

HDMA Baseline Technical Recommendations for Compliance With California Pedigree Law

I. Introduction

The following information was developed by HDMA to assist companies in determining compliance strategies that can meet the track-and-trace requirements of the current California law. HDMA worked closely with Active Distributor and Associate Manufacturer members with business interests in the state of California to develop these technical recommendations.

These recommendations are intended to serve only as a baseline reference tool for healthcare supply chain partners. They were developed in consultation with industry representatives and in consideration of existing and developing third-party standards and currently available technologies.

This document is intended for informational and educational use only and does not constitute legal advice. HDMA offers a wide range of resources to its members and other supply chain partners. Note that the information presented here is intended to inform and assist companies in developing their individual operational and regulatory policies. Individual readers should consult with their company's legal counsel to determine the impacts of any applicable federal and state laws and regulations and whether individual business decisions should be made depending on the preferences and needs of supply chain partners. HDMA disclaims any or all liability arising from any use of the material contained herein.

II. Background

The goal of the California Legislature upon enacting Senate Bill 1307 (2008) was to further protect California citizens from the threat of counterfeit drugs. The legislation was developed with the intent that supply chain partners employ the most advanced technologies available to enhance efficiency and safety.

Section 4034 of the California Business and Professions Code defines pedigree and sets parameters for the basic process of "passing pedigree" among supply chain partners. In California, a pedigree must be established at the point of manufacture and accompany every prescription drug.¹ Specific requirements include the following:

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).

Pedigree is defined as “a record, *in electronic form*, containing information regarding each transaction resulting in a *change of ownership* ... , 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.*”²

“*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.”³

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. To accomplish this, the law outlines a phase-in of serialization and tracking of prescription drugs, beginning in 2015 with the serialization of product at the item level by manufacturers. Beginning July 1, 2016, a distributor, or “wholesaler,” 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. For pharmacies, the requirement to purchase pedigreed-only product begins on July 1, 2017. It is important to note that the law does not stipulate what type of data carrier or technology should be used to meet the requirements.

A list of the relevant sections of the California Business and Professions Code is provided later in this document. HDMA reminds its members that each company must use its own independent business judgment with respect to compliance with the California law 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 California Legislature enacted the S.B. 1307 requirements, it intended that pedigrees would be maintained and passed electronically. The legislature also envisioned that the pedigree would track and trace individual items to distinguish one prescription medicine from another. Meeting this goal according to the parameters outlined in the law 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 it appears that EPCglobal and GS1 standards offer some of the best available guidance for companies trying to develop interoperable pedigree systems.

² CAL.BUS. & PROF. CODE § 4034 (*emphasis added*).

³ CAL.BUS. & PROF. CODE § 4034

Pedigree, as defined by California law, is not based on the lot number or e-pedigree systems available today. Rather, the state envisions the use of current (data matrix bar codes) and emerging technologies (such as RFID tags) 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 ...⁴

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

Since the enactment of the California law, the FDA has issued guidance for industry regarding the use of standardized numerical identifiers (SNI) for prescription drug packages, as directed under Section 505 D of the *Federal Food, Drug, and Cosmetic Act* (the Act). By issuing this guidance, the FDA intended to assist with the development of standards and systems for identification, validation, authentication and the tracking and tracing of prescription drugs. The FDA defines SNI for package-level identification at the unit level.

According to the FDA guidance, the SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the 10-digit National Drug Code (NDC) (as set forth in 21 CFR Part 207) that corresponds to the specific drug product (including the particular package configuration)⁴ combined with a unique serial number, generated by the manufacturer or repackager for each individual package. Serial numbers should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers).

⁴ (CAL.BUS. & PROF. CODE § 4034 (i)). (*emphasis added*)

While the California law does not specifically call for use of the SNI or reference FDA guidance, it is likely that the SNI standard would be compatible with California's unit-level identification requirement.

HDMA and its members actively participate in various work groups and have supported GS1 in the standards development process for track and trace, including serialization, e-pedigree messaging and data carriers. GS1 is an international not-for-profit standards development organization focusing on the development of supply chain standards. When GS1 establishes a track-and-trace standard, HDMA anticipates that companies will migrate toward that standard to help support pedigree requirements and gain other benefits

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. EPCglobal is an international, subscriber-driven standards organization comprising 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.

Available Technologies — Data Matrix Bar Codes & RFID

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.

Bar codes are used today throughout the supply chain to identify products. Currently, different levels of information can be carried in a linear bar code, including a product's National Drug Code (NDC) and expiration date. Data matrix bar codes are a specific type of "two-dimensional" bar code that can enable the assignment of unique product identifiers to individual prescription medicine packages. HDMA members generally follow GS1 standards for applying bar codes to products.

Both data matrix bar codes and RFID tags allow manufacturers to uniquely serialize individual prescription medicines in compliance with the California pedigree requirements. However, each has its own benefits and detriments, depending on different business considerations of individual companies or segments of the supply chain.

For example, while data matrix barcode technology may be initially less expensive, products with data matrix bar codes may travel at a much slower rate through the supply chain and incur higher labor costs because of the need to scan individual packages at each transaction point. Consequently, adopting businesses may realize fewer collateral benefits. Conversely, RFID may incur 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 HDMA Work Group Perspective

HDMA member companies should work with their individual vendors, suppliers and customers to develop the best possible solutions to comply with the California 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 1,226 manufacturers and suppliers and nearly 164,000 pharmacies, hospitals, nursing homes, clinics and others nationwide.

HDMA distributor members store, manage and deliver approximately 86 percent⁵ of all prescription medicines sold in the United States. A typical distribution center receives approximately 1,460 orders and ships nearly 85,575 units per day. Based on the current volume of product moving through the supply chain on a daily basis, the eventual use of a non-line-of-sight technology (such as RFID) has been thought to offer promise for maintaining high levels of efficiency and service — necessary components to preserving 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 GS1 DataMatrix bar codes or RFID as the technology for compliance with California law at the item level. Some trading partners may choose to use RFID currently or choose to migrate to RFID in the future. HDMA recognizes that the choice will be trading partner dependent.

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 GS1 DataMatrix bar codes and RFID technology at the item level.

⁵ Based on U.S. sales of pharmaceutical products of \$262.56 million per year. Center for Healthcare Supply Chain Research, *2010-2011 HDMA Factbook* (2010).

IV. Technical Recommendations

Following are baseline technical recommendations for levels of product packaging commonly found in the supply chain. 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.⁶

It is expected that GS1 DataMatrix bar codes and RFID tags will be used at the item level. It is recommended that the same information be encoded in the carrier regardless of choice of technology. Based on current industry feedback, the GS1 DataMatrix bar code will be the primary carrier at item level and RFID would be optional.

CASE-LEVEL IDENTIFICATION

For identification of prescription medicines at the case level, HDMA recommends the use of EPCglobal UHF Gen 2 RFID tags as the primary carrier. A bar code using GS1-128 linear standards would be optional. On cases too small for linear bar codes, GS1 DataMatrix 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 ensure compliance with the California pedigree requirements, and allow trading partners time to develop and test new business processes, HDMA members believe that it will be

⁶(CAL. BUS. & PROF. CODE § 4034 (I))

necessary to begin uniquely identifying and tagging individual products (as previously described) at least six months before the law's effective date. HDMA recommends that trading partners begin discussions now regarding potential plans to comply with the California law.

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 dates approach. We also recommend the following additional resources:

California Board of Pharmacy website: <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, Sections 4022, 4025, 4033, 4034, 4040.5, 4043, 4044, 4045, 4163, 4163.1, 4163.2, 4163.3, 4163.4, 4163.5, 4164, 4165, 4166, and 4169)

EPCglobal: <http://www.gs1.org/epcglobal>

GS1 US: <http://www.gs1us.org/>

FDA on Combating Counterfeits: <http://www.fda.gov/oc/initiatives/counterfeit/>

FDA Guidance for Standardized Numerical Identifiers:
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm>

APPENDIX I

HDMA 2015 California Technical Recommendations

HDMA believes the information should be provided in machine-readable and human-readable forms at all levels of packaging.

Pallet Level

Preferred Carrier: RFID UHF Gen 2 with a SSCC-96 encoded EPC value utilizing the current version of EPC Tag Data standard

Secondary Carrier: Linear barcode using GS1-128 encoding AI(00) SSCC

Case Level — Homogenous Product

Preferred Carrier: RFID UHF Gen 2 with a SGTIN-96 encoded EPC value per the current version of the EPCglobal Tag Data standards

Secondary Carriers:

Linear barcode GS1-128 encoding concatenated AI (01) GTIN + AI (21) serial number in the primary bar code and AI(17) lot, AI(10) expiration date and AI(30) quantity concatenated in the secondary bar code. Primary and secondary bar codes are two separate bar codes on case labels.

GS1 data matrix (ECC200), encoding the same data as the linear bar codes described in the above paragraph. The x-dimension of the symbol should be a minimum of 30.0 mils (.0300 in). This could be an additional bar code on the shipping label or used for cases too small to be able to accommodate linear barcode labels.

Refer to HDMA's Barcode Guidelines for further details on case labels and bar codes, available at www.ShopHDMA.org.

Case Level — Mixed Product

Preferred Carrier: RFID – UHF Gen 2 with a SSCC -96 encoded EPC value per the current version of the EPC Tag Data standard

Secondary Data Carriers: Linear barcode using GS1-128 encoding AI(00) SSCC

Item Level

Primary Carrier: GS1 Data Matrix (ECC200) encoding AI(01) GTIN + AI(21) serial number. The GTIN is 14 digits and has the NDC encoded in the data. Human readable should be included when space permits (review FDA guidance).

Optional Data Carrier: RFID UHF Gen 2 with a SGTIN-96 encoded EPC value, per the current version of the EPCglobal Tag Data Standards. When using RFID, a GS1 DataMatrix bar code should be included as a back-up machine readable carrier. The same information should be encoded in each carrier.