain participants treat all pedigrees with the assumption that they will need to fulfill the strictest pedigree law. We now summarize some of the key pedigree requirements that differ from state to state with an emphasis on the strictest law in any given requirement. All EPCIS pedigree proposals should be weighed against these requirements.

#### 2.1.1 Custody or Ownership

One key difference between pedigree laws is whether the pedigree must be updated on a change of custody or a change in ownership. Most existing laws, including California, Indiana, Nevada and PDMA require the pedigree to reflect each change in *ownership*. Movement of product within a given owner’s network of facilities does not have to be included on the pedigree. The Florida pedigree law is different because it requires that changes in *custody* be shown on a pedigree, even when ownership has not changed. The difference becomes critical whenever business processes are executed where chain of ownership does not follow the chain of custody. Drop shipments, in which a wholesaler takes ownership of product without

taking physical possession (i.e. custody), are an example of this. The Drug Pedigree Messaging Standard does not dictate when a pedigree is updated so either custody or ownership updates, or both, may be made.

### 2.1.2 Serialized or Non-Serialized

California's pedigree law is the only law that currently requires a unique serial number on each unit of pharmaceuticals bought and sold in the state. To ensure uninterrupted nationwide distribution, industry stakeholders would need to serialize all items so that they are sellable in California. However, this may be impractical for the next few years so it is likely that there will be a mix of serialized and non-serialized products within the supply chain for some period of time. The Drug Pedigree Messaging Standard can accommodate a mix of both serialized and non-serialized items.

### 2.1.3 Paper or Electronic

Outside of California, all states with pedigree laws, including the Federal PDMA, allow paper or electronic forms. However, in those states, the practicality of an inspection may typically be performed using paper, even when the pedigree is held and transmitted electronically. For example, when pedigrees are inspected in Florida, electronic pedigrees are printed first.

Because our modern pharmaceutical supply chain is so complex and handles such huge volumes of products, the storage, maintenance and transmission of pedigrees in anything other than electronic form is impractical. Best practice dictates that all pedigrees be held and exchanged electronically. In reality, however, some companies have elected to produce and exchange pedigrees in paper form for shipment into Florida, particularly for kits. This is legal in Florida and cannot be blocked.

The Drug Pedigree Messaging Standard is an electronic format suitable for message exchange, electronic inspection and as a source for rendering pedigrees in printed form when necessary and allowed. The Drug Pedigree Messaging Standard also describes how to convert from electronic form to printed form and vice versa.

### 2.1.4 Certification and Authentication

The concepts of pedigree certification and authentication are often confused. When referring to pedigree processes, the definition of these terms is extracted from pedigree legislation and deviate slightly from their traditional definitions. Pedigree *authentication* is the act of verifying that the information on a received pedigree is complete and accurate. Pedigree *certification* is the signing of an oath that the information contained in the pedigree is true and accurate. When a company is certifying and authenticating a pedigree, they are doing so for all of the information on the pedigree including the information that was supplied by previous companies.

Most pedigree laws refer to some type of "certification" by the shipping and/or receiving party. Generally, pedigree laws avoid specifying technology, including the specification for exactly how the "certification" must be accomplished. The Florida pedigree law is an exception to this general rule. Florida requires the use of specific FIPS (Federal Information Processing Standards) standards—specified by number—for electronic pedigrees. These FIPS standards describe the use of PKI (Public Key Infrastructure) digital signatures. The Drug Pedigree Messaging Standard requires the use of digital signatures that follow the Florida requirements for shipping events and pedigree certifications. This ensures that all Drug Pedigree Messaging Standard-based pedigrees will comply with the digital signature requirements of Florida and also fulfills the vaguer "certification" requirements of the other pedigree laws.

The Florida pedigree law requires companies receiving pedigrees to "authenticate" them prior to receiving the product that they document. While the California Pedigree law does not use the word "authenticate", members of the California Board of Pharmacy have indicated to industry representatives that an authentication step is required.

The nested digital signatures in Drug Pedigree Messaging Standard pedigrees allow them to be electronically self-authenticated, eliminating the need to perform the manual authentication steps that would be necessary for compliance. This is a very important labor-saving feature. These signatures also provide a vital measure of security to the pedigrees themselves so that the content can be trusted. Any kind

of tampering with upstream information is easy to detect because each signature protects all of the previous information as well as the newly added information.

### 2.1.5 Data Format

No existing pedigree law identifies a specific pedigree data format. However, the California law specifically requires a standardized nonproprietary data format and architecture that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a drug. The implied goal is to ensure pedigree message interoperability across the supply chain. This is clearly more than simply including the list of data elements that are called out in the text of the law. Unless the arrangement, relationship and structure of those data elements are well defined in a specification, interoperability will be impossible to achieve. The Drug Pedigree Messaging Standard is the only standardized, nonproprietary pedigree data format and architecture that is currently uniformly used by all segments of the supply chain. Other proposed approaches, like [ABCIBM], are not widely deployed, are not interoperable with Drug Pedigree Messaging Standard-based pedigrees and would require a new standard that would not be backward compatible with existing pedigree systems that are already deployed across the industry, thus destroying the interoperability that currently exists.

## 2.2 Benefits of Nationwide Compliance and Interoperability

We have already defined the terms “Nationwide Compliance” and “Interoperability” above. Now we would like to discuss the benefits of focusing on those concepts when selecting a pedigree strategy. We observe that, too often, users and vendors focus their attention on a state-by-state compliance strategy that addresses short-term needs but fails to address the longer term. But this is self-defeating because it results in a cyclic repetition of projects every time another state enacts a new pedigree requirement. Companies that have nationwide or large regional operations will benefit in the following ways by taking a nationwide approach in the development of a long-term strategy:

- Products distributed nationally or across regions that include multiple states will use a common pedigree approach without regard to variations in pedigree laws, thereby gaining the operational efficiencies of standardized and repetitive processes.
- As new states are added to the list of states with pedigree laws it is simple to “switch on” pedigree compliance.
- The monetary value of each product is maximized because they can be staged at any distribution center within the company network and can be shipped to any locality within the US at any time to meet normal or unexpected demand without regard to variations in pedigree requirements.

In short, if your business is national, your pedigree strategy must also be national.

The important benefits of pedigree interoperability are sometimes lost in the desire to replace pedigrees with a “track and trace” system, as if they are diametrically opposed to each other. In fact, pedigrees contain almost all of the data wanted in a track and trace system and they fulfill the “trace” part quite well. To provide the “track” part, all that is needed is the addition of *controlled visibility* of the pedigree data. As we will see below, EPCIS-based business applications can fill that need very nicely in a system that is not in opposition with the Drug Pedigree Messaging Standard, but embraces it. The combination of these two standards results in something greater than the sum of the parts because, as we propose it, true interoperability results. Our proposal provides an evolutionary path from compliance to the ability to participate in full track and trace without the loss of interoperability or backward compatibility. There is no need to discard investments in systems based on the Drug Pedigree Messaging Standard or EPCIS to move forward in that evolution. This is a huge benefit to the many companies who have already invested in one or the other or both.

Now let us turn our attention to the choices we have for exactly *how* to use EPCIS in pedigree compliance.

### 3 Using EPCIS in Pedigree Business Processes

In this section, we address how EPCIS can be employed to help carry out business processes requiring drug pedigrees. We first consider (in Section 3.1) an approach in which pedigree data is composed directly from EPCIS events. This is an intuitively appealing approach, but as we will show, it leads to a series of technical challenges. By the time these issues are addressed, the approach loses much of its appeal, as we argue in Section 3.2. We then present (in Section 3.3) an alternative approach based on linking EPCIS data with pedigree data represented using the existing GS1 EPCglobal Drug Pedigree Messaging Standard 1.0. This approach has a number of benefits, including a clean separation of concerns, the ability to leverage existing investments in Drug Pedigree Messaging Standard-based systems, and the flexibility to accommodate different trading partner preferences regarding when and if EPCIS data is to be exchanged. Section 3.4 gives a precise specification of this approach.

#### 3.1 Composing Pedigrees from EPCIS Events (“EPCIS-only”)

It is natural to ask whether a drug pedigree can be composed from a series of EPCIS events, thereby eliminating the need for a separate standard like the Drug Pedigree Messaging Standard. After all, at a superficial level, a drug pedigree appears to be a time-ordered series of commissioning, shipping, and receiving records pertaining to serialized product. EPCIS data consists of time-annotated events, each of which records the completion of a business process step such as commissioning, shipping, and receiving. Surely, then, a drug pedigree can be reconstructed from the relevant EPCIS events, perhaps with extensions to accommodate specific data element required in the pedigree, such as license information, signatures, and so on. This would imply that EPCIS is the only standard needed to satisfy both serial number visibility and pedigree requirements. Hereafter, we refer to this as the “EPCIS-only” approach.

While the EPCIS-only approach seems appealing, difficulties arise when the details are considered. To be viable, any drug pedigree solution must meet all requirements imposed upon supply chain participants by laws and regulations (Nationwide Compliance as defined in Section 2), as well as business requirements demanded by the participants themselves. For the sake of analysis, we take as the “gold standard” the GS1 EPCglobal Drug Pedigree Messaging Standard 1.0, which provides an example of one system that meets all of these requirements. The Drug Pedigree Messaging Standard was ratified after extensive vetting by 44 companies who participated in its creation. All known passed and pending legislation was considered in creating that standard.

We therefore consider requirements that are met by the Drug Pedigree Messaging Standard, and show what would be required of an EPCIS-only approach in order for that approach to match or exceed what the Drug Pedigree Messaging Standard provides. In particular, there are four requirements that present challenges in constructing a pedigree from EPCIS events:

- *Change of ownership as opposed to change of custody* Pedigree data must track changes of ownership, which in some instances do not correspond to any serial number visibility event normally captured in EPCIS
- *Data elements required by pedigree laws* Pedigree laws require tracking certain data that would not otherwise be included in EPCIS data.
- *Pedigree Completeness* At each step, the complete pedigree must be available, and so it is necessary to insure that all and only the relevant data is available and included.
- *Pedigree Integrity, Authenticity, and Non-Repudiation* At each supply chain step, a company must validate and vouch for the authenticity and correctness of the pedigree data. This authenticity assertion must cover not just the current transaction, but all prior transactions as well.

Each of these requirements is met by the Drug Pedigree Messaging Standard. In the following sections, we show how these requirements are challenging to meet if a pedigree is composed from individual EPCIS events alone, without using the Drug Pedigree Messaging Standard. This analysis is summarized in Section 3.2.

Sections 3.1.1 through 3.1.4 assume some knowledge of the EPCIS and Drug Pedigree Messaging standards but readers without that knowledge will still benefit from reading them.

### 3.1.1 Change of Ownership, not Necessarily Change of Custody

The essential requirement for drug pedigrees is to track every change of ownership experienced by a product from manufacture to receipt by a pharmacy. As discussed in Section 2.1.1, changes of ownership do not necessarily coincide with changes of custody. Neither is one a subset of the other. Here are two examples illustrating this point:

- A wholesaler sells to a pharmacy, and uses a common carrier (such as UPS, Fedex, etc) to deliver the product. There is a change of ownership from the wholesaler to the pharmacy, but custody passes from the wholesaler to the carrier to the pharmacy.
- A wholesaler buys from a manufacturer and sells to a pharmacy, but does not actually take custody of the product. The product is drop-shipped by the manufacturer directly to the pharmacy. (This scenario is described in [DPMS], Section 12.1.11) Here there is a change of ownership from manufacturer to wholesaler to pharmacy, but custody passes directly from the manufacturer to the pharmacy.

The drug pedigree laws require the pedigree to record changes of ownership. Thus, in the first example, the pedigree includes the wholesaler and the pharmacy, but not the carrier, while in the second example the pedigree includes the manufacturer, wholesaler, and pharmacy even though the wholesaler never touched the product.<sup>1</sup>

EPCIS, in contrast, is typically used to record serial number visibility events that are derived from physical operations. Thus, in the first example, EPCIS data might include data from the common carrier even though the pedigree does not, while in the second example EPCIS data would not normally include data from the wholesaler, even though the pedigree requires it. In addition, EPCIS often includes internal visibility events that do not correspond to a change of custody or ownership.

The following diagram illustrates the second example, which we will carry through the remainder of the discussion. As a starting point, we show EPCIS and pedigrees being managed by entirely *separate and disconnected* systems: EPCIS for physical product serial number visibility, and drug pedigrees as documents according to [DPMS]. In the diagram time goes from left to right. The top row shows EPCIS events generated from physical visibility observations, and the bottom row shows drug pedigrees generated. For purposes of illustration, only one internal EPCIS event is shown (the “pack” step at the Manufacturer); in a real use case, there would be many of these internal events at each party who takes custody. Note that the physical act of shipping to the pharmacy occurs at the manufacturer, even though ownership has by that point passed to the wholesaler (which is why the Manufacturer appears twice in the time sequence).

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<sup>1</sup> The EPCglobal Drug Pedigree Messaging Standard [DPMS] is slightly confusing owing to its use of the terms “shippedPedigree” and “receivedPedigree” in the pedigree document format, as well as references to “chain of custody” that occur throughout the specification document. The text of the specification, however, makes it clear that it is changes of ownership, not custody, that are tracked, as the law requires.

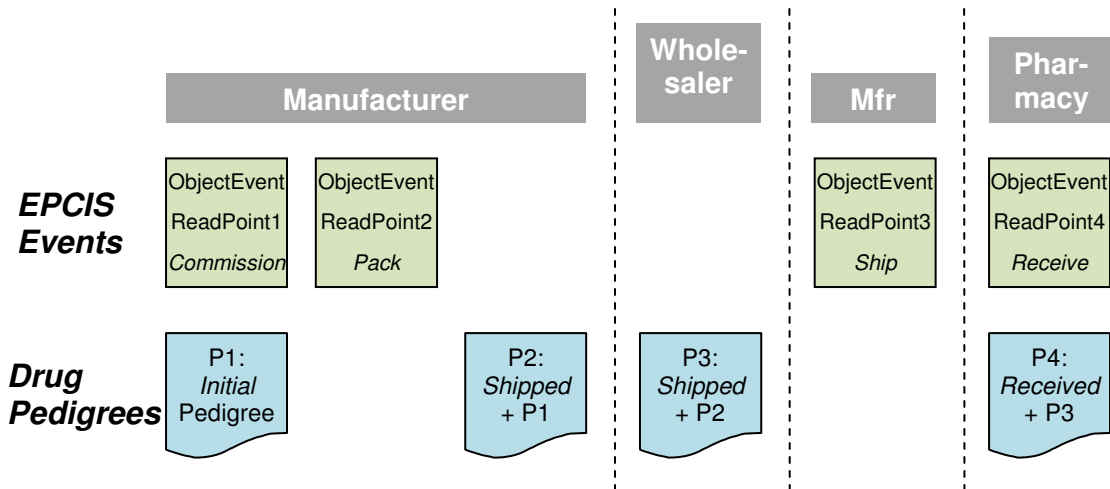


Figure 1. Manufacturer-initiated Drop Ship Scenario, with Separate EPCIS and Pedigree Systems

The steps in this flow are as follows:

1. The manufacturer commissions the EPCs on the product at manufacture time. The Manufacturer creates an EPCIS event with an appropriate read point and a business step of “commission” (along with other serial number visibility-related fields not illustrated in the figure). The Manufacturer also creates an initial pedigree P1 using the Drug Pedigree Messaging Standard. In the figure, the EPCIS “commission” event and the pedigree P1 are shown in the same column to illustrate that they are created at the same time, but they are otherwise not connected (in this first example).
2. As part of internal operations, the manufacturer packs the drugs into different packaging. The Manufacturer creates an EPCIS event with a business step of “pack.”
3. The manufacturer initiates a business transaction to sell to the pharmacy using the wholesaler as an intermediary. The manufacturer creates a new pedigree P2 recording the sale and the corresponding change of ownership. This pedigree is a “shippedPedigreee” according to [DPMS], and embeds a copy of P1. Because this is a purely financial transaction with no product movement, there is no EPCIS serial number visibility event at this step.
4. The wholesaler completes the change of ownership to the pharmacy by creating a new pedigree P3 that records the sale. This pedigree is also a “shippedPedigree,” and embeds a copy of P2.
5. The manufacturer is now free to drop-ship the product to the pharmacy. It generates an EPCIS event with an appropriate read point and a business step of “ship.”
6. The pharmacy receives the product and validates the incoming pedigree P3. It generates an EPCIS event recording the physical receipt (business step “receive”) and a new pedigree P4 of type “receivedPedigree,” embedding a copy of P3.

If the EPCIS events in the diagram were in one-to-one correspondence with the pedigrees, the use of EPCIS to carry pedigree information might be straightforward, but we see that even in this simple example we have columns that contain a pedigree but not an EPCIS event and vice versa.

How to correct this problem? One way is to introduce additional EPCIS events to fill the gaps in the diagram. Since these are physical observations, a business transaction event might be appropriate. This leads to a diagram like this:

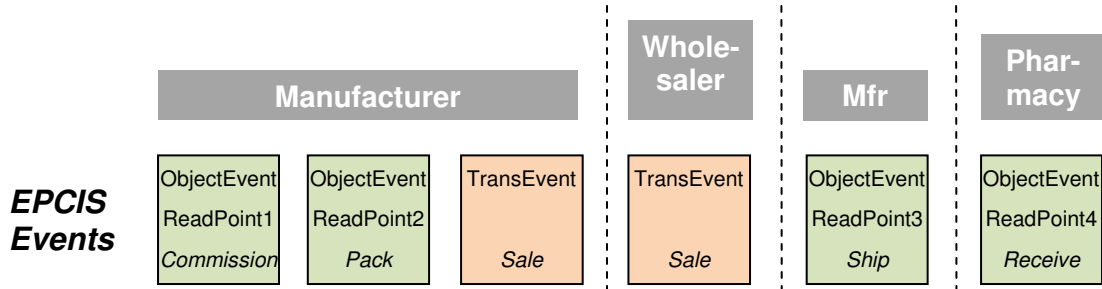


Figure 2. Drop-Ship Scenario, EPCIS-only Augmented with “Sale” EPCIS Events

The two new TransactionEvents have a business step of “sale,” indicating that the events record a change in ownership. They lack a read point, as they are not physical observations.

At this point, the EPCIS event stream at least includes an event at each step where pedigree information is required. But the data content of the EPCIS events does not include everything that is required in a pedigree. We address this in the next few sections.

**3.1.2 Required Data Elements**

Basic EPCIS events have four dimensions of “what, when, where, and why.” This information includes some of what goes into a drug pedigree message. In particular, the “what” dimension (EPC codes or class+quantity for unserialized information) and the “when” dimension (timestamp) directly correspond to pedigree information. The Business Step field of the “why” dimension can also be used to distinguish the pedigree layer (initial vs “shipped” vs “received”).

Pedigrees, however, contain additional information. An initial pedigree includes detailed information about the products in question. Some of this is product-level information, such as product name, dosage form, strength, and so on. This can reasonably be represented as Master Data in EPCIS. Other information is at the item level, including lot and expiration date. This information needs to be included in the EPCIS commission event in order for that event to carry the same information content as the initial pedigree. Likewise, “shipped” and “received” pedigrees have detailed information about the parties to the change in ownership, including state license information, shipping addresses, and so on. This, too, needs to be carried in the corresponding EPCIS events (with some static information like addresses for a particular shipper ID being carried in Master Data).

The diagram below shows EPCIS events augmented to include information that would otherwise be found in the pedigree.

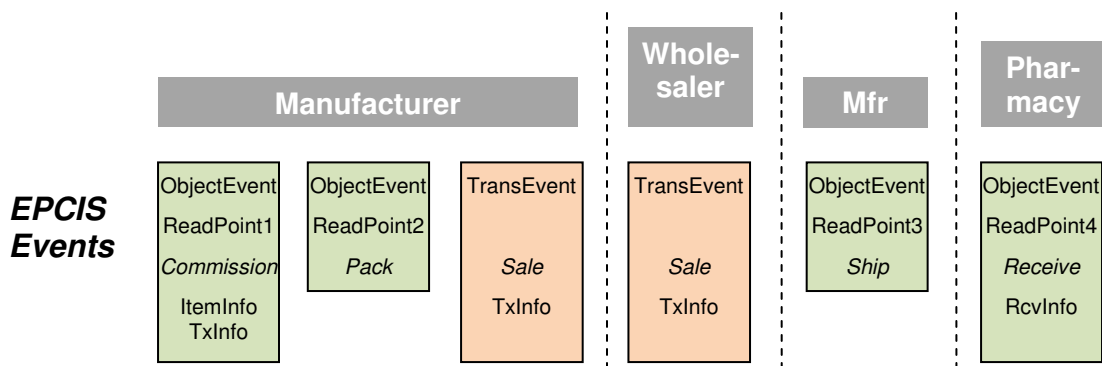


Figure 3. Drop-Ship Scenario, EPCIS-only Augmented with Pedigree Business Data

In this diagram, “ItemInfo”, “TransactionInfo” (abbreviated “TxInfo”), and “ReceiveInfo” (abbreviated “RcvInfo”) are the same as defined in the Drug Pedigree Messaging Standard.

With these additions to EPCIS events, the set of relevant EPCIS events now includes all of the data that would otherwise be available in the pedigrees. (As specified in the Drug Pedigree Messaging Standard, pedigrees also include “DocumentInfo” and “SignatureInfo”; these are dealt with in the following sections.) At this point it is reasonable to ask how well EPCIS serves the applications that require data. There are two types of applications to consider:

- *Visibility Applications* Visibility applications are the applications for which EPCIS data was originally intended, for example, serial number track-and-trace applications. From the perspective of these applications, the EPCIS data stream now contains extraneous information, both in the form of unwanted events (the orange “TransEvents” in the diagram), and unwanted data (the additional pedigree-related data that occurs on both green and orange events in the diagram). The volume of this data will be non-trivial.
- *Pedigree Applications* Pedigree applications are responsible for carrying out the pedigree business process mandated by law. These applications must sift through the EPCIS events to find the relevant ones (i.e., not including the small green boxes in the diagram which carry no pedigree information), and then extract the relevant data which is carried in a mix of standard EPCIS fields and pedigree extensions.

Neither application seems to be served especially well in this scenario, because the different concerns are mixed together in the event stream. We will return to this point when we describe an alternative approach in Section 3.2.

### 3.1.3 Pedigree Completeness

At this point, we have EPCIS events that individually contain the business data of a single stage in a pedigree document. We now ask the question: is a collection of these events equivalent to a pedigree?

Consider the receiving step at the Pharmacy in our example. The Pharmacy must validate the pedigree as it exists up to that point prior to completing the receive operation. If the Drug Pedigree Messaging Standard were used, this would be a matter of examining the information in Pedigree P3 in the earlier figure. But now, this information is distributed among three EPCIS events, two at the Manufacturer and one at the Wholesaler. So the Pharmacy must query to receive this data. This may involve so-called “discovery services” in order to find all parties that have relevant data. Alternatively, as suggested in [ABCIBM], the parties may have prearranged to stage all relevant data at the immediate supply chain predecessor; that is, the Pharmacy need only query the Wholesaler, who is responsible for having previously queried the Manufacturer and cached the latter’s data.

How does the Pharmacy know it has all the relevant data to validate the pedigree? The first thing the Pharmacy must do is filter out events that contain no pedigree information. But this still leaves open the question of whether the Pharmacy has *all* the relevant events. How can the Pharmacy be sure there were not additional changes of ownership, for which the Pharmacy didn’t happen to receive event data? This is especially worrisome considering that a dishonest party has an interest in concealing their involvement, and can simply not respond to the EPCIS query.

To address this problem, it must be possible to detect missing EPCIS events. The [ABCIBM] proposal suggests one method, which is to give each EPCIS event a unique identifier (UUID), and have the next EPCIS event in the chain of ownership refer to the previous event using its UUID. In other words, each event has a UUID field, and a “previous UUID” field (which is null for the commission event). Graphically, these two fields can be depicted as a pointer from one event to its immediate predecessor in the pedigree chain of ownership, like so:

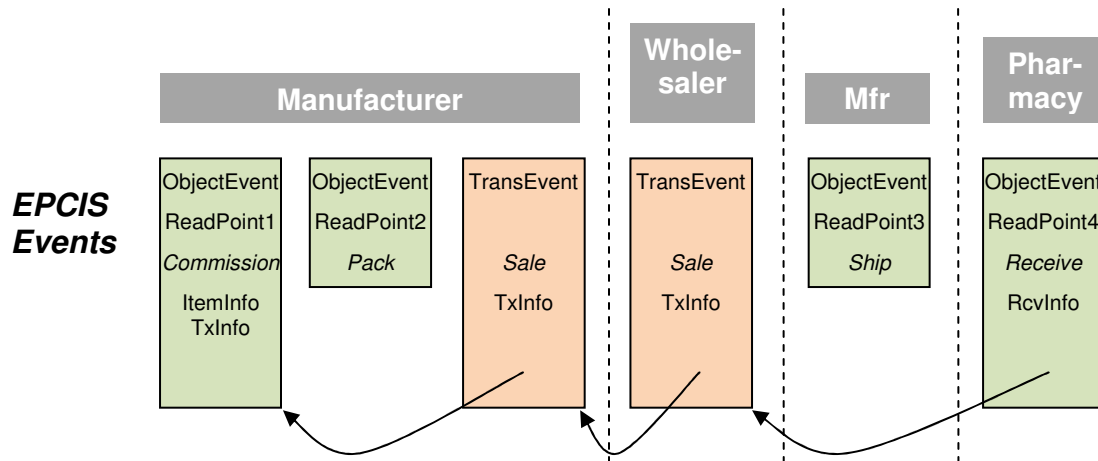


Figure 4. Drop-ship Scenario, EPCIS-only Augmented with Event Chaining for Pedigree Completeness

When the Pharmacy queries to reconstruct the pedigree, it can now verify that the set of events received form a complete chain back to the commission event, and therefore that all data has been received.

This addresses the completeness of the pedigree (and, incidentally, the “DocumentInfo” component of a Drug Pedigree Messaging Standard [DPMS] pedigree). The next section addresses security issues.

### 3.1.4 Pedigree Integrity, Authenticity, and Non-Repudiation

A key feature of the Drug Pedigree Messaging Standard is the use of digital signatures at each step in the process. This is mandated by the Florida pedigree law and may be implied in the California law<sup>2</sup>. Use of digital signatures insures that pedigree information is not tampered with (integrity). Moreover, it allows each party to understand and confirm the identity of the other parties who have signed the pedigree (authenticity), and also provides a legal record so that a party cannot later deny having vouched for the data in the pedigree (non-repudiation). This last aspect is extremely important to regulators and law enforcement officials, who may want to use pedigree data to help prosecute malefactors. See section 2.1.4 for more discussion of digital signatures.

How is the protection of the “SignatureInfo” part of [DPMS] to be achieved in an EPCIS-only solution? At first glance, it appears that what we need to do is create a digital signature for each EPCIS event, signed by the party that produced that event. This leads to a picture like the following. Signed events are indicated by the presence of a *message digest*, which summarizes the content of the event, and a *signature* computed by encrypting the digest using the private key of the signer (M for Manufacturer, W for Wholesaler, or P for Pharmacy in the example). The digest is shown explicitly for reasons that will be explained shortly.

<sup>2</sup> It is not yet clear whether the California Board of Pharmacy requires the use of digital signatures to fulfill the “certification” clause in the law. The text of the law does not explicitly mention any specific means to certify but individuals have reported that digital signatures were mentioned by board members in on-on-one conversations. This must be clarified by the California Board of Pharmacy.

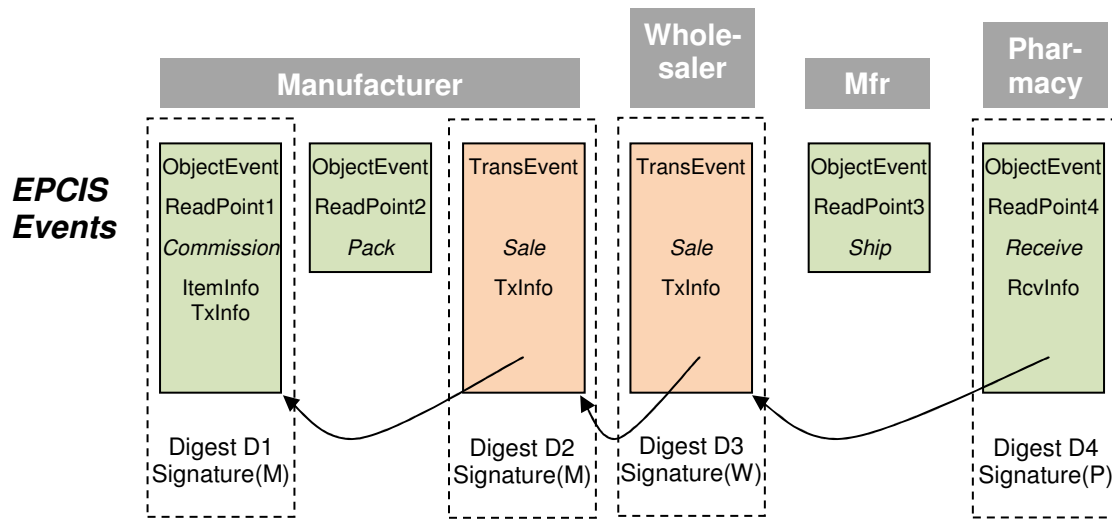


Figure 5. Drop-Ship Scenario, EPCIS-only Augmented with Per-Event Signatures

While this seems straightforward, in fact there are significant technical difficulties that arise in trying to implement event signatures within the EPCIS framework:

- All EPCIS data pertaining to a single event exists in the form of per-event fields. So it would seem that the event signature must be a field of the EPCIS event. Doing so would allow the signature to travel with the event as it is queried for and stored in other trading partners' databases. But this creates a complication in calculating the signature: the signature is intended to cover all fields of the event, but if the signature itself is to be an event field it obviously must be excluded when the signature is calculated. Moreover, EPCIS events are immutable, so it is not clear how a signature may be added to an event after the fact.
- Signature algorithms are defined in terms of calculating a message digest, which in turn is defined as an operation on a byte stream. Therefore, to calculate the signature of an event it must first be serialized into a byte stream. How is this to be done? One approach would be to utilize the XML schema defined for EPCIS events, and use the XML canonicalization rules specified in [Canonical-XML]. But the EPCIS specification defines the XML schema as a data exchange interface, *not* as a canonical representation of event data. In particular, the EPCIS specification does not specify the order in which extension elements appear in the XML, but all parties in the supply chain must do this consistently if they are to validate signatures. There is a lot of technical detail to be worked out here, which is not currently addressed in [ABCIBM].

These difficulties are non-trivial, but in principle not insurmountable. In the figure above, the digest and signature are depicted outside the event proper, to help underscore the fact that they are calculated as a function of the other event data.

But per-event signatures by themselves do not provide the same level of security as in [DPMS]. In the Drug Pedigree Messaging Standard, each level of a pedigree wraps the prior pedigree, and the signature at each level is calculated *including the prior pedigrees*. This is essential, as it guarantees that an inner element is not tampered with by a downstream party, and therefore that at each stage a party can be assured they are seeing exactly the same information for the earlier steps as the other parties have.

In the EPCIS-only approach, this issue manifests itself in the following way. Suppose the Wholesaler validates the prior pedigree by querying the Manufacturer for EPCIS events (the commission event). Satisfied that this data is acceptable, the Wholesaler creates its own EPCIS event and signs it. Later, the Pharmacy queries both the Manufacturer and Wholesaler for EPCIS events. But when the Manufacturer responds to the Pharmacy's query, it returns an event with *different data* than the one sent to the Wholesaler. The replacement event must contain the same UUID (otherwise, the chain described in

Section 3.1.3 would not validate), but the other data could be altered without the Pharmacy realizing it. The Pharmacy and Wholesaler, then, will have received different data regarding the commissioning; for example, the Manufacturer could have altered the expiration date to make an expired drug appear to still be viable.

The nested approach taken in [DPMS] avoids this vulnerability, for the reasons stated above. It is possible to make a similar correction in the EPCIS-only approach, which we present below. To our knowledge, this idea is original to this paper:

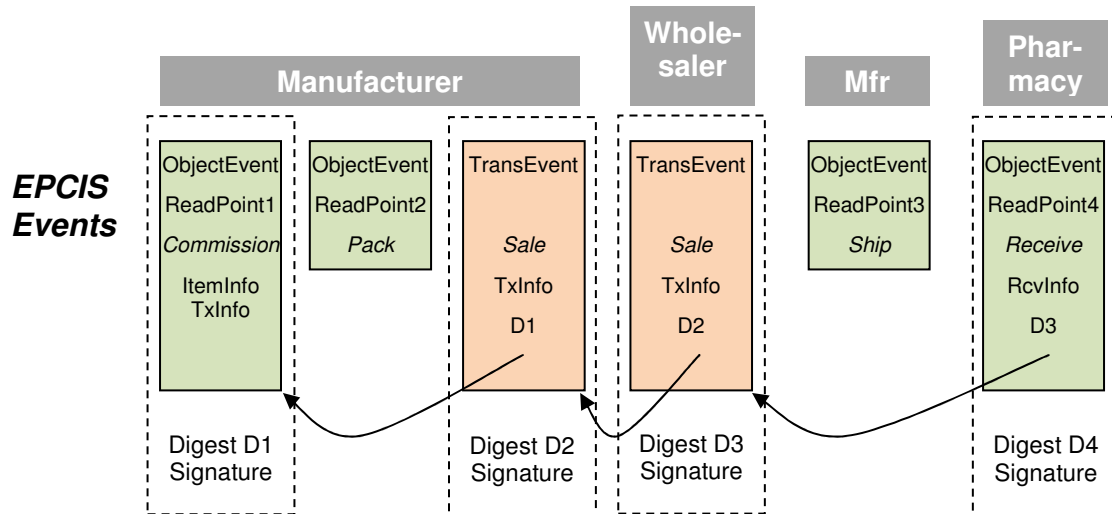


Figure 6. Drop-Ship Scenario, EPCIS-only Augmented with Digest Linking

This diagram is almost the same as the earlier one, except that each event includes not only the UUID of the prior event, but also the *message digest* of the prior event as was used in the latter's signature. No event can be modified without disturbing its digest value, and so the computed digest will no longer match the digest stored in the next event, or if the latter is modified to match, its signature will no longer validate.

### 3.2 Critique of Composing Pedigrees from EPCIS Events

As the previous sections have shown, it is not straightforward to represent drug pedigree information as a collection of EPCIS events, if all of the requirements incumbent on drug pedigrees are to be met. To summarize the difficulties highlighted in the last section:

- EPCIS events are generated as operational process steps are completed, typically upon change of custody or internal product handling events. Pedigree data, in contrast, tracks changes of ownership. Therefore, pedigree data is not a clean subset or superset of traditional EPCIS data. Additional events need to be added to capture change of ownership in the absence of any physical handling, and other events that mark physical handling but not change of ownership must be excluded from consideration when building a pedigree.
- The pedigree laws require particular data elements to be included. Some of these, such as the timestamp, EPCs, and certain location information, are standard EPCIS fields. Others, such as license information, are not. Extracting pedigree information from EPCIS events therefore requires considering a mix of standard and extension fields, while ignoring other fields. Conversely, applications interested in serial number visibility data may be burdened with the inclusion of unwanted pedigree-related data in certain events.
- Pedigree completeness requires that at each step, a supply chain participant validates not only the immediate transaction, but all prior transactions comprising the pedigree. Therefore, the system must record the chain of relevant events, so that the validator can be assured of seeing all and only the

events comprising the pedigree. This requires threading a chain of links through the EPCIS events. This chain is only relevant to pedigrees, and would be irrelevant or misleading when viewed by other applications that consume EPCIS data.

- Pedigree integrity, authenticity, and non-repudiation require that each supply chain participant vouch for the pedigree at each step by providing a digital signature. This must cover not only the current transaction, but all prior transactions comprising the pedigree. There are at least two significant challenges here:
  - To include all prior events in the signature without actually embedding those prior events requires a more sophisticated linking scheme, such as the one based on secure hash codes as described above. This introduces yet another layer of complexity in the EPCIS data.
  - A signature cannot merely be included as another field of an EPCIS event. To properly define a digital signature, it is necessary to specify a canonical representation for the data in question, and then provide the signature in an envelope or some other place that sits outside the signed data. This is not straightforward to do in the current EPCIS specification, for the reasons cited earlier.

These technical challenges are considerable, though not insurmountable. But by the time they are all addressed, we will have come very far afield from the original intuition behind the EPCIS-only approach. If a pedigree is not a straightforward application of EPCIS data as it would naturally be collected, what is the benefit of trying to force-fit pedigree data into the EPCIS mold?

Moreover, this approach has significant drawbacks, quite apart from the technical challenges discussed above. These include:

- Any EPCIS-only approach must co-exist with systems that only manipulate [DPMS] documents. If pedigrees are composed from individual EPCIS events, this implies that supply chain participants must implement systems that deal with two entirely different representations of pedigree data. This is an unnecessary burden that has no value from an end user's perspective.

The EPCIS-only approach surely will not *replace* the Drug Pedigree Messaging Standard approach, for several reasons:

- Florida demands a self-contained document-based approach, and the EPCIS-only approach would not be legal there.
- Many supply chain participants will need to implement pedigree due to legal requirements, but may otherwise be uninterested in track-and-trace or the other benefits of EPCIS. Supporting all the features of EPCIS is an unnecessary burden for those parties, which they will be unwilling to bear.
- The Drug Pedigree Messaging Standard is deployed today, while EPCIS is not (for pedigrees). So there is at a minimum a ramp-up period in which both would necessarily co-exist.
- The final jurisdictional destination of drugs received at a wholesaler's national DC is unknown and so it will be impossible to determine which type of pedigree is necessary: Drug Pedigree Messaging Standard for Florida, EPCIS-only for others.
- The EPCIS-only approach makes it much more difficult to conduct audits, legal investigations, prosecutions and other user cases that require *ex post facto* examination of pedigrees. The reason is that the data is not self contained as it is in the Drug Pedigree Messaging Standard, but must instead be assembled from pieces whenever it is needed. This means that all EPCIS providers must be available and ready to respond, even long after the business transactions have been completed. The more cause there is to suspect a participant of bad behavior, the less likely this will be the case.
- One of the chief benefits of EPCIS in serial number visibility applications is that it can be used in a query or "pull" mode, as opposed to the "push" mode of traditional EDI. This can lead to a great savings in network traffic if data is only needed intermittently; e.g., if EPCIS data is used only to resolve exceptional situations. But in the case of drug pedigree laws, pedigrees must accompany every

business transaction, and therefore all data will be queried all the time. A pull-based protocol is actually less efficient in that case.

### 3.3 Alternative Approach: Linking EPCIS and the Drug Pedigree Messaging Standard

As we have argued in the previous two sections, the EPCIS-only approach, while workable in principle, is complex and has significant disadvantages compared to the Drug Pedigree Messaging Standard as originally conceived. We do believe, however, that EPCIS and the Drug Pedigree Messaging Standard can complement each other, and that a system that uses both EPCIS and the Drug Pedigree Messaging Standard is the ideal solution for the industry.

The basic premise of our proposed approach is that pedigree information is always carried in Drug Pedigree Messaging Standard-compliant messages, and that serial number visibility data is always carried in EPCIS events. Unlike the “separate worlds” picture in Figure 1, however, in this approach EPCIS and the Drug Pedigree Messaging Standard work together in the following ways:

- Each time a new pedigree is generated (according to the rules in [DPMS]), a new EPCIS TransactionEvent is generated. This EPCIS event carries a business step of “PedigreeCreation” to distinguish it from all other EPCIS events, and is generated in addition to any other EPCIS events that may happen to be created concurrently for serial number visibility purposes. The “pedigree creation” EPCIS event contains a pointer to the pedigree by including the pedigree’s UUID as a business transaction identifier. The event may also include the relevant EPC’s, to allow for queries that look up pedigrees based on EPC.
- Optionally, EPCIS events generated for serial number visibility purposes at the same time a pedigree is created may include a reference to the relevant pedigree by including that pedigree’s UUID as a business transaction identifier. This further assists in correlating serial number visibility events with pedigree information.
- Optionally, a second new EPCIS event may be created containing the pedigree itself. This is similar to the “Pedigree Creation” event described above, except that the business step is “Pedigree”, and in addition to containing the UUID of the pedigree the entire pedigree itself is included as an extension field. The purpose of this event is to allow for the transmission of pedigree documents using the EPCIS Query Interface. This is optional, because some end users may prefer to transmit pedigree documents using EDI, web services or other means.

The basic picture, without the two optional ingredients listed above is depicted below.

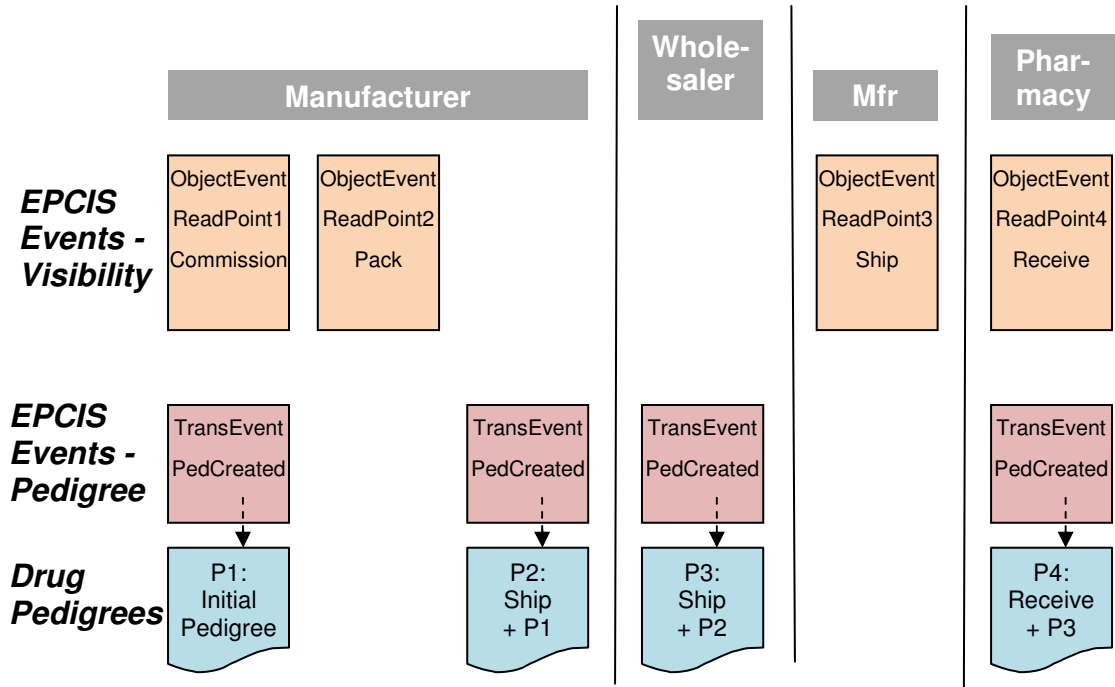


Figure 7. Drop-Ship Scenario, EPCIS+DPMS Linked Approach (minimal)

The complete picture, with all optional ingredients, is depicted below.

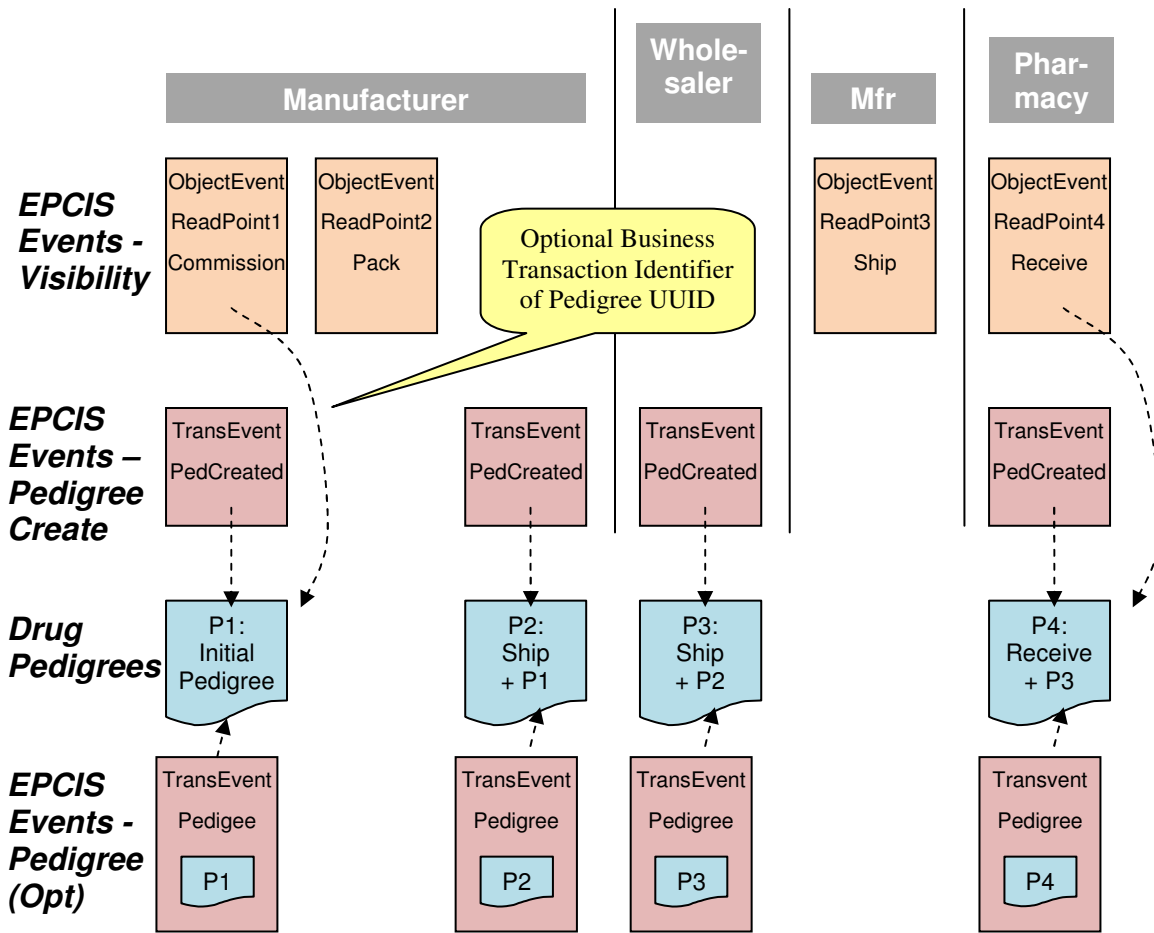


Figure 8. Drop-Ship Scenario: EPCIS+DPMS Linked Approach (full)

This linked approach has several advantages compared to either the “separate worlds” approach or the “EPCIS-only” approach:

- The existing Drug Pedigree Messaging Standard is leveraged. There is only one representation for pedigree information.
- Pedigrees are self-contained, and so easily accessible by regulators, law enforcement, and other *ex post facto* scenarios.
- Visibility events do not contain unwanted pedigree information. Visibility applications can query for serial number visibility events and not be burdened with additional data.
- Pedigrees may be transmitted either by EDI, web services or other non-EPCIS means, or by EPCIS.
- An application can easily discover the UUIDs of all pedigrees associated with an EPC, by querying for all “Pedigree Create” events for that EPC. The application can then request the pedigree either by EPCIS (by querying for a “Pedigree” event with a matching UUID in the BizTransaction field if those events are supported) or some other means.
- An application can easily discover any pedigrees that might pertain to a specific serial number visibility event of interest, by looking in the BizTransactionList field for an identifier of type Pedigree UUID, if present.

- The overall scheme extends naturally if new business processes arise in the future that require new types of documents (that is, a third thing besides serial number visibility events and pedigrees). The information content of a visibility event does not keep expanding.

### 3.4 Linked Approach: Specification

This section provides a precise specification of the proposal that is outlined in Section 3.3. *Readers not interested in implementation details may skip this section by jumping to Section 4 on page 24.*

As noted in the previous section, this proposal has three parts:

- A new EPCIS event to indicate the creation of a new pedigree. This is a TransactionEvent with a business step of “PedigreeCreated,” as specified in Section 3.4.1 below.
- (Optional) A pointer that may be used in ordinary EPCIS serial number visibility events to indicate the correlation to a pedigree event. This takes the form of a new business transaction type identifier that may be used in the business transaction list of any EPCIS event, as specified in Section 3.4.2 below.
- (Optional) A new EPCIS event that encapsulates an entire Drug Pedigree Messaging Standard pedigree, so that pedigrees may be transported using the EPCIS Query Interface. This is a TransactionEvent with a business step of “Pedigree,” together with an extension field containing the Drug Pedigree Messaging Standard pedigree envelope, as specified in Section 3.4.3 below.

These three parts are specified in the following subsections.

In the specifications that follow, identifiers such as

`urn:epcglobal:epcis:pedigree:bizStep:pedigree` are specified. These are intended to be illustrative; we expect that the exact spelling of these identifiers as well as other fine details of this kind would be worked out by an appropriate EPCglobal technical Working Group.

#### 3.4.1 Pedigree Creation Event

The Pedigree Creation event is an EPCIS TransactionEvent as specified below. It SHALL be generated each time a new pedigree is created (either an initial pedigree or a shipped/receivedPedigree that wraps an existing pedigree), by the party that creates and signs the pedigree.

Field	Type	Required	Description
eventTime	Time	Required	As specified in [EPCIS].
recordTime	Time	Optional	As specified in [EPCIS].
eventTimeZoneOffset	String	Required	As specified in [EPCIS].
bizTransactionList	List<Business-Transaction>	Required	SHALL contain a single BusinessTransaction element as specified in Section 3.4.2. This identifies the pedigree to which this event refers.
parentID	String	Optional	If specified, it SHALL be an identifier that identifies the overall shipment or unit to which the associated pedigree applies; e.g., a pallet SSCC. MAY be omitted if there is no suitable identifier.

Field	Type	Required	Description
epcList	List<String>	Optional	If specified, it SHALL include the EPCs of all products named in the associated pedigree's itemInfo. MAY be omitted if the pedigree's itemInfo does not include serialized identifiers.
action	Action	Required	SHALL be the value ADD.
bizStep	BusinessStepID	Required	SHALL be the value urn:epcglobal:epcis:pedigree:bizStep:pedigree_created
disposition	DispositionID	Omitted	SHALL be omitted
readPoint	ReadPointID	Optional	SHALL be omitted if no EPCIS visibility event is created in conjunction with creating the pedigree. If an EPCIS visibility event is created in conjunction with creating the pedigree, this field MAY be a copy of the readPoint field of that event, or it MAY be null.
bizLocation	BusinessLocationID	Optional	SHALL be omitted if no EPCIS visibility event is created in conjunction with creating the pedigree. If an EPCIS visibility event is created in conjunction with creating the pedigree, this field MAY be a copy of the bizLocation field of that event, or it MAY be null.

Here is an example pedigree creation EPCIS event, rendered into XML:

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<epcis:EPCISDocument
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  creationDate="2005-07-11T11:30:47.0Z"
  schemaVersion="1">
  <EPCISBody>
    <EventList>
      <TransactionEvent>
        <eventTime>2005-04-03T20:33:31.116-06:00</eventTime>
        <eventTimeZoneOffset>-06:00</eventTimeZoneOffset>
        <bizTransactionList>
          <bizTransaction
            type="urn:epcglobal:epcis:pedigree:btt:pedigree">urn:uuid:f81d4fae-7dec-11d0-a765-
            00a0c91e6bf6</bizTransaction>
          </bizTransactionList>
        <epcList>
```

```

    <epc>urn:epc:id:sgtin:0614141.107346.2017</epc>
  </epcList>
  <action>ADD</action>
  <bizStep>urn:epcglobal:epcis:bizstep:pedigree:pedigree_created</bizStep>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

### 3.4.2 Pedigree Business Transaction Identifier

A new business transaction identifier is specified here, allowing any EPCIS event to refer to a Drug Pedigree Messaging Standard pedigree by including it in the `bizTransactionList` field of the event. This is used in two places:

- (Required) A Pedigree Creation event as specified in Section 3.4.1 SHALL include a pedigree business transaction reference as the sole `BusinessTransaction` in its `bizTransactionList`. This specifies the pedigree to which the Pedigree Creation Event refers.
- (Optional) Any EPCIS event that is normally used in serial number visibility applications MAY include a pedigree business transaction reference in its `bizTransactionList`, in addition to any other business transaction identifiers that may be present. The pedigree business transaction reference, when present in a serial number visibility event, indicates that a pedigree was created in conjunction with completing the business step that the visibility event describes.

A pedigree `BusinessTransaction` has fields as follows:

Field	Type	Required	Description
<code>type</code>	<code>BusinessTransactionTypeID</code>	Required	SHALL contain the value <code>urn:epcglobal:epcis:pedigree:btt:pedigree</code>
<code>bizTransaction</code>	<code>BusinessTransactionID</code>	Required	SHALL contain the UUID of the referenced pedigree, as an RFC4122-compliant URI. This value SHALL be identical to the <code>serialNumber</code> field within the <code>DocumentInfo</code> section of the referenced pedigree.

Here is an example XML fragment showing a pedigree business transaction reference as it might appear within an EPCIS event rendered into XML:

```

  <bizTransactionList>
    <bizTransaction
type="urn:epcglobal:epcis:pedigree:btt:pedigree">urn:uuid:f81d4fae-
7dec-11d0-a765-00a0c91e6bf6</bizTransaction>
  </bizTransactionList>

```

Section 3.4.1 shows an example pedigree creation event, including the pedigree business transaction reference.

Here is an example EPCIS visibility event that has been augmented to include a pedigree business transaction reference, in addition to other business transaction identifiers (this is the same event as the first event in the example in [EPCIS], Section 9.6):

```

<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<epcis:EPCISDocument
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  creationDate="2005-07-11T11:30:47.0Z"
  schemaVersion="1">

```

```

<EPCISBody>
  <EventList>
    <ObjectEvent>
      <eventTime>2005-04-03T20:33:31.116-06:00</eventTime>
      <eventTimeZoneOffset>-06:00</eventTimeZoneOffset>
      <epcList>
        <epc>urn:epc:id:sgtin:0614141.107346.2017</epc>
      </epcList>
      <action>OBSERVE</action>
      <bizStep>urn:epcglobal:epcis:bizstep:fmcg:shipped</bizStep>
      <disposition>urn:epcglobal:epcis:disp:fmcg:unknown</disposition>
      <readPoint>
        <id>urn:epc:id:sgln:0614141.07346.1234</id>
      </readPoint>
      <bizLocation>
        <id>urn:epcglobal:fmcg:loc:0614141073467.A23-49</id>
      </bizLocation>
      <bizTransactionList>
        <bizTransaction
type="urn:epcglobal:fmcg:btt:po">http://transaction.acme.com/po/12345678</bizTransaction>
        <bizTransaction
type="urn:epcglobal:epcis:pedigree:btt:pedigree">urn:uuid:f81d4fae-7dec-11d0-a765-
00a0c91e6bf6</bizTransaction>
      </bizTransactionList>
    </ObjectEvent>
  </EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

### 3.4.3 Pedigree Event

The Pedigree event is an EPCIS TransactionEvent as specified below. It MAY be generated each time a new pedigree is created (either an initial pedigree or a shipped/receivedPedigree that wraps an existing pedigree), by the party that creates and signs the pedigree. The Pedigree event encapsulates an entire Drug Pedigree Messaging Standard pedigree envelope so that it may be transmitted via the EPCIS Query Interface.

The pedigree envelope itself is carried in an extension field. As proposed below, the XML namespace for the extension field is urn:epcglobal:epcis:pedigree:xsd:1 and the element name within that namespace is pedigree.

Field	Type	Required	Description
eventTime	Time	Required	As specified in [EPCIS].
recordTime	Time	Optional	As specified in [EPCIS].
eventTimeZoneOffset	String	Required	As specified in [EPCIS].
bizTransactionList	List<Business-Transaction>	Required	SHALL contain a single BusinessTransaction element as specified in Section 3.4.2. This identifies the pedigree that this event encapsulates. Repeating this as an EPCIS field facilitates querying.

Field	Type	Required	Description
parentID	String	Optional	If specified, it SHALL be an identifier that identifies the overall shipment or unit to which the associated pedigree applies; e.g., a pallet SSCC. MAY be omitted if there is no suitable identifier. Repeating this as an EPCIS field facilitates querying.
epcList	List<String>	Optional	If specified, it SHALL include the EPCs of all products named in the associated pedigree's itemInfo. MAY be omitted if the pedigree's itemInfo does not include serialized identifiers. Repeating this as an EPCIS field facilitates querying.
action	Action	Required	SHALL be the value ADD.
bizStep	BusinessStepID	Required	SHALL be the value urn:epcglobal:epcis:pedigree:bizStep:pedigree
disposition	DispositionID	Omitted	SHALL be omitted
readPoint	ReadPointID	Optional	SHALL be omitted
bizLocation	BusinessLocationID	Optional	SHALL be omitted
urn:epcglobal:epcis:pedigree:xsd:1#pedigree	PedigreeEnvelopeType as defined in [DPMS]	Required	SHALL be the pedigree that this event encapsulates

Here is an example pedigree EPCIS event, rendered into XML:

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<epcis:EPCISDocument
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:epcis-pedigree="urn:epcglobal:epcis:pedigree:xsd:1"
  xmlns:pedenv="urn:epcGlobal:PedigreeEnvelope:xsd:1.1"
  creationDate="2005-07-11T11:30:47.0Z"
  schemaVersion="1">
  <EPCISBody>
    <EventList>
      <TransactionEvent>
        <eventTime>2005-04-03T20:33:31.116-06:00</eventTime>
        <eventTimeZoneOffset>-06:00</eventTimeZoneOffset>
        <bizTransactionList>
          <bizTransaction
            type="urn:epcglobal:epcis:pedigree:bt:pedigree">urn:uuid:f81d4fae-7dec-11d0-a765-
            00a0c91e6bf6</bizTransaction>
          </bizTransactionList>
        <epcList>
          <epc>urn:epc:id:sgtin:0614141.107346.2017</epc>
        </epcList>
        <action>ADD</action>
      </TransactionEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

```
<bizStep>urn:epcglobal:epcis:bizstep:pedigree:pedigree</bizStep>
<epcis-pedigree:pedigree>
  <pedenv:pedigreeEnvelope>
    <pedenv:serialNumber>urn:uuid:f81d4fae-7dec-11d0-a765-
00a0c91e6bf6</pedenv:serialNumber</pedenv:serialNumber>
    <!-- remainder of pedigree goes here -->
  </pedenv:pedigreeEnvelope>
</epcis-pedigree:pedigree>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>
```

## 4 Conclusion

EPC Information Services (EPCIS) is a standard for sharing of product serial number visibility information between trading partners, facilitating track and trace and other business processes that can benefit from knowing where things are. The Drug Pedigree Message Standard has been widely adopted to meet the requirements of drug pedigree regulations whose aim is to assure the security and authenticity of pharmaceutical products. Both product serial number visibility and product security are important goals for the pharmaceutical industry, and so EPCIS and the Drug Pedigree Message Standard have complementary roles to play.

While EPCIS and the Drug Pedigree Message Standard have some superficial similarity in the kind of information they record, we believe it is wrong to conclude that one standard can subsume the other. A closer examination of each standard shows that despite the superficial similarity, there are important differences in the construction and consumption of serial number visibility and pedigree data. These differences have led to fundamentally different approaches in each standard: distributed, fine-grained event data based on physical handling steps in the case of EPCIS, versus aggregated, signed data based on ownership changes in the case of the Drug Pedigree Message Standard. These differences make it quite difficult to adapt one standard to serve the other's purpose. In particular, we believe that proposals to derive pedigree data exclusively from EPCIS event data are overly complex and fail to meet key regulatory and business requirements.

We firmly believe, however, that EPCIS and the Drug Pedigree Message Standard can and should be used in combination to get the best of both worlds. We have proposed a simple way to link EPCIS serial number visibility data to pedigree data expressed in the Drug Pedigree Message Standard. Compared to other approaches, the resulting combination retains all the strengths of each standard, makes it just as easy for applications to use both types of data together, and provides a much gentler adoption path. We believe our paradigm of loose coupling between EPCIS and the Drug Pedigree Message Standard can serve as a model for integration of other business processes and data with EPCIS that will scale well as more applications are added.

Together, EPCIS and the Drug Pedigree Message Standard form the foundation of the pharmaceutical track and trace system that the industry will rely on in coming years.

## 5 References

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