

**CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS  
HOUSE OF DELEGATES**

**OCTOBER 10 & 12, 2008**

**PROPOSAL K**

**PROPOSAL:** To adopt Professional Policy on e-Pedigree

**SUBMITTED BY:** CSHP Board of Directors

**DATE:** May 16, 2008

**DESCRIPTION OF CURRENT SITUATION:**

1. In 2004, legislation was passed requiring the development and implementation of an electronic pedigree system for any “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 deadline for implementation was extended to January 1, 2009 and for injectable drugs to January 1, 2010. Current legislation will potentially extend this deadline again to 2012-2013.
2. This issue is also being discussed at the federal level. The Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992, requires implementation of a pedigree requirement on prescription drugs. The implementation of regulations has been stayed and implementation is pending. Several states have started discussions on implementing e-Pedigree programs within their state. A program has been implemented in Florida in 2006.
3. The Board of Pharmacy has had significant discussions on e-Pedigree. This discussion has been lead by EPC Global, working with PHARMA organizations and wholesalers to develop a standard for labeling, RFID, etc. and the issues at the beginning stages of the supply chain. To date there have been limited discussions with pharmacies and health-systems that are at the end of the supply chain.
5. Manufactures and wholesales that each state will develop a different process that will be impossible for them to maintain. In addition, there is uncertainty as to what the federal requirements will be. Pharmacy is concerned that differing systems will be developed requiring multiple processes and equipment to receive medications from all sources to decommission the pedigree.
6. CSHP commissioned a task force last year to provide representation at meetings, develop a policy statement and determine an educational plan for membership. Members are Elaine Levy (Sharp HealthCare San Diego), Thomas Dotts (Pomona Valley Hospital), Rita Shane (Cedars Sinai Med Ctr), Candace Fong (Sutter Roseville Medical Center), Terry Nishizaki (UC Davis Medical Center) and Maria Serpa, (Sutter Medical Center Sacramento).

**DESCRIPTION OF DESIRED SITUATION:**

1. To have clear direction on e-Pedigree and the needs of pharmacy communities to assure a reasonable, safe, fiscally responsible and functional system is developed.

**PROPOSED ACTION(S):**

1. To adopt a Professional Policy statement as follows:

**E-Pedigree and Tracking of the Medication Supply Chain**

CSHP advocates for improved processes to assure the integrity of medications throughout the supply chain, specifically to eliminate or minimize the persistent and increasing threat from counterfeit, misbranded, adulterated, or diverted drugs.

1. Support the California State Board of Pharmacy's model for a comprehensive electronic pedigree system to track and trace the passage of medications through the entire supply chain.
2. Require the technology and process implemented be compatible with national and international standards so as not to impede the supply of medications within the California marketplace.
3. Require the technology(s) adopted must be a single, shared interoperable system to allow health-systems to receive medications from all sources in a single process.
4. Advocate that the technology developed has the future ability to extend the validation of the pedigree to the level of patient administration throughout the continuum of care.
5. Assure that health-systems be an active participant in the development of technology, process design and implementation. .
6. Advocate that the implementation deadlines for the supply chain be a phased in approach allowing health-systems time to implement after the deadlines for manufacturers and distributors.
7. Required that "grandfathered" inventory be addressed in the implementation plan to minimize inventory losses.
8. Advocate for a streamlined process to allow medication returns and "emergency" borrowing of medications within the documentation process.