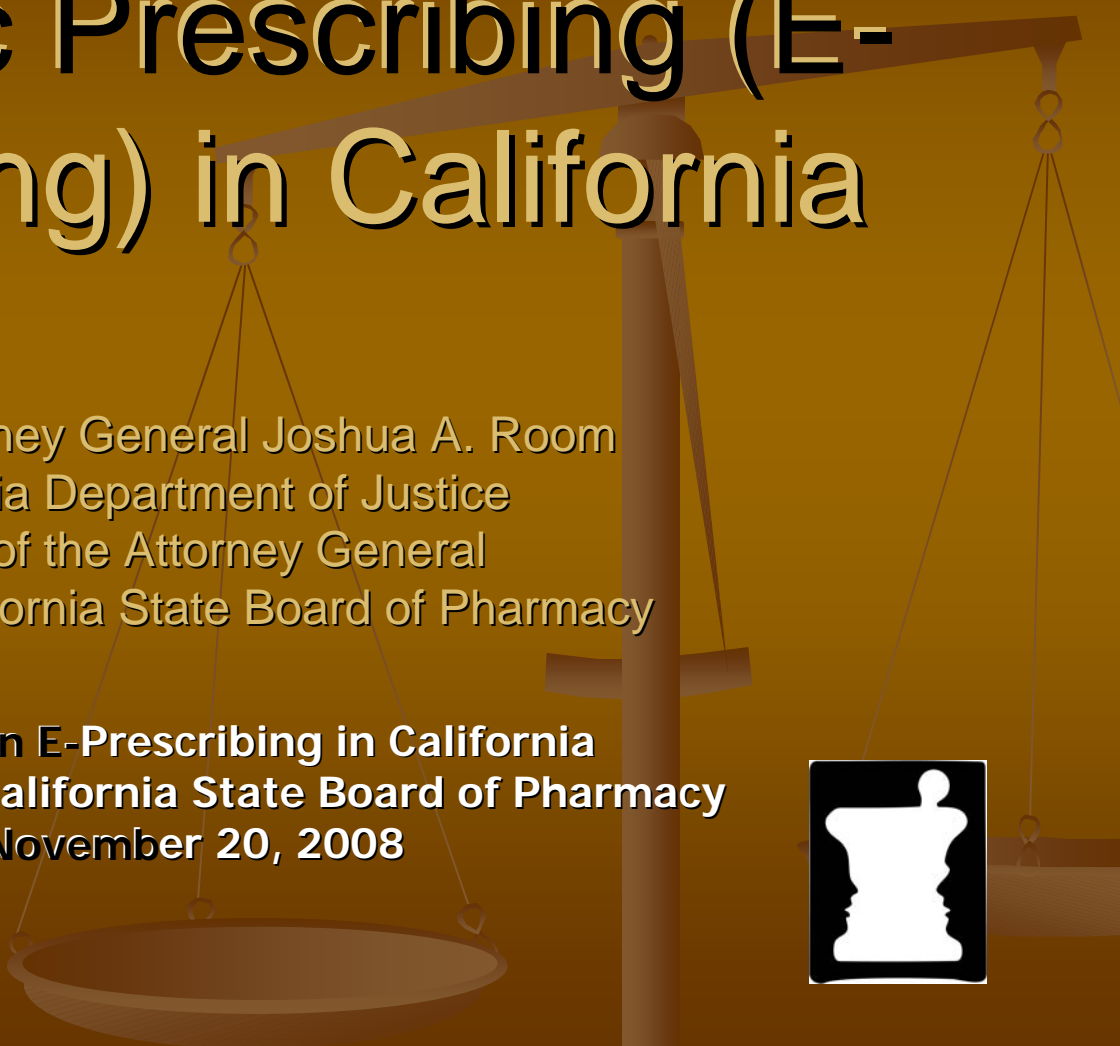


The Legal Landscape for Electronic Prescribing (E-Prescribing) in California



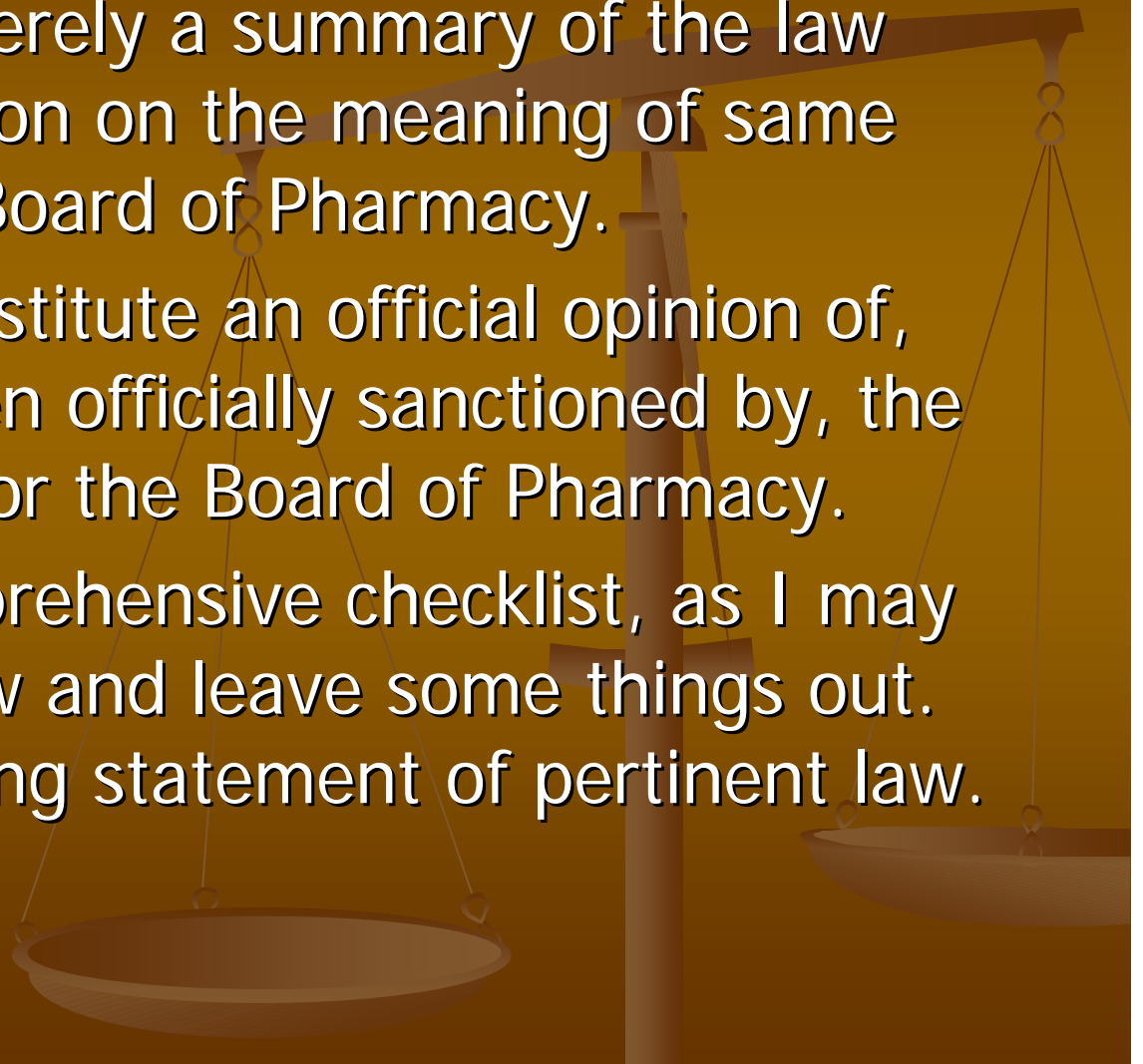
Deputy Attorney General Joshua A. Room
California Department of Justice
Office of the Attorney General
Liaison to California State Board of Pharmacy

Summit on E-Prescribing in California
Hosted by the California State Board of Pharmacy
November 20, 2008



A Few Words of Caution

- What follows is merely a summary of the law and my own opinion on the meaning of same prepared for the Board of Pharmacy.
- These neither constitute an official opinion of, nor have they been officially sanctioned by, the Attorney General or the Board of Pharmacy.
- This is not a comprehensive checklist, as I may summarize the law and leave some things out. This is not a binding statement of pertinent law.



CA is E-Prescribing “Friendly”

- “California regulates e-prescribing and is one of the most e-friendly states . . . the state has an open-ended definition of e-prescriptions that allows for different and emerging technologies.”

(Todd, *E-Prescribing in a Changing Legal Environment* (Spring 2006) 12 Rich. J.L. & Tech. 12, 20.)

California Has Embraced Electronic Prescribing For At Least 14 Years

- Since at least 1994, California has allowed e-prescribing for dangerous (prescription) drugs (and controlled substances), though pertinent to the latter is ongoing refusal of the DEA to permit e-prescribing by DEA registrants of controlled substances.
- So far, California has allowed VOLUNTARY participation. This may soon change.

Prescriptions May Be Electronic

- For at least 14 years, California law (Bus. & Prof. Code, § 4040; Health & Saf. Code, § 11027) has defined a “prescription” to include an “electronic transmission” order, in turn defined as:
 - “Electronic transmission prescription” includes both image and data prescriptions. “Electronic image transmission prescription” means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. “Electronic data transmission prescription” means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

General Requirements

- Further e-prescribing requirements are stated by California Code of Regulations, title 16, section 1717.4, and include requirements that:
 - The e-prescription include specified information about the prescriber, the date of transmission, and the recipient (Subdivision (c));
 - The “interim storage device” (file) into which an e-prescription is saved also record and maintain specified information on dates and recipients, and be secure from unauthorized access and use of prescription information, including dispensing information (Subdivision (d));
 - The e-prescription be transmitted only to the pharmacy of the patient's choice, except in acute care hospitals (Subdivision (f)); and
 - That persons transmitting, maintaining, or receiving any prescription or prescription refill orally, in writing or electronically is responsible for the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein (Subdivision (g)).
- Summary: Requirements are general, and not technology-specific. This permits the use of different formats and technologies. This is part of the “friendliness” of the California legal environment.

Other Enabling Statutes – 1 of 3

- E-prescriptions for non-controlled substances do not have to be reduced to writing if prescription and dispensing information can be retrieved per request. (Bus. & Prof. Code, § 4070, subd. (b).)
- E-prescription and dispensing record must not be subject to alteration or destruction during retention period, and any correction or addition may only be made and approved by pharmacist. (Bus. & Prof. Code, § 4070, subd. (c).)

Other Enabling Statutes – 2 of 3

- Agents may transmit e-prescriptions for prescribers, except for Schedule II drugs. (Bus. & Prof. Code, § 4071.)
- Authorized prescriber, prescriber's agent, or pharmacist may enter prescription into pharmacy or hospital computer (i.e., via remote access); dispensing requires RPh approval. (Bus. & Prof. Code, § 4071.1.)

Other Enabling Statutes – 3 of 3

- Licensee (RPh, RN, LVN, etc.) with authority to do so, employed by or serving as consultant for licensed skilled nursing, intermediate care, or other health care facility, may use e-prescription transmission to furnisher on all except Schedule II drugs. (Bus. & Prof. Code, § 4072.)
- Prescriber may indicate “Do not substitute” on e-prescription without manual signature or initial. (Bus. & Prof. Code, § 4073.)

Controlled Substances – Awaiting DEA Approval

- General allowance for e-prescribing of all drugs (except Schedule II drugs in certain circumstances) overridden by more specific limitations on electronic prescribing (and dispensing electronic prescriptions) controlled substances.
- Summary: Awaiting DEA approval.

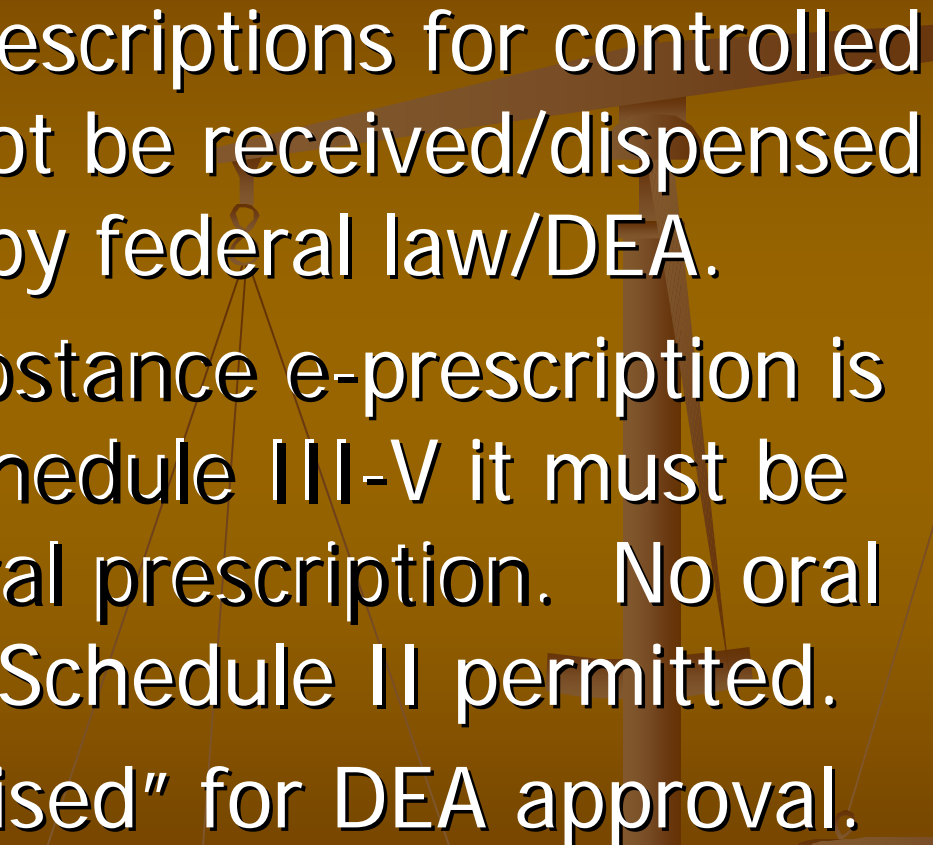
Controlled Substances – 1 of 3

- Schedule III-V (not Schedule II) drugs can be dispensed pursuant to e-prescriptions; dispensing pharmacist must still reduce to writing (i.e., print) and sign e-prescription. (All parties responsible, specified data is to be maintained, prescriber's agent allowed to transmit all but Schedule II.) (Health & Saf. Code, § 11164, subd. (b).)
- However . . . (and this is crucial) . . .

Controlled Substances – 2 of 3

- Only with the approval of the Board of Pharmacy and the Department of Justice, and only if authorized by federal law and DEA regulations may hospital or pharmacy receive e-prescriptions (or “direct entry” of electronic prescriptions) for any controlled substance (Schedule II-V). (Health & Saf. Code, § 11164.5, subd. (a).)

Controlled Substances – 3 of 3

- Summary: E-prescriptions for controlled substance cannot be received/dispensed until permitted by federal law/DEA.
 - If controlled substance e-prescription is received, for Schedule III-V it must be treated as an oral prescription. No oral prescription for Schedule II permitted.
 - California is “poised” for DEA approval.
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DEA Approval Pending

- In 2006, DEA and HHS held joint public informational meeting(s). Proposed DEA rule published June 27, 2008 to permit e-prescribing of controlled substances – sets up specific, fairly detailed, requirements.
- Comment period on rulemaking closed September 25, 2008. Board of Pharmacy among 400+ entities and persons to submit comments on proposed rules.
- Not sure if or when rule will be finalized.

Medicare Part D

- Medicare Modernization Act of 2003 (MMA), included a requirement that Medicare Part D drug plans support e-prescribing. Participation by prescribers and/or dispensers only voluntary.
- Between 2005 and 2008, as required by MMA, CMS promulgated regulations with standards for e-prescribing (and affiliated transactions). Now in final rule status.

Medicare Improvement Act

- Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provides financial incentives (then penalties) for prescribers participating in Medicare Part D to reach certain e-prescribing thresholds between 2009 and 2013.
- Incentives: 2009-2010 – 2%; 2011-2012 – 1%; 2013 – 0.5%. Penalties: 2013 – 1.5%; 2014 and beyond – 2%.

California is Falling Behind

- Despite friendly legal environment, speed of e-prescribing adoption in California is not great.
- SureScripts-RxHub SafeRx rankings: California # 14 in 2005, # 18 in 2006, # 22 in 2007. This is based on total percentages of prescriptions now transmitted electronically: 0.17% in 2005, 0.43% in 2006, and 1.44% in 2007. Despite a growth in e-prescribing, these statistics reflect that only 3% of prescribers used e-prescribing in 2007. Clearly, prescriber usage is the greater obstacle, as the same statistics show that 61% of CA pharmacies do/can accept e-prescriptions.

Attempts to Encourage

- California anti-kickback laws (Bus. & Prof. Code, § 650 et seq., Welf. & Inst. Code, § 14107.2) have twice been amended (AB 225 in 2006 and AB 55 in 2008) to provide “safe harbor” for provision of hardware and software to prescribers to facilitate electronic prescribing.
- This conforms with similar efforts as part of Medicare Part D regulations to permit provision of hardware and software.

Possibility of State Mandate

- In 2008, Governor proposed legislation (ABX1) that, among other things, would have required by January 1, 2012 all prescribers, prescribers' agents, and pharmacies, have ability to transmit and receive e-prescriptions, and given licensing boards the authority to enforce this requirement. ABX1 also would have set out standards for such electronic transmissions, including a requirement that the system(s) permit real-time benefit and formulary confirmations, and provide a receipt to the patient for the transmitted e-prescription.

E-Prescribing and Medicare

- President-Elect Obama repeatedly stated during the campaign that cost savings in Medicare (and Medicaid) could be realized with electronic health records (EHRs) and affiliated technologies. E-prescribing has a well-recognized cost-saving component.
- Reasonable to expect federal mandate (at least as to Medicare and Medicaid) soon.

Conclusions

- California law generally permits electronic prescribing. California has not specified a particular technology or methodology.
- E-prescribing of controlled substances is dependent on (upcoming?) DEA approval.
- Federal and state incentives. Thus far, all participation voluntary. Expected that the move to mandatory is forthcoming soon, at state level, and possibly federal.

Questions and Discussion

