

HDMA Baseline Technical Recommendations for Compliance With Requirements of California's SB 1476 (2006)

I. Introduction

The following information was developed by HDMA in an effort to assist companies in determining compliance strategies that can meet the requirements of the current California law. In developing these technical recommendations, HDMA worked closely with Active distributor members with business interests in the state of California.

These recommendations are intended to serve only as a baseline reference tool for healthcare supply chain partners. They are based on industry input, existing and developing third-party standards and currently available technologies.

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II. Background

The goal of the legislature upon enactment of Senate Bill 1476 (2006) was to ensure that California citizens are further protected from the threat of counterfeit drugs, and that supply chain partners employ the most advanced technologies available in order to enhance efficiency and safety.

Section 4034 of the California Business and Professions Code defines pedigree, its contents and sets parameters for the basic process of "passing pedigree" among supply chain partners. These requirements include the following:

- ✦ A pedigree must accompany every prescription drug;¹
- ✦ Established at point of manufacture;
- ✦ Defined as "a record, *in electronic form*, containing information regarding each transaction resulting in a *change of ownership* . . . , from sale by a manufacturer, through

¹ The California requirement refers to prescription drugs as "dangerous drugs." This is a term defined by the state and not intended to be interpreted as meaning "high risk," but merely "requiring a prescription." (See CAL.BUS. & PROF. CODE § 4022).

acquisition(s) and sale(s) by one or more wholesaler, manufacturers, or pharmacies, until final sale to a pharmacy or other person . . .”;

- ◆ Pedigree shall be “. . . *created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.*”;
- ◆ “*Interoperable electronic system*” as defined under California law “means an electronic track-and-trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers and pharmacies for the pedigree of a dangerous drug”;
- ◆ A distributor, or “wholesaler” in statute, may not purchase a prescription drug in the state of California without receiving a pedigree, nor can they sell a prescription drug without providing its pedigree; and
- ◆ Injectable drugs shipped from the manufacturer to an authorized prescriber or other entity for administration to the patient are exempt from pedigree requirements until January 1, 2010.

These statutory requirements meet the Board of Pharmacy’s goal of being able to determine the transaction history – or chain of custody – of any prescription medicine in the state of California. The ability to track a unique product from the manufacturer, to the distributor, to the final dispensing pharmacy or healthcare provider is an essential requirement of the California law.

For your convenience, relevant portions of SB 1476 are reproduced in Appendix II. HDMA reminds its members that each company must use its own independent business judgment with respect to compliance with SB 1476 or any other federal or state law or regulation. Companies should always consult with their own independent legal counsel when making such autonomous decisions.

Track and Trace in the Context of California law

When the authors of the California law enacted these requirements, they intended for pedigrees to be maintained and passed via electronic means. It was also the intent of the legislation that pedigree in California would track and trace individual items in order to distinguish one prescription medicine from another. Meeting this goal likely will require the use of advanced technologies and the development of systems that allow trading partners to communicate pedigree data from the beginning to the end of the supply chain. Today, EPCglobal and GS1 standards offer the best available guidance for companies trying to develop interoperable pedigree systems.

Pedigree, as defined by California law, is not based on lot number or e-pedigree systems that are available today. Rather, the state envisions the use of current and emerging technologies (such as EPC tags or 2D bar codes) to uniquely identify individual items. Specifically, the law states that the pedigree shall track each dangerous drug at the smallest package received by the pharmacy or another person furnishing, administering or dispensing the dangerous drug.

III. Compliance Options

Standards

The intent of the California Legislature and the California Board of Pharmacy is not to dictate the technologies that should be used to meet the law's requirements; however, the current law states,

“. . . the electronic track and trace system for dangerous drugs . . . uses a unique identification number . . . contained within a *standardized* nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree . . .”²

It is believed that the inclusion of this language in the statute was meant to give all supply chain partners access to - and encourage the development of – standardized implementation methods. Presumably, this was done in order to help companies satisfy the requirements of the law and ensure “interoperability” while developing individual compliance mechanisms.

In the area of track-and-trace technology, and more specifically, Radio Frequency Identification (RFID), EPCglobal currently is the leading organization engaged in developing industry-recognized standards for use in the area of pedigree. EPCglobal is an international, a subscriber-driven standards organization comprised of industry leaders and organizations focused on creating global standards for the Electronic Product Code™ (EPC) and the EPCglobal Network™. EPCglobal's goal is increased visibility and efficiency throughout the supply chain and higher quality information flow between companies and their key trading partners.

HDMA and its members have been active participants in various work groups, and have supported EPCglobal and its parent organization, GS1, in the standards development process for track and trace, including serialization, e-pedigree messaging and data carriers. When there is an approved track-and-trace standard, HDMA expects that the great majority of companies will adopt the standard to support pedigree requirements, as well as gain other benefits.

Available Technologies – RFID vs. 2D

Based on today's available technologies, as well as current and developing standards, either RFID or barcode technologies could be used to comply with California law, depending on individual company preferences and business needs.

Today, bar codes are used throughout the supply chain to identify products. Currently, different levels of information can be carried in a bar code, including a product's National Drug Code (NDC) and expiration date. “2D” or “Two Dimensional” bar codes represent one type of bar code that can enable the assignment of unique product identifiers to individual prescription medicine packages.

² (CAL.BUS. & PROF. CODE § 4034 (i)).

Unique product identification can also be accomplished through the use of Electronic Product Code (EPC) tags and an RFID infrastructure for reading those tags. The Federal Food and Drug Administration has recognized the ability of RFID to enable tracking of a prescription drug from the manufacturer, to the distributor, to the pharmacy, and has promoted the technology as a key way to help prevent counterfeits from entering the legitimate supply chain.

Both of these technologies allow manufacturers to uniquely serialize individual prescription medicines in compliance with the California pedigree requirements. Each, however, has its own benefits and detriments, depending on different business considerations of individual companies or segments of the supply chain.

For example, while 2D barcode technology may be less costly initially, products with 2D bar codes may travel at a much slower rate through the supply chain, incur higher labor costs due to the need to scan individual packages at each transaction point and adopting businesses may realize fewer collateral benefits. Conversely, RFID may have greater costs at the outset for supply chain partners, but it supports non-line-of-sight product scanning to support increased efficiencies and offers added benefits to adopters, such as theft prevention and inventory management.

The Distributor Perspective

HDMA member companies should work with their individual vendors, suppliers and customers to develop the best possible solutions for compliance with California's law. Because of their unique position at the center of the supply chain, distributors also may be able to assist other stakeholders in developing compliance solutions. Conversely, distributors also are subject to the individual business decisions of more than 1,150 manufacturers and 144,000 pharmacy customers.

HDMA distributor members store, manage and deliver approximately 80 percent³ of all prescription medicines sold in the United States. A typical distribution center receives more than 1,387 orders and ships nearly 67,600 units per day. Based on the current volume of product moving through the supply chain on a daily basis, a non-line-of-sight technology, such as RFID, offers the most promise for maintaining high levels of efficiency and service, needed to preserve patient access to safe medicines.

This recommendation is based on supply chain partner experience with pilot projects, current process analysis and regulatory compliance efforts in other states. These technical recommendations are therefore based on a business case using RFID as the primary technology for compliance with California law. However, we recognize that in some cases – depending on trading partner preferences – 2D bar codes may be the technology of choice.

In the following recommendations – meant to serve merely as a baseline reference tool for companies engaging in the development of processes and systems for compliance with California law – we focus on RFID, with 2D bar codes used as a “back up,” or secondary technology.

³Based on U.S. sales of pharmaceutical products of \$275 million per year. Healthcare Distribution Management Association, *HDMA 2007-2008 Factbook* (2007).

IV. Technical Recommendations

As mentioned above, there may be multiple possibilities for assigning “unique identification numbers” that might satisfy the California pedigree requirements. However, HDMA observes that the current state of technological and standards development, along with the typical business model of distributors, favors use of radio frequency identification (RFID) tags using EPCglobal standards (where applicable) as the primary data carrier. Linear bar codes (using GS1 standards) and 2D bar codes may serve as possible secondary data carriers. Again, this recommendation is based on pilot programs, existing technological capabilities and the volume of products that travel through the supply chain.

Currently, there are EPCglobal standards for RFID tags that HDMA believes, if used, could meet California’s pedigree requirements. The EPCglobal UHF Gen 2 item-level tag is available for use today. When available in production volumes, EPCglobal HF version 2 tags also show potential for use, and may increase tag readability for products with certain properties, including liquids.

Additionally, based on their technical capabilities to support unique identifiers, 2D data matrix bar codes and/or linear bar codes may prove to be useful as a secondary, or “back up” technology that can be used when RFID tags malfunction, or otherwise cannot be scanned. This type of bar code would include an NDC number incorporated into the GS1 GTIN format and serial number.

Hierarchical shipment data, including serial numbers would be communicated in advance to the customer. Such data could include case-to-item aggregation information provided by the supplier. For example, companies that receive pallets frequently may require aggregation up to and including pallet identification information. Identifying serial numbers would be applied to individual items, as well as larger packaging containers (pallets, cases, totes, etc.) in order to help maintain efficiency and service levels in the supply chain.

Following are baseline technical recommendations (See also Appendix I) for each of these levels of product packaging. In making these recommendations, HDMA considered the availability of technologies and industry-recognized standards, as well as results from early pilots and the California pedigree provisions.

ITEM-LEVEL IDENTIFICATION

Section 4034 of the California Business and Professions Code specifies that the required track-and-trace pedigree system employ unique identification numbers for prescription drugs, established at the point of manufacture and contained within a standardized, nonproprietary data format and architecture that is uniformly used by manufacturers, distributors and pharmacies.⁴ Currently there is an EPCglobal UHF Gen 2 item level tag available for use that HDMA believes could enable compliance with this requirement at the item level. When available in production

⁴ (CAL.BUS. & PROF. CODE § 4034 (i)).

volumes, EPCglobal HF version 2 tags also could be used to increase tag readability for certain products, such as liquids.

2D data matrix bar codes are recommended as a “back up,” secondary identifier at the item level. The 2D bar code would include two application identifiers (AI) for NDC and unique serialization. The two AIs are encoded into the GS1 2D data carrier.

CASE-LEVEL IDENTIFICATION

For identification of prescription medicines at the case level, HDMA believes trading partners likely would prefer EPCglobal UHF Gen 2 RFID case level tags. A bar code using GS1 linear standards could be a secondary option. On cases too small for linear bar codes, 2D data matrix bar codes could be used.

PALLET-LEVEL IDENTIFICATION

For locations that frequently receive products in pallet quantities, EPCglobal UHF Gen 2 RFID tags may be requested by distributors to facilitate receiving. This will be communicated by specific trading partners.

V. Implementation

To help assure compliance with the California pedigree requirements, and give trading partners time to develop and test new business processes, HDMA members believe that it will be necessary to begin uniquely identifying and tagging individual products, as described earlier, at least six months prior to the law’s effective date. HDMA recommends that trading partners begin discussions now about potential plans for compliance with California law SB1476.

VI. Conclusion / Resources

HDMA has compiled the information contained in this document to assist companies working toward compliance with California’s requirements. In addition to these recommendations, HDMA urges individual companies to consult with their trading partners, professional and trade associations, technology vendors and standards organizations as the California effective date approaches. We also recommend the following additional resources:

- California Board of Pharmacy Web site: <http://www.pharmacy.ca.gov/>
- California Business and Professions Code: <http://www.leginfo.ca.gov/cgi-bin/calawquery?codesection=bpc&codebody=&hits=20> (See Chapter 9)
- California Administrative Code:
- EPCglobal: <http://www.epcglobalinc.org/home>
- FDA on Combating Counterfeits: <http://www.fda.gov/oc/initiatives/counterfeit/>

Appendix I

Suggested Technical Specifications

Item Level

RFID – PRIMARY Carrier

- UHF Gen 2 with a SGTIN-96 encoded EPC value per the EPCglobal Tag Data Standards V1.3, Section 3.5, with optional product code (e.g.: NDC)
- HF Generation 2 will be supported when standards are completed.

Bar Code – BACK-UP Carrier

2D ECC Data Matrix encoding AI(01) GTIN + AI(21) serial number

Case Level – Homogenous Product

RFID – PRIMARY Carrier

- UHF Gen 2 with a SGTIN-96 encoded EPC value per the EPCglobal Tag Data Standards V1.3, Section 3.5

Bar Code – BACK-UP Carrier

- Linear GS1 Code 128 encoding concatenated AI (01) GTIN + AI (21) serial number – for cases large enough to have linear bar codes.
- 2D data matrix (ECC200) encoding concatenated AI (01) GTIN + AI (21) serial number should be used for cases too small to have a linear bar code.

Case Level – Mixed Product

RFID – PRIMARY Carrier

- UHF Gen 2 with a SSCC-96 encoded EPC value

Bar Code – BACK UP Carrier

- Linear GS1 Code 128 encoding AI(00) SSCC-18

Pallet Level

RFID – PRIMARY Carrier

- UHF Gen 2 with a SSCC-96 encoded EPC value

Bar Code – BACK UP Carrier

- Linear GS1 Code 128 encoding AI(00) SSCC-18

Filter Values should be as follows:

	RFID Filter Value	
	Decimal	Binary
Unit dose	0	000
Item level	1	001
Inner pack	2	010
Case	3	011
Pallet	4	100
Reserved	5	101
Reserved	6	110
Reserved	7	111

Appendix II

Relevant Portions of California SB 1476 (2006)

The law, in relevant part, provides:

4034. (a) “Pedigree” means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, 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 of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.

...

(i) “Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

CAL. BUS. & PROF. CODE § 4034.