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http://www.pharmacy.ca.gov/meetings/agendas/2013/13_mar_enf_mat2.pdf
starting on page 4.

Edits in this document are recommended by Dirk Rodgers of RxTrace.com to enable the use of GS1 standards other than the GS1 Drag Pedigree Messaging Standard (DPMS). See the RxTrace essay, "Draft Regulations On Certifications Within California ePedigrees", April 15, 2013.

Certification

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

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

(1) The name and principal address of the source through direct reference or through secure supply chain master data reference that is resolvable to a singular set of values by all parties in the supply chain, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.

Comment [Dirk1]: This language is intended to enable the use of any Network Centric ePedigree (NCeP) architecture

Comment [Dirk2]: Intended to enable the use of a central or semi-central NCeP

Comment [Dirk3]: Intended to enable the use of GLN in place of the full address, but there would have to be a common way to resolve the references, and the GLN Registry used to resolve the references would have to be secured

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength through direct reference or through secure supply chain master data reference that is resolvable to a singular set of values by all parties in the supply chain, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address through direct reference or through secure supply chain master data reference that is resolvable to a single set of values by all parties in the supply chain, and federal or state registration and/or license number(s) permitting sale or transfer, and the dangerous drug shipping information, including the name and address through direct reference or secure supply chain master data reference that is resolvable to a single set of values by all parties in the supply chain of each person certifying delivery or receipt of the dangerous drug.

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

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

The electronic pedigree provided or made accessible by the source to the recipient shall ~~include a digital signature by a responsible party for the source~~ make use of a security technology that prevents any alteration, tampering, or other change to the pedigree during transmission to the recipient or to the secured repository, and that guarantees that the data is immutable and non-repudiable by the source.

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

(c) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of or access to an electronic pedigree, the recipient shall receive or access an electronic pedigree from or made accessible by the source that corresponds to the dangerous drug being delivered or transferred. The recipient shall certify receipt of the dangerous drug by verifying the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, confirming there is nothing in the transaction history that raises suspicion, verifying correspondence between the

Comment [Dirk4]: Intended to enable the use of GTIN in place of the full product details, but there would have to a common way to resolve the references, and the technique for resolving references would have to be secure

Comment [Dirk5]: Intended to eliminate the specification of a particular technology for accomplishing security and leaving it up to the industry to define an approach that meets the remaining specified requirements.

Comment [Dirk6]: Intended to enable the separation of non-repudiability and immutability and to allow these properties to be fulfilled by separate technology approaches. This is critical for enabling the use of GS1 EPCIS-based approaches.

pedigree data and the dangerous drug received~~, and by including in the pedigree a digital signature by a responsible party for the recipient that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the recipient.~~

(d) If a trusted third-party is used to as an intermediary to receive, hold and make accessible the pedigree on behalf of the source and recipient, the security technology used to protect the pedigrees shall prevent any alteration, tampering or other change to the pedigree except for the first source to place it there initially and subsequent owners of the drug to append information to the pedigree to ensure that it accurately reflects the true ownership history, and for contributing parties to update the information they originally contributed pursuant to correcting unintended errors as long as no original data is changed or destroyed, and guarantee that the data is immutable.

Comment [Dirk7]: Removal intended to enable the separation of non-repudiability and immutability and to allow these properties to be fulfilled by separate technology approaches. This is critical for enabling the use of GS1 EPCIS-based approaches.

Comment [Dirk8]: Intended to enable the separation of non-repudiability and immutability and to allow these properties to be fulfilled by separate technology approaches. This is critical for enabling the use of GS1 EPCIS-based approaches.

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