Saint Louis University Journal of Health Law & Policy

Volume 5
Issue 1 *Implementing Health Reform: Fairness, Accountability & Competition*

Article 11

2011

Regulatory Barriers When Implementing E-prescribing of Controlled Substances: Could Model Language Be the Solution?

Charles S. Hartig
chartig@slu.edu

REGULATORY BARRIERS WHEN IMPLEMENTING E-PRESCRIBING OF CONTROLLED SUBSTANCES: COULD MODEL LANGUAGE BE THE SOLUTION?

Arguably nothing in our health-driven society permeates our everyday life more than prescription drugs. Evidence of this comes from all avenues of the prescription drug industry. Prescription drug direct-to-consumer advertising is a multi-billion dollar market.[1] Prescription drug revenues totaled $300.3 billion dollars in 2009,[2] and over 3.6 billion prescriptions were dispensed.[3] In light of these trends, it is no surprise that prescription drug markets have been pushed to enhance delivery of medications from the physician to patient. This article will focus on the relatively new realm of electronic prescribing ("e-prescribing") and the effect new Drug Enforcement Agency ("DEA") regulations[4] will have on the practical implementation and delivery of prescription medications.

Health information technology ("HIT"), electronic health records ("EHR"), and e-prescribing are some of the flagships of healthcare reform.[5] However, this isn't a new phenomenon, EHR and e-prescribing initiatives were implemented prior to the Clinton Administration within the Department of Veterans Affairs' health system, under the VIST-A program.[6] VIST-A was

1. Theresa Howard, *Push Is on to End Prescription Drug Ads Targeting Consumers*, USA Today, (Aug. 10, 2009, 11:10 AM), http://www.usatoday.com/money/advertising/adtrack/2009-08-09-adtrack-prescription-drug-ads_N.htm.

2. Bill Berkrot, *U.S. Prescription Drug Sales Hit $300 bln in 2009*, REUTERS (Apr. 1, 2010, 1:34 PM), http://www.reuters.com/article/idUSTRE6303CU20100401.

3. *Id.*

4. *See* Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311).

5. Daniel J. Gilman & James C. Cooper, *There Is a Time to Keep Silent and a Time to Speak, the Hard Part Is Knowing Which Is Which: Striking the Balance Between Privacy Protection and the Flow of Health Care Information*, 16 MICH. TELECOMM. & TECH. L. REV. 279, 280, 286, 288 (2010); *see also* ATTILA HERTELENDY ET AL., AM. HEALTH INFO. MGMT. ASS'N (AHIMA), THE IMPLICATIONS OF HEALTH REFORM FOR HEALTH INFORMATION AND ELECTRONIC HEALTH RECORD IMPLEMENTATION EFFORTS 1 (2010), *available at* http://perspectives.ahima.org/PDF/Summer_2010/Implications_of_Health_Reform/Implications_of_Health_Reform_on_Health_Information_final.pdf.

6. DOUGLAS GOLDSTEIN ET AL., *Case Studies of VistA Implementation—United States and International*, *in* MEDICAL INFORMATICS 20/20, at 223, 226, 263 (2007), *available at* http://www.jblearning.com/samples/0763739251/39251_CH09_223_284.pdf; *see also*

the first major venture into the realm of EHR and e-prescribing, with the computerization of Veteran Affairs' health records.[7] The reach of e-prescribing is realizing new levels of integration with the promulgation of the DEA's new rule regulating e-prescribing of controlled substances.[8] In March 2010, the DEA issued rules allowing e-prescribing of controlled substances by all eligible, DEA-approved prescribers.[9]

I. E-PRESCRIBING EXAMINED

Before delving into the barriers of implementation and the potential solutions, an examination of e-prescribing is warranted. E-prescribing is defined as the transmission of prescription information through electronic media between the prescriber, pharmacy, pharmacy benefit manager, and/or health insurance plan.[10] E-prescribing can be a two-way or a multi-step transmission process.[11] At its core, the eligible prescriber types a prescription and sends it electronically (not by fax but via a closed secured internet network) to a participating pharmacy.[12] This information may go directly to a pharmacy or it may first be redirected to a health plan or managed care entity, such as a pharmacy benefit manager ("PBM"), for insurance approval.[13] Prescribers now have the option of sending electronic

June M. Sullivan, *Recent Development and Future Trends in Electronic Medical and Personal Health Records*, HEALTH LAW., Jan. 2007, at 16, 17.

7. GOLDSTEIN ET AL., *supra* note 6, at 226, 227, 263.

8. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,236.

9. The prescriber must meet all the formal requirements of the rule which includes a DEA registration number in good standing with the DEA. *Id.* at 16,313.

10. EHEALTH INITIATIVE, A CLINICIAN'S GUIDE TO ELECTRONIC PRESCRIBING 1 (2008), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/472/electronic-e-prescribing.pdf; *see also* NAT'L GOVERNORS ASS'N, ACCELERATING THE ADOPTION OF ELECTRONIC PRESCRIBING 1 (2009), *available at* http://www.nga.org/files/live/sites/NGA/files/pdf/0907EPRESCRIBING.PDF. The National Governors Association "electronic prescribing, or e-prescribing, is computer-based electronic generation and transmission of a prescription." *Id.* at 2.

11. CAL. HEALTHCARE FOUND., E-PRESCRIBING 21 (2001), *available at* http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/E/PDF%20EPrescribing.pdf.

12. *Id.* at 5; *see also* EHEALTH INITIATIVE, *supra* note 10, at 7, 25; *see also* SIEMENS, E-PRESCRIBING: THE PATH TO PHYSICIAN ADOPTION OF HIT 6 (2009), *available at* http://www.medical.siemens.com/siemens/en_INT/rg_marcom_FBAs/images/News/2010_01_HIT/EPrescribewhitepaperA91339721v3.pdf.

13. CAL. HEALTHCARE FOUND., *supra* note 11, at 20. Many e-prescribing initiatives can involve the insurance and formulary process to streamline insurance eligibility and coverage problems. EHEALTH INITIATIVE, *supra* note 11, at 1, 4. However, it is common for the e-prescribing relationship to be executed directly to retail pharmacies where a pharmacist and pharmacy technician handle insurance processing, prior authorizations, or any other insurance coverage/formulary issues. CAL. HEALTHCARE FOUND., *supra* note 11, at 20.

prescriptions via wireless devices such as secure PDAs or cellular phones.[14] Pharmacies in turn receive the information through their closed pharmacy network and computer dispensing software that performs dispensing and screening functions.[15] Providers have two general approaches for implementing e-prescribing in their environment either: (1) stand-alone systems; or (2) integrated EHR systems with e-prescribing capabilities.[16] The latter involves a complete electronic overhaul of medical records including medical charting, lab results, billing information, and e-prescribing.[17] The stand-alone system is a separate software program that allows physicians to use traditional hospital resources in conjunction with a separate e-prescribing software component.[18]

E-prescribing has been scientifically studied and statistically proven to bring a number of benefits to the practice of medicine and pharmacy.[19] E-prescribing reduces medication errors,[20] and establishes a system to warn physicians of drug interactions and contraindications.[21] E-prescribing can economize a physician's practice if properly integrated into the workflow.[22]

14. CAL. HEALTHCARE FOUND., *supra* note 11, at 30.

15. Most major pharmacy software companies include e-prescribing software that integrates into an existing pharmacy system. *Surescripts Certified Pharmacy Software*, SURESCRIPTS, http://www.surescripts.com/connect-to-surescripts/pharmacy-software.aspx (last visited Nov. 8, 2011).

16. EHEALTH INITIATIVE, *supra* note 10, at 2.

17. *Id.*

18. *Id.*

19. Gordon D. Schiff & T. Donald Rucker, *Computerized Prescribing: Building the Electronic Infrastructure for Better Medication Usage*, 279 JAMA 1024, 1024 (1998). "According to the Center for Information Technology Leadership, use of e-prescribing and advanced decision-support capabilities could help prevent 130,000 medication errors annually." NAT'L GOVERNORS ASS'N, *supra* note 10, at 4.

20. David W. Bates et al., *The Impact of Computerized Physician Order Entry on Medication Error Prevention*, 6 JAMA 313, 319 (1999). Clinical decision support systems in e-prescribing software can perform checks against the patient's current medications for drug interactions, drug-allergy interactions, diagnoses, body weight, age, and correct dosing. EHEALTH INITIATIVE, *supra* note 10, at 3

21. EHEALTH INITIATIVE, *supra* note 10, at 3. It alerts prescribers to contraindications, adverse reactions, and duplicate therapy by using drug reference information, such as the Physician's Desk Reference (PDR) or Wolters Kluwer Health, Facts and Comparison. *Id.*; *Facts & Comparisons: About Us*, WOLTERS KLUWER HEALTH, http://www.factsandcomparisons.com/about-us.aspx (last visited Nov. 8, 2011).

22. Dereck L. Hunt et al., *Effects of Computer-Based Clinical Decision Support Systems on Physician Performance and Patient Outcomes: A Systematic Review*, 280 JAMA 1339, 1344 (1998); *see also* Amit X. Garg et al., *Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review*, 293 JAMA 1223, 1223 (2005).

E-prescribing also curbs illegible doctor's scrawl,[23] and misinterpreted oral orders for medication.[24] Additionally, e-prescribing reduces time spent on the phone with pharmacies, insurers, and other health care providers and it streamlines the medication delivery process.[25] E-prescribing has been shown to increase medication adherence and improve formulary management for patients.[26] If these benefits are not enough evidence, the e-prescribing adoption rate speaks for itself. Between 2008 and 2009 e-prescribing levels grew 284%.[27] All of these benefits culminated in the Institute of Medicine's ("IOM") recommendation that by 2010 "all prescribers should write, and all pharmacies should be able to receive, electronic prescriptions."[28]

Another major benefit to e-prescribing is the significant "buy-in" from the federal government. Beyond the new DEA rule, there have been several initiatives to foster e-prescribing adoption. The Medicare Modernization Act ("MMA") established the Medicare Part D drug benefit through privatized insurance companies.[29] With the Bush Administration's urging, one

23. EHEALTH INITIATIVE, *supra* note 10, at 3; The Institute of Medicine (IOM) estimates doctor's illegible handwriting kills thousands of people each year. Jeremy Caplan, *Cause of Death: Sloppy Doctors*, TIME (Jan. 15, 2007), http://www.time.com/time/health/article/0,8599,1578074,00.html.

24. Many oral prescription orders over the phone can be misinterpreted from the doctor or doctor's agent to the pharmacist or pharmacist technician. EHEALTH INITIATIVE, *supra* note 10, at 3.

25. *Id.*; CAL. HEALTH CARE FOUND., *supra* note 11, at 5; "Physicians and pharmacists spend up to 25% of their time clarifying prescription orders and processing renewal requests." NAT'L GOVERNORS ASS'N, *supra* note 10, at 4. The lost wages, time and productivity from these clarification duties may be limited by reducing potential communication failures. *Id.*

26. "It is estimated that 20% of paper-based prescription orders go unfilled by the patient—at least in part due to the hassle of dropping off a paper prescription and waiting for it to be filled." EHEALTH INITIATIVE, *supra* note 10, at 4. "By eliminating or reducing this wait, e-prescribing may help reduce the number of unfilled prescriptions." *Id.* Additionally e-prescribing allows health providers to track and analyze medication usage and efficacy. NAT'L GOVERNORS ASS'N, *supra* note 10, at 4. Beyond the medical community, private payors and self-insured employers recognize the benefits of e-prescribing and interoperable health records. Larry S. Boress, *An Extreme Makeover for the Employer's House of Health Benefits*, 32 J. LEGAL MED. 51, 59 (2011).

27. SURESCRIPTS, ADVANCING HEALTHCARE IN AMERICA: 2009 NATIONAL PROGRESS REPORT ON E-PRESCRIBING, PLUS WHAT'S AHEAD IN 2010 AND BEYOND 6 (2010).

28. Robert Steinbrook, *The (Slowly) Vanishing Prescription Pad*, 359 NEW ENG. J. MED. 115, 116 (2008); *see also* INST. OF MED., PREVENTING MEDICATION ERRORS: QUALITY CHASM SERIES 16 (2006).

29. This legislation provides seniors and individuals with disabilities with a prescription drug benefit, more choices with privatized insurers, and better benefits under Federal Medicare coverage. *See* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2072 (codified as amended at 42 U.S.C. § 1395w-101(a)(1)(B)(iii)).

provision of MMA required all insurance plans participating in the new prescription benefit must support e-prescribing.[30] Although MMA did not mandate prescribers or pharmacies to accept electronic prescriptions,[31] this insurance plan requirement was a step toward universal adoption of e-prescribing and EHR utilization. In 2008, Congress authorized the Center for Medicare and Medicaid Services ("CMS") to implement a Physician Incentive Program[32] under the federal statute, Medicine Improvements for Patients and Providers Act ("MIPPA").[33] The Physician Incentive Program[34] established by CMS offers financial incentives to providers who implement electronic health records with e-prescribing capabilities.[35] One of the requirements under the program is that prescribers must "meaningfully use" e-prescribing with a "certified" electronic health record system.[36] E-

30. *See id.* § 101, 117 Stat. at 2087 (codified as amended at 42 U.S.C. § 1395w-103(e)(2)(A)); *see generally* 42 U.S.C. §§ 1395w-101 to -154 (2006).

31. Lisette Hilton, *Steady Progress in E-prescribing*, AHIP COVERAGE (July/Aug. 2008), http://216.52.120.13/content/default.aspx?bc=31%7C130%7C136%7C24075%7C24080; *see* U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICARE PART D E-PRESCRIBING STANDARDS: EARLY ASSESSMENT SHOWS PARTIAL CONNECTIVITY 4 n.9 (2009), *available at* http://oig.hhs.gov/oei/reports/oei-05-08-00320.pdf; *see also* Medicare Prescription Drug Improvement and Modernization Act § 101, 117 Stat. at 2087, 2089 (codified as amended at 42 U.S.C. § 1395w-103(e)).

32. "[M]edicare Improvements for Patients and Providers Act of 2008 (MIPPA) authorizes a new and separate incentive program for eligible professionals who are successful electronic prescribers . . . . This new incentive program . . . began on January 1, 2009 . . . . To participate in the . . . eRx Incentive Program, individual eligible professionals must report on their adoption and use of a qualified eRx system by submitting claims information . . . on their Medicare Part B claims." *Overview: Electronic Prescribing (eRx) Incentive Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/ERxIncentive/01_Overview.asp#TopOfPage (last visited Nov. 5, 2011) [hereinafter *eRx Incentives*]. To be considered for the incentive program and potentially qualify to earn a 2% incentive payment on each eRx claim, prescribers must report the eRx measure in at least 50% of the cases. *Id.*

33. *See* Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, Pub. L. No. 110-275, § 132, 122 Stat. 2494, 2527 (to be codified at 42 U.S.C. 1395w-4).

34. *eRx Incentives, supra* note 32. *But see* Lindsey Getz, *E-Prescribing Standards — More Clarity Needed*, FOR THE RECORD, Apr. 26, 2010, at 14, 15. ("There are still many roadblocks in the way of more widespread adoption, perhaps the most significant being the confusion that continues to surround the process. . . . [T]he biggest problem currently seems to be a lack of understanding about what's expected . . . .").

35. AM. MED. ASS'N, UNDERSTANDING THE BASICS OF MEDICARE'S ELECTRONIC PRESCRIBING INCENTIVE PROGRAM 1, *available at* http://www.ama-assn.org/assets/eprescribing/downloadable_resources/faq-cms-incentive-program.pdf.

36. "Basically, 75% of the prescriptions have to be ePrescribed using a certified EHR technology to meet the meaningful use guidelines." *Percent of ePrescribing for Meaningful Use*, EMR & HIPAA (April 30, 2010), http://www.emrandhipaa.com/emr-and-hipaa/2010/04/30/percent-of-eprescribing-for-meaningful-use; *see also* D. Scott Jones & Howard B. Kessler, *Can Electronic Medical Records Really Improve Quality? The Obama Administration Bets Yes*, J. HEALTH CARE COMPLIANCE, Jan.–Feb. 2010, at 39, 40.

prescribing capabilities are explicitly highlighted and emphasized as one component of the incentive program.[37] E-prescribing of controlled substances will likely augment the prescription values used in calculating "meaningful use," but this has yet to be seen at the regulatory level.[38] Although this topic is beyond the scope of the DEA's regulation, it is important to note the DEA regulation will have significant impact on practically defining "meaningful use" of e-prescribing for the incentive program under MIPPA.[39]

The private sector has spurred the growth of e-prescribing as well. Several private initiatives, by insurers and other payors, have increased the frequency of e-prescribing.[40] Most notably the National ePrescribing Patient Safety Initiative ("NEPSI") coalition is dedicated to the increased use of e-prescribing software.[41] NEPSI has offered free software to physicians that

37. Jones & Kessler, *supra* note 36, at 40.

38. This has yet to be discussed or implemented but the ONC (Office of the National Coordinator for Health Information Technology), a branch of HHS, has the duty and plans to implement Stage 2 of the incentive program and the new DEA regulation will likely be addressed at that time. *See* OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP'T OF HEALTH & HUMAN SERVS., HIT POLICY COMMITTEE: MEANINGFUL USE WORKGROUP REQUEST FOR COMMENTS REGARDING MEANINGFUL USE STAGE 2, at 1, 5 (2011), *available at* http://healthit.hhs.gov/portal/server.pt/document/954501/mu_rfc__2011-01-12_final_pdf. "[C]MS will have an eye on incorporating the Department of Justice's policy regarding the electronic prescribing of Schedule II drugs, perhaps as soon as the implementation of Stage Two eRx meaningful use criteria." Mark Faccenda & Lara Parkin, *Meaningful Use—What Does It Mean to You?*, HEALTH LAW., Feb. 2011, at 10, 13. This author speculates that if the physician must e-prescribe a certain percentage of prescriptions each quarter or annually, the controlled substances will be included in those calculations once controlled substances are able to be e-prescribed. *See id*. Additionally, it could be speculated that controlled substances would not be used in the calculation if a given state were not allowing providers to e-prescribe controlled substances.

39. *Electronic Prescriptions for Controlled Substances*, DRUG ENFORCEMENT ADMIN. (Mar. 31,2010), http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/eapplications.htm [hereinafter DEA eRx].

40. A small list of private initiatives include: Massachusetts eRx Collaborative, Southeastern Michigan e-Prescribing Initiative, National ePrescribing Patient Safety Initiative, BlueCross Blue Shield E-Prescribing Programs, and Individual State Initiatives. CTR. FOR HEALTH TRANSFORMATION, ELECTRONIC PRESCRIBING: BUILDING, DEPLOYING, AND USING E-PRESCRIBING TO SAVE LIVES AND SAVE MONEY 16-24 (2008), *available at* http://www.surescripts.com/media/660347/cht_eprescribing_paper_06.10.2008.pdf.

41. "This coalition-based program is comprised of healthcare, technology and provider companies dedicated to positively impacting the national prescribing process through electronic prescribing (ePrescribing) delivery. NEPSI delivers on this commitment by offering free ePrescribing to every physician and medication prescriber in America." *About Us*, NAT'L EPRESCRIBING PATIENT SAFETY INITIATIVE (2008), http://www.nationalerx.com/about-us.htm.

encounter financial barriers in their practice.[42] The private initiatives noted are merely a small sample of programs started to encourage the growth of e-prescribing.[43] Beyond the MMA,[44] Physician Incentive Program,[45] and private or state initiatives,[46] the new DEA regulation will have significant impact in removing the "controlled substance barrier" or excuse stopping prescribers from implementation.[47] The DEA rule closes a major loophole in e-prescribing language by authorizing e-prescribing for all medications.

There are barriers to implementation of e-prescribing for providers, pharmacies, and patients. There is a substantial financial cost to providers, pharmacies, and insurers to set-up the necessary hardware and software, not to mention the requisite training for staff, to ensure a successful e-prescribing program is in place.[48] In particular, independent physician offices and small health systems may not immediately realize the return on investment ("ROI") from e-prescribing.[49] With high initial set-up costs and a low pay-out, for efficiency and streamlined communication, cash-strapped physician offices have had little incentive to implement an e-prescribing system.[50] However, large health systems that have implemented an all encompassing EHR system have found it much easier to integrate an e-prescribing component.[51]

42. "NEPSI aims to eliminate the burdens and barriers to ePrescribing adoption that can be experienced by providers." *Prescribers*, NAT'L EPRESCRIBING PATIENT SAFETY INITIATIVE (2008), http://www.nationalerx.com/prescribers.htm. Allscripts, a leading e-prescribing intermediary that hosts the e-prescribing service, offers software, internet hosting, training, and support to all eligible prescribers. *Id*. Ultimately the NEPSI project helps implement, promote, and utilize e-prescribing practices for poor, small, and sometimes rural physician offices. *See id*.

43. CTR. FOR HEALTH TRANSFORMATION, *supra* note 40, at 16.

44. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

45. *See* Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, Pub. L. No. 110-275, § 132, 122 Stat. 2494, 2527 (to be codified at 42 U.S.C. 1395w-4); *eRx Incentives*, *supra* note 32.

46. CTR. FOR HEALTH TRANSFORMATION, *supra* note 40, at 16-24.

47. *See* Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311).

48. EHEALTH INITIATIVE, *supra* note 10, at 4-5; Steinbrook, *supra* note 28, at 115; CAL. HEALTHCARE FOUND., *supra* note 11, at 37.

49. EHEALTH INITIATIVE, *supra* note 10, at 4, 6. Stand-alone e-prescribing systems cost approximately $3,000 per physician; fully integrated systems can cost $50,000 per physician. NAT'L GOVERNORS ASS'N, *supra* note 10, at 2; *see also* Sullivan, *supra* note 6, at 19.

50. EHEALTH INITIATIVE, *supra* note 10, at 4.

51. *See* Ashish K. Jha et al., *A Progress Report On Electronic Health Records in U.S. Hospitals*, 29 HEALTH AFF. 1951, 1956 (2010); CAL. HEALTHCARE FOUND., *supra* note 11, at 38; NAT'L GOVERNORS ASS'N, *supra* note 10, at 2.

There will always be inherent flaws in any e-prescribing system such as typos, computer crashes, entry mistakes, unauthorized record retrieval, and other errors.[52] The data retrieved from a working e-prescribing system is only as good as the data that is originally entered.[53] Another obstacle that has providers and health systems dragging their feet toward e-prescribing adoption is the inherent distrust of computer software.[54] Computer software cannot take into account every patient's condition and prognosis; what may be a dangerous contraindication for one patient may be a life-saving therapy for another.[55] The fail-safe warnings and alerts can seem cumbersome and dangerous in certain areas of medical practice.[56] It is also important to note a cultural barrier associated with e-prescribing, for many physicians and pharmacists the way prescriptions are delivered has not changed since the advent of facsimile.[57] This new technology is interfering with the usual workflow of health care providers.[58]

Until recently controlled substances, 10% to 11% of all prescriptions, were not eligible for e-prescribing and this may have been a significant barrier for practices that focused on prescribing narcotics (i.e. pain clinics, headache clinics, and surgical care centers that discharged patients with pain medication).[59] A final barrier that should be noted one states' varying

52. Ross Koppel et al., *Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors*, 293 JAMA 1197, 1198-1200 (2005).

53. *See id.* at 1200-01.

54. Scot Silverstein, *Barriers to Computerized Prescribing*, 280 JAMA 516, 516 (1998). "The United States ranks in the bottom half (out of 11 countries) on every metric used to measure adoption, including use of electronic medical records (10th), electronic prescribing (10th), electronic clinical note entry (10th), electronic ordering of laboratory tests (8th), electronic alerts/prompts about potential drug dose/interaction problems (8th) and electronic access to patient test results (7th)." Thomas R. Nathan, *Federal Communications Commission, National Broadband Plan, Health Care*, *in* 1 BROADBAND & CABLE INDUSTRY LAW 161, 168 (2011).

55. *See* Gordon D. Schiff & David W. Bates, *Can Electronic Clinical Documentation Help Prevent Diagnostic Errors?*, 362 NEW ENG. J. MED. 1066, 1067-68 (2010).

56. Tyler Chin, *Doctors Pull Plug on Paperless System*, AM. MED. NEWS (Feb. 17, 2003), http://www.ama-assn.org/amednews/2003/02/17/bil20217.htm; *see* Thomas Bodenheimer & Kevin Grumbach, *Electronic Technology: A Spark to Revitalize Primary Care?*, 290 JAMA 259, 261-63 (2003).

57. Silverstein, *supra* note 54, at 516; Chin, *supra* note 56; *see* Bodenheimer & Grumbach, *supra* note 56, at 260.

58. EHEALTH INITIATIVE, *supra* note 10, at 5. *But see* Gerard P. Filicko, *Don't Drop the Baton: e-Prescribing and e-Results Improve Workflow*, VITALSTATISTICS, Summer 2006, at 24, 24, *available at* http://www.medvirginia.net/includes/20060705_VS_eRx.pdf.

59. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236, 16,237 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311); *see* Douglas Blayney, *ePrescribing and Scheduled Narcotics for Pain Control in Cancer Patients*, ASCO CONNECTION (Jan. 23, 2009, 1:40 AM), http://connection.asco.org/commentary/article/id/2648/eprescribing-and-scheduled-narcotics-for-pain-control-in-cancer-patients.aspx.

rules and legislative language.[60] This legislative or regulatory disarray could cause a significant slow-down in the adoption of e-prescribing of controlled substances.

II. THE NEW DEA RULE SYNOPSIS

The new DEA rule promulgated in March 2010 has significant impact in the area of e-prescribing. First, the DEA authorized the electronic prescribing of controlled substances.[61] This essential step closes the disjoint between incentivizing the use of e-prescribing but not encompassing 10-11% of all drugs prescribed nationally, controlled substances.[62] By allowing controlled substances to be prescribed electronically, physicians and pharmacists have one less barrier (or excuse) to hinder their implementation of e-prescribing.[63]

Second, the regulation enumerates who may e-prescribe controlled substances.[64] It cannot be an agent (e.g. nurse, receptionist) but must be the prescriber.[65] Prescribers are eligible if they possess a valid DEA license, which may be linked to the e-prescribing information to assist with a seamless transition.[66] Third, the DEA regulation has implemented recordkeeping requirements for e-prescribing of controlled substances.[67] The records must be readily retrievable and must be kept for up to two years, which is consistent with the current recordkeeping standards for paper prescriptions of controlled substances.[68] Additionally, e-prescribing software must allow prescribers the ability to review monthly logs of all controlled

60. EHEALTH INITIATIVE, *supra* note 10, at 5.

61. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,307.

62. *Id.* at 16,237.

63. *See* Kate Ackerman, *Long-Awaited DEA Rule on Controlled Substances Could Boost E-Rx Rates*, IHEALTHBEAT (April 8, 2010), http://www.ihealthbeat.org/features/2010/longawaited-dea-rule-on-controlled-substances-could-boost-erx-adoption.aspx#.

64. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,311-12.

65. *Id.* at 16,311. DEA guidance has confirmed and clarified that DEA registrants should not delegate prescribing to an agent because a non-prescribing agent is not able to make a clinical decision in the place of a prescriber. *See also* 21 C.F.R. § 1306 (2010). Agents' duties are limited to ministerial acts in connection with communicating prescription information to a pharmacy. Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies, 75 Fed. Reg. 61,613, 61,614 (Oct. 6, 2010) (to be codified at 21 C.F.R. pt. 1306).

66. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,245, 16,307, 16,312.

67. *Id.* at 16,306-07.

68. *Id.* at 16,307. This was an issue of contention. The first rule had a 5-year window for record retrieval but after significant "push-back" from medical and pharmacy practitioners, the DEA revised this to a 2-year window as is consistent with current paper recordkeeping standards. *Id.* at 16,261.

medications.[69] Prescribers are not required to sign off on monthly reports, but must have the software capabilities to retrieve the reports.[70]

Finally, and most importantly, the DEA established a "two factor authentication" requirement.[71] The requirement mandates that prescribers use two out of three types of authentication to verify their identity before transmitting an e-prescription for a controlled substance.[72] The three types of authentication have been hotly contested, as seen in the comments of the DEA Rule.[73] The rule requires two of the three methods of authentication: (1) a hard token or key type device that the prescriber must have on them;[74] (2) a password or knowledge-based security measure;[75] or (3) a biometric security measure.[76] Succinctly put, something the prescriber knows, has in

69. *Id.* at 16,263

70. Initially, the rule called for prescribers to review and sign a monthly log and keep the log in a separate record for DEA review. After the initial comment period, this rule was reduced to simply printing and retrieving such logs. Physicians successfully argued that with the implementation of e-prescribing and more paperwork this monthly log redundancy would severely inhibit workflow. *Id.* at 16,262-63.

71. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,312. Commentators voiced initial concern that a two-factor method would be too burdensome; however, the DEA insisted on a two-factor security measure citing specific internal security issues. *Id.* at 16,249. "The problem DEA is addressing with the requirement for two-factor authentication credentials is not that someone may use their own authentication credential to alter or create a prescription, but that a nonregistrant will use a registrant's authentication credential to create and sign a prescription." *Id.* The risk for a single authentication/password to be duplicated or given out is too great a risk to the internal security of a physician's office. *Id*.

72. *Id.* at 16,312.

73. *Id.* at 16,249.

74. The hard token itself must be separate from the computer and physically in possession of the prescriber. *Id.* at 16,312. During the rules comment period, commenters suggested a swipe card, key-like device, or any other physical object, which would identify and give access to the physician. *Id.* at 16,253. For example, if a physician had a password and token the computer entry would be similar to an ATM interaction. *Id*. at 16,243.

75. The DEA recognized and addressed password security standards in reference to length, complexity, and prescriber's ability to remember the password. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,312 (citing KAREN SCARFONE & MURUGIAH SOUPPAYA, NAT'L INST. OF STANDARDS & TECH., NIST SPECIAL PUB. 800-118, GUIDE TO ENTERPRISE PASSWORD MANAGEMENT (DRAFT) ES1 (2009), *available at* http://csrc.nist.gov/publications/drafts/800-118/draft-sp800-118.pdf). Software companies are expected to produce password authentication measures based on these generally accepted password standards. *Id.* at 16,249.

76. The DEA found that 18% of prescribers use (and 36% plan to use) biometric markers for log-in to EHR systems which compelled the DEA to include, but not mandate, use of biometrics. *Id.* at 16,250. Biometric passcodes could include fingerprint scans, retina scans, etc . . . which must operate at a generally acceptable accuracy and "false match rating." *Id.* at 16,312.

his or her possession, or the prescribers himself or herself.[77] In addition to these authentication measures, the DEA has recognized that an actual electronically scanned signature could accompany the prescriptions.[78]

There have been other specific concerns brought to light within the comments but many of those addressed were grouped together and summarized by the DEA's response.[79] Arguably many of these concerns are minor in nature and can be solved through DEA guidance in the future. It is reasonable to assume the DEA cannot solve unascertained problems given that e-prescribing technology is constantly evolving.

III. THE STATE AND FEDERAL INTERPLAY

With the implementation of these new rules it could be argued that finally, after years, e-prescribing is reaching full integration into the health care delivery model.[80] Prior to the new rule, prescribers and pharmacies were not allowed to write for or dispense prescriptions for controlled substances (CI-CV) via electronic means.[81] Controlled substance prescriptions make up 10 – 11% of all prescribed medications and until now were a missing link in the chain of medication delivery.[82] Controlled substances are habit-forming medications that are rated on their medical necessity and potential for abuse.[83] From drugs that are labeled CI (e.g.

77. *Id.* at 16,312.

78. The DEA wants to grant prescribers the flexibility and the authority to customize their prescriptions. *Id.* at 16,260. The DEA further notes that the use of a physical signature is optional but the "two-factor" authentication is mandatory. *Id.* The reliance on a single password system is not secure enough and is often considered the weakest link in technology security. *Id.* at 240.

79. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,244. The DEA gave consideration to over 200 different comments while drafting the interim final rule that is now being implemented. DEA eRx, *supra* note 39; *see also* Ken Tubman, *ePrescribe Controlled Substances in 2010?*, E-PRESCRIBING BLOG (Mar. 30, 2010), http://www.epre scribing.org.

80. *Overview: E-Prescribing*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms. gov/eprescribing/ (last visited Jan. 2, 2012).

81. M. Susan Ridgley & Michael D. Greenberg, *Pharmacy, Facsimile, and Cyberspace: An Examination of Legal Frameworks for Electronic Prescribing*, 13 ALB. L.J. SCI. & TECH. 1, 33 (2002).

82. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,237; Lawrence Bell, *Health Care Primer: E-Scripts, Physician-Pharmacists Safe Harbors, Additional Physician Revenue*, J. COMPENSATION & BENEFITS, May/June 2008, at 14, 24 (2008); *see also* Ackerman, *supra* note 63.

83. DRUG ENFORCEMENT ADMIN., U.S. DEP'T OF JUSTICE, PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 5, 6 (2006) [hereinafter PRACTITIONER'S MANUAL], *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/ pract/pract_manual012508.pdf; *see generally* 21 C.F.R. §§ 1308.11-.15 (2010) (categorizing specific substances and chemical compounds).

heroin) to drugs labeled CV (e.g. codeine cough syrup) the Secretary of Health and Human Services ("HHS") categorizes and enforces federal regulations on all habit-forming medications.[84] The authority to do so was granted by Congress in the Controlled Substance Act ("CSA")[85] and subsequent DEA regulations.[86] The DEA however, does not have the authority to preempt state laws or mandate states enforce e-prescribing of controlled substances at the state level.[87] While the constitutionality of the DEA regulations is beyond the scope of this article, the interplay between state and federal regulations of controlled substances must be addressed to truly understand how this regulation may be implemented.[88]

Although the CSA grants the federal government authority over all controlled substance, from manufacturing to dispensing, HHS and DEA work in close collaboration with state regulatory agencies (e.g. state boards of medicine, pharmacy, nursing).[89] States retain the ability to legislate and regulate more stringently beyond the DEA and other federal regulations concerning controlled substances.[90] Traditionally, the federal role in prescription drug management has been three-fold: (1) the DEA has the authority to register providers and dispensers of controlled substances; (2) the DEA has the ability to classify narcotic medications; and (3) the DEA enforces all federal drug policy.[91] The DEA registers[92] and regulates pharmacies.[93] Every pharmacy that dispenses controlled substances has a

84. The Secretary of HHS has the actual authority to schedule all controlled drugs but does so at the professional expert opinions of both the FDA and DEA. 21 C.F.R. § 1308.43 (2010).

85. *See generally* 21 U.S.C. §§ 801-890 (2006).

86. *See generally* 21 C.F.R. §§ 1300-1316 (2010) (granting DEA approval and regulatory authority over controlled substance activities).

87. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,304.

88. Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 177 (2004).

89. "The DEA registration grants practitioners federal authority to handle controlled substances. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located." Practitioner's Manual, *supra* note 83, at 7.

90. *Id.*

91. *See generally id.* at 5-13 (describing the DEA's procedures for registration, classification, and reporting).

92. The DEA requires each individual prescriber to register if they wish to write prescriptions for controlled substances. *Id.* at 7. Individual pharmacists do not need to register, but rather the pharmacy entity itself must register with the DEA if they wish to dispense controlled drugs. *Id.* at 8.

93. "[Pharmacist/Pharmacy] must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs." DRUG ENFORCEMENT ADMIN., U.S. DEP'T OF JUSTICE, PHARMACIST'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED

DEA registration number and must execute special "222 Order Forms" to procure prescription medication from a drug wholesaler or manufacturer.[94]

Coupled with the DEA influence over controlled substances, individual states have significant power to influence controlled substance regulations.[95] States may create controlled substance regulations that are more stringent than the CSA[96] or DEA regulations[97] either through classification of medications, recordkeeping requirements, or even where controlled medication may be stored.[98] An example of a state legislating beyond the DEA is in Illinois. Illinois classified the drug Talwin® (pentazocine) as a CII narcotic[99] whereas the DEA classified the drug as a CIV a narcotic.[100] States always reserve the right to implement stricter regulations than those

SUBSTANCES ACT 10 (2010) [hereinafter PHARMACIST'S MANUAL], *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

94. There are a number of forms that pharmacies must execute to be eligible for the purchase, transfer, and dispensing of controlled drugs (e.g. 222 Form, 41 Form, 224 Form, etc.). *Id.* at 13; DRUG ENFORCEMENT ADMIN., FORM DEA-224 APPLICATION FOR REGISTRATION, *available at* http://depts.washington.edu/uwmedres/professional/faq_files/224_form_0905.pdf (last visited Jan. 2, 2012); SAMPLE DEA FORM 222, *available at* http://www.zoopharm.net/images/pdf/dea222-sample.pdf (last visited Jan 2, 2012).

95. For example, West Virginia and Arizona have in place a more stringent controlled substance monitoring program in addition to a separate registration of all prescribers. *See* W. VA. CODE ANN. § 60A-9-3 (LexisNexis 2011); ARIZ. REV. STAT. § 36-2608 (LexisNexis 2011). Iowa has had a separate registration process in effect for a number of years. *See* IOWA BD. OF PHARMACY, NEW IOWA CONTROLLED SUBSTANCES ACT REGISTRATION APPLICATION (2011), *available at* http://www.iowa.gov/ibpe/pdf/csa-new.pdf. Delaware has set-up a separate group, Delaware Office of Controlled Substances, to deal with all controlled substance monitoring and prescribing within the state. DEL. CODE ANN. tit. 16, §§ 4701-4796 (2011).

96. *See* 21 U.S.C. §§ 801-890 (2006).

97. The examples in note 95 go above and beyond the call of the DEA regulations and the normal standards set forth by the federal agency. *See generally* 21 C.F.R. §§ 1300-1316 (2010).

98. *See* 720 ILL. COMP. STAT. 570 / 312(a) (2010). Wisconsin requires that all CII narcotic medication be either stored in a safe or stored in a manner that is not easily accessible. WIS. ADMIN. CODE PHAR. § 6.07 (2010).

99. 720 ILL. COMP. STAT. 570 / 312(a) (2010). The Illinois Department of Financial and Professional Regulations, an overarching department including the Illinois Board of Pharmacy, has found Talwin® (pentazocine/naloxone) to be a drug of particular abuse in certain regions of Illinois and has thus scheduled it separately from the DEA regulations. May Annexton, *Pentazocine Reclassified in Illinois*, 240 JAMA 2234, 2235 (1978). The Illinois Board of Pharmacy requires special "222-like" order forms be completed and sent to the Board in order for any pharmacy to purchase and dispense Talwin®. *Id*.

100. DRUG ENFORCEMENT ADMIN., U.S. DEP'T OF JUSTICE, CONTROLLED SUBSTANCES—BY DEA DRUG NUMBER 10 (2011), *available at* http://www.deadiversion.usdoj.gov/schedules/orangebook/d_cs_drugcode.pdf.

established by the DEA.[101] Another example of states legislating around the CSA is a more stringent record-keeping requirement. Some states (Nebraska[102] and Oregon[103]) require that pharmacies maintain controlled substance records for several years after dispensing the medication. The DEA regulation only requires records to be maintained for two years.[104]

It is possible to have a disconnect between the goals and standards of the DEA and the execution, implementation, and enforcement of regulations at the state level. A competing interest might influence how this new DEA regulation may be enforced. Ultimately, the practical implications of e-prescribing controlled substances rests within the states' control, and the DEA's regulations are simply a baseline for the states to implement.[105]

With this new rule, health care providers will be able to write for and dispense all prescriptions electronically, if they so choose.[106] Health care providers, pharmacies, and government entities are reexamining barriers to e-prescribing, as evidenced by the comments to the DEA rule.[107] Some of these traditional barriers to e-prescribing will still be at issue, such as financial barriers,[108] cultural barriers,[109] training,[110] and privacy.[111] However, additional barriers at the state level may be of increasing concern,

101. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236, 16,304 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311); PRACTITIONER'S MANUAL, *supra* note 83, at 7.

102. Controlled substance records must be retained for five years. NEB. REV. STAT. § 28-411 (2008).

103. Records of all prescriptions must be kept for three years. OR. REV. STAT. § 689.508 (2009).

104. PHARMACIST'S MANUAL, *supra* note 93, at 13. However, many states only require a two-year record keeping standard as well. *See, e.g.*, 04-02-0010 ARK. CODE R. § 70 (LexisNexis 2010); MINN. STAT. ANN. § 151.211 (West 2011); IOWA ADMIN. CODE r. 657-21-5 (2009).

105. PRACTITIONER'S MANUAL, *supra* note 83, at 7.

106. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,236.

107. *Id.*; *see also* Ackerman, *supra* note 63.

108. EHEALTH INITIATIVE, *supra* note 10, at 4; Ackerman, *supra* note 63.

109. Silverstein, *supra* note 54, at 516.

110. EHEALTH INITIATIVE, *supra* note 10, at 4.

111. Michael D. Greenberg et al., *Electronic Prescribing and HIAPA Privacy Regulation*, 41 INQUIRY 461, 466 (2004); Angela Ferneding, *Regional Health Information Organizations: Lower Health Care Costs, Fewer Iatrogenic Illnesses, and Improved Care—What Are We Waiting For?*, 22 J. L. & HEALTH 167, 181-82 (2009); Sullivan, *supra* note 6, at 18.

such as regulatory inconsistencies at the state level,[112] drug diversion, or data security.[113]

IV. FOCUSING IN ON STATE REGULATORY BARRIERS: UNADDRESSED ISSUES

This may leave the DEA and e-prescribing stakeholders in a precarious position. The DEA has promulgated a rule that took years to come to fruition.[114] At least two presidential administrations[115] and Congressional sessions[116] have backed e-prescribing; and now the rule is ready to be implemented. States may still legislate around the DEA rule by passing more stringent laws and regulations.[117] This paper will address the varying legislative structure of states' e-prescribing laws and the motivating factors behind their decisions to legislate or to stay silent on this new medication delivery process that the federal government has so heavily invested in.[118]

States may for many reasons see e-prescribing as a potential risk. States may be resistant to e-prescribing because of privacy issues,[119] forgery or diversion risks,[120] increase in costs to small or rural prescribers,[121] or simply

112. Most states have not addressed e-prescribing and STARK and anti-kickback implications. Ferneding, *supra* note 111, at 178-180; Sullivan, *supra* note 6, at 19. *See generally* Bell, *supra* note 82, at 22-24.

113. Gilman & Cooper, *supra* note 5, at 282-83; Ferneding, *supra* note 111, at 183-84; Sullivan, *supra* note 6, at 17-18.

114. The first attempt at e-prescribing of controlled substances was on April 1, 2005. Lisa M. Power, *DEA Final Rule Sets The Course For E-Prescribing of Narcotics*, HEALTH LAW., Aug. 2005, at 32, 32; *Overview: E-Prescribing*, *supra* note 80.

115. Jones & Kessler, *supra* note 36, at 41; Seth H. Lundy et al., *Just What the Doctor Ordered? CMS and DEA Introduce New Measures to Facilitate E-Prescribing*, J. HEALTH & LIFE SCI., July 2009, at 79, 85.

116. Lundy et al., *supra* note 115, at 85.

117. Precedent of disregard for the DEA's regulations is prominently illustrated by California's regulation and validation of marijuana prescriptions. CAL. HEALTH & SAFETY CODE § 11362.5 (West 2011). Other states have created legislation to legislate around less controversial DEA regulations. *See, e.g.*, NEB. REV. STAT. § 28-411 (2008), 720 ILL. COMP. STAT. 570 / 312(a) (Supp. 2009).

118. In 2010 alone, CMS budgeted and spent over $24 million dollars for e-prescribing and requested $27.7 million in 2011. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2011: JUSTIFICATION AND ESTIMATES FOR APPROPRIATIONS COMMITTEES 3, 66 (2011), *available at* http://www.cms.gov/PerformanceBudget/Downloads/CMSFY11CJ.pdf.

119. Greenberg et al., *supra* note 111, at 466; Ferneding, *supra* note 111, at 183; Sullivan, *supra* note 6, at 18.

120. Gilman & Cooper, *supra* note 5, at 283; Ferneding, *supra* note 111, at 182-83; Sullivan, *supra* note 6, at 17-18.

121. EHEALTH INITIATIVE, *supra* note 10, at 4; Ackerman, *supra* note 63.

lag behind the DEA regulation change,[122] an statute and rule language disarray.[123] To further analyze states responses to the DEA rule this analysis must delve into state language and motivations to better understand the nature of implementation of e-prescribing.

California may be the most favorably situated state to implement e-prescribing of controlled substances.[124] California's statutory and regulatory language seems consistent with the DEA regulation and is so flexible that there seems to be cohesion between statute,[125] regulation,[126] and enforcement guidelines.[127]

> With the approval of the CA BoP and the Department of Justice, a pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders for C II, III, IV, or V drugs if authorized by federal law and in accordance with regulations promulgated by DEA. The CA BoP shall maintain a list of all such requests and approvals granted.[128]

Additionally, the deputy attorney general has pressed for a quick adoption to e-prescribing of controlled substances.[129] Current statutes allow for adoption of e-prescribing of controlled substances as soon as feasibly possible.[130] The California legislature wisely adopted language that gave

122. *See Narcotic Enforcement*, N.Y. DEP'T OF HEALTH, http://www.health.state.ny.us/professionals/narcotic/ (last visited Jan. 2, 2012).

123. Many states have conflicting legislation and code language *See* W. VA. CODE ANN. § 30-5-12c(a), (c) (LexisNexis 2011).

124. Jeff Todd, *E-prescribing in a Changing Legal Environment*, RICH. J.L. & TECH., Spring 2006, at 1, 11-12.

125. "Electronic transmission of prescriptions is generally permitted." CAL. BUS. & PROF. CODE § 4040 (West 2011). For over fourteen years, California has included e-prescription as a valid mode of prescription transfer in its laws. Joshua A. Room, Deputy Att'y Gen., Cal. Dep't Justice, Presentation to the California Board of Pharmacy: The Legal Landscape of Electronic Prescribing (E-Prescribing) in California (Nov. 20, 2008), *available at* http://www.pharmacy.ca.gov/meetings/agendas/legal_landscape.pdf.

126. California regulations requiring the components of a prescription are not technology-specific and, as such, can be interpreted within e-prescribing mediums. Room, *supra* note 125.

127. Upon DEA approval, the Board of Pharmacy in California and the local DOJ liaisons have the authority to "green-light" e-prescribing of controlled substances. *Id.; see also* CAL. HEALTH & SAFETY CODE § 11164.5(a) (West 2011); Stephen Barlas, *DEA Opens the Door to e-Prescribing of Controlled Substances: But Pharmacies Balk at Security Rules*, 33 P&T 626, 626 (2008).

128. HEALTH & SAFETY § 11164.5(a).

129. The deputy attorney general noted that California is "poised" for DEA approval. Room, *supra* note 125.

130. *See* HEALTH & SAFETY § 11164.5(a).

the Board of Pharmacy, Department of Justice, and DEA the final check on any e-prescribing of controlled substance policies.[131]

California has amended its laws to skirt anti-kickback rules by creating "safe harbors" for e-prescribing.[132] This potentially will facilitate a greater adoption of the practice. States that do not have safe harbors or carve-outs to anti-kickback legislation may find that prescribers expose themselves to fraud and abuse liability.[133] This issue is addressed on a federal level,[134] and certain states may have addressed this after the adoption of e-prescribing of non-controlled substances,[135] however, states that employ

131. 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 a hospital or pharmacy receive e-prescriptions for any controlled substance. *Id*. Additionally, one of the California Board of Pharmacy's stated objectives in their strategic plan to is analyze and implement the legal requirements of e-prescribing of controlled substances at the earliest date. CAL. STATE BD. PHARMACY, STRATEGIC PLAN 2006-2011, at 12 (2009), *available at* http://www.pharmacy.ca.gov/publications/strategicplan_2009.pdf.

132. CAL. WELF. & INST. CODE § 14107.2(c)(4) (West 2011); *CMS Proposes New Exemptions for 2012 E-Prescribing Penalty*, CAL. MED. ASS'N. (May 31, 2011), http://www.cmanet.org/news/detail?article=cms-adds-new-exemptions-for-2012-e-prescribing.

133. *See* Kathy Poppit et al., *New E-Prescribing and EHR Exceptions and Safe Harbors*, HEALTH LAW. NEWS, Nov. 2006, at 24, 25-26, *available at* http://www.healthlawyers.org/Members/PracticeGroups/LS/Documents/Poppitt.pdf; *see also Federal Fraud and Abuse: Anti-Kickback Statute*, TELEHEALTH RESOURCE CENTER, http://www.telehealthresourcecenter.org/toolbox-module/federal-fraud-and-abuse-anti-kickback-statute (last visited Jan. 2, 2012) (explaining that states can have anti-kickback statutes varying from the federal one, but that specific exceptions for electronic prescribing can exist). Many states have anti-kickback statutes, including California, Florida, Georgia, Massachusetts, New Jersey, North Carolina, and Texas. *Anti-Kickback Law and Suspect Financial Agreements: FAQ*, AM. C. OF RADIOLOGY (Apr. 1999), http://www.acr.org/secondarymainmenucategories/businesspracticeissues/featuredcategories/antikickback/antikickbacklawandsuspectfinancialagreementsfaqdoc3.aspx.

134. The e-prescribing STARK law exception was required by the Medicare Prescription Drug Improvement and Modernization Act of 2003, and states that the agency's authority to issue the electronic medical record exception is justified under the agency's "legal authority under section 1877(b)(4) of the [Social Security Act]." Medicare Program; Physicians Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45,140, 45,140 (Aug. 8, 2006) (to be codified at 42 C.F.R. pt. 411). This exception was effective in October 2006 and expires in 2013. Ferneding, *supra* note 111, at 179; *see* 42 C.F.R. §1001.952 (2010). This 2006 rule by CMS preempts states from disallowing e-prescribing for any federally funded plans and carves out e-prescribing from the anti-kickback statute. *Id*. However, non-federally funded individuals are still regulated by the laws of the state via private insurance companies; Medicaid is not mandated by incentive programs to e-prescribe yet either. *Id.*; *see also* NAT'L CONFERENCE OF STATE LEGISLATURES, ELECTRONIC PRESCRIBING 4-5 (2009), *available at* http://www.ncsl.org/documents/health/eprscrb0209.pdf (noting that although Medicaid does not fall under the Medicare e-prescribing program, efforts exist in states to establish similar programs).

135. EHEALTH INITIATIVE, *supra* note 10, at 7.

anti-kickback legislation may need to accommodate for a new surge in adoption of e-prescribing.[136]

In 2008, California Governor Arnold Schwarzenegger proposed legislation to mandate e-prescribing capabilities for all California prescribers and pharmacies.[137] Another great driver of California's favorable e-prescribing environment is the California HealthCare Foundation ("CHCF") which has championed the cause through pilot projects, market assessments, and facilitation of discussions.[138] California's incentive programs are numerous at the public and private level. Private insurance payors are incentivizing e-prescribing beyond the scope of the federal initiatives.[139] California's flexible, all-encompassing statute and rule language will allow for what appears to be a seamless adoption of the DEA regulations. Some states are not far behind California's example. Arizona is similarly situated with legislation that reads:

> For electronic transmission of a Schedule II, III, IV, or V controlled substance prescription order, the medical practitioner and pharmacy shall ensure that the transmission complies with any security or other requirements of federal law.[140]

This law seems to be in compliance with the new DEA regulation making Arizona ready to implement e-prescribing of controlled substances. Utah is another forward thinking state with its passage of the Electronic Prescribing Act.[141] Utah requires, a prescriber to ask the patient if they would like to opt into an e-prescribing program.[142] The law also requires all pharmacies be

136. *See* NATIONAL CONFERENCE OF STATE LEGISLATURES, *supra* note 134 at 4-5.

137. Governor Schwarzenegger's health plan, under Senate Bill ABX1 1, would have mandated all pharmacies, prescribers, and insurance plans be able to e-prescribe by January 1, 2012. CAL. STATE S., S. HEALTH COMM. ANALYSIS, HEALTH INSURANCE REFORM, ABX1 1, 1st Extraordinary Sess., at 40 (2008), *available at* http://senweb03.senate.ca.gov/committee/standing/health/ABX1.pdf.

138. *Fostering Adopting of E-Prescribing in California*, CAL. HEALTHCARE FOUND. (Nov. 2008), http://www.chcf.org/projects/2008/fostering-adoption-of-eprescribing-in-california.

139. The state Medicaid program, Medi-Cal, has worked with local providers, pharmacists, and private insurance entities to facilitate comprehensive pilot programs to iron out any wrinkles to the e-prescribing system. SUSAN L. LEONG, L.A. CARE HEALTH PLAN, E-PRESCRIBING PILOT PROJECT 3 (2008), *available at* http://www.pharmacy.ca.gov/meetings/agendas/eprescribing_pilot_project.pdf; "Medco Health Solutions Inc. and CalPERS (California Public Employees Retirement System) have released results of a pilot electronic prescribing initiative that showed dispensing rates for generic drugs were 11% higher for physicians who used such technology." *Generics Use Rises with E-Prescribing*, CHAIN DRUG REVIEW (Oct. 25, 2010), http://findarticles.com/p/articles/mi_hb3007/is_18_32/ai_n56218400/.

140. ARIZ. ADMIN. CODE § R4-23-407(F)(2) (2009).

141. UTAH CODE ANN. § 58-82-201(1) (2010).

142. *Id.*

eligible to receive electronic prescriptions.[143] The law preemptively accommodates the DEA rule by mandating that a practitioner may not e-prescribe a drug or device that is prohibited by federal law or federal rule.[144]

States like Arizona, Utah, and California[145] now are only waiting on the proper, secure hardware and software for the two-factor authentication methods to be implemented at the prescriber level.[146] The DEA along with several technology stake-holders[147] are issuing studies and pilot programs to take the DEA regulation and put into practice appropriate, verification technology.[148] To comply with technology requirements of the DEA regulation:

> The application provider must either hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. The auditor or certification body will issue a report that states whether the application complies with DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions.[149]

143. *Id.* § 58-82-201(3).

144. *Id.* § 58-82-201(2).

145. Other states are included in this list as well. Alabama has included administrative language that states: "Prescriptions for controlled substances, whether scheduled pursuant to state or federal law, are not authorized until the DEA has adopted applicable regulations, at which time all prescriptions for controlled substances must comply with the provisions of any such regulation or any later amendments or changes thereto." ALA. ADMIN. CODE r. 680-X-2-.32(1)(d) (2011).

146. *See* DEA eRx, *supra* note 39.

147. *Id.*; *see also Knowledge Base: Physician/Prescribers*, SURESCRIPTS (Mar. 31, 2010), http://www.surescripts.com/support/knowledge-base/physiciansprescribers.aspx#3189 (SureScripts does not provide any technology, but rather helps pharmacies ensure their existing medical software is properly certified to meet e-prescribing requirements); *see also ePrescribing of Controlled Substances*, ADVANCEDMD, http://www.advancedmd.com/products-solutions/eprescribing/eprescribing-controlled-substances/ (last visited Jan 2, 2012) [hereinafter ADVANCEDMD] (offering software for e-prescribing systems that ensure DEA compliance).

148. Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 36,722, 36,730 n.12 (Jun. 27, 2008) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306, 1311). The DEA has sent letters to all eligible stakeholders to permit e-prescribing of controlled substances pending verification of secure software and internet hosting. Letter from Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, to Provider of Electronic Prescription Application(s) or Pharmacy Application(s), *available at* http://www.deadiversion.usdoj.gov/ecomm/e_rx/epcs_app_provider_ltr.pdf. Additionally, it is important to point out that e-prescribing for controlled substances is currently allowed; however, the verification process for secured computer software is currently being developed, ADVANCEDMD, *supra* note 147.

149. *See* DEA eRx, *supra* note 39.

A third-party audit must be conducted before e-prescribing of controlled substances are written by a prescriber or dispensed by a pharmacy.[150] Thankfully for practitioners and pharmacies, the third-party audit applies to the provider of the e-prescribing software, usually the intermediaries or software architects.[151] The audit itself maintains explicit technological requirements that are beyond the scope of this article, but needless to say the DEA takes the verification process seriously because external and internal security of the system is one of the highest priorities of e-prescribing.[152]

Unlike those states with flexible statutory language that seems to coincide with the DEA regulation there are states that have confusing or conflicting rules. State legislation is in constant flux.[153] States seem to be caught in a situation where their statutes conflict with the new DEA regulation. In Iowa, the administrative code states:

> A prescriber may initiate and authorize a prescription drug order utilizing a computer or other electronic communication or recording device. The prescription drug order shall contain all information required by Iowa Code section 155A.27. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 21.3(124,155A).[154]

It goes further by stating and incorporating:

> 21.7(1) Controlled Substances. A prescription for a controlled substance prepared pursuant to this rule may be transmitted to a pharmacy via facsimile transmission.
>
> 21.7(2) Noncontrolled prescription drugs. A prescription for a noncontrolled prescription drug prepared pursuant to this rule may be transmitted to a pharmacy via computer-to-computer transmission as provided in rule 21.8.[155]

150. *Id.*

151. The burden of proving security will fall to e-prescribing intermediaries such as SureScripts, AllScripts, and other software vendors. *Id.*

152. *See Electronic Prescriptions for Controlled Substances—Interim Final Rule with Request for Comment Questions and Answers for Pharmacies*, DRUG ENFORCEMENT ADMIN. (Mar. 31, 2010), http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/pharmacies.htm ("The audits must undergo either a WebTrust, SysTrust, or SAS 70 audit conducted by a person qualified to conduct such an audit." Alternatively an audit may be done by "a Certified Information System Auditor who performs compliance audits as a regular ongoing business activity or a DEA approved entity.").

153. Todd, *supra* note 124, at 17.

154. IOWA ADMIN. CODE r. 657-21.7 (2009).

155. *Id.*

This type of inconsistent language between the statute and the new DEA regulation illustrates where the majority of states are situated. Much like the Iowa Administrative Code, most state statutes and rules are less flexible and cannot be read to interpret and then implement e-prescribing of controlled substances.[156] As seen in Rule 21.7(1) controlled substances may be prepared via a facsimile but not via electronic transmission.[157] This inflexible language by the administrative code warrants change by Iowa regulators.[158] This change will come with little regulatory difficulty, but the devil is in the details of the DEA regulation and state rule comparisons.[159] If a majority of states need to implement new language how will practitioners and stakeholders know if language is consistent throughout each state? Most attorneys and legislative aficionados can spot the inconsistency in this language, but not all prescribers and pharmacists may focus in on legislative nuances.

Many states after adoption of the DEA regulation will need new legislation or rulemaking to provide for clear and concise standards for prescribers, pharmacists, and regulators. These inconsistencies are not reserved to a select few states but rather are the norm.[160] Additionally, a goal of these states should be to draft language that can be interpreted liberally with flexibility to the ever-changing technology of medication delivery.

156. *Id.*

157. Although CIII-CV prescriptions may be filled and written pursuant to a facsimile prescription, CII prescriptions still require a paper prescription with the eligible DEA prescriber's hand written signature. *Id.* 657-10.21(1). CII narcotic prescriptions may also be filled via facsimile under certain exceptions. Narcotics can be filled via facsimile for emergency fills, *id.* 657-10.22(2) (2009), or for hospice or long-term care patients, *id.* 657-10.23(2).

158. In a recent August 2011 update, the Iowa Board of Pharmacy proposed a change to the administrative code, at IOWA ADMIN. CODE r. 657-21.7(1), which would amend the regulation to: "A prescription for a controlled substance may be transmitted by a prescriber to a pharmacy via electronic transmission pursuant to DEA [Drug Enforcement Administration] requirements for electronic prescribing of controlled substances." *Update on e-Prescribing of Controlled Substances*, IOWA BOARD OF PHARMACY NEWS (Iowa Bd. of Pharmacy, Des Moines, IA), Aug. 2011, at 5, *available at* http://www.nabp.net/publications/assets/IA082011.pdf. Although this amendment to the Iowa regulations is comprehensive it does not expressly address the DEA certification process, transmitting procedures by third party stakeholders, or storage of electronic CII prescriptions. In addition, it is unknown at which time, and if, the Board will adopt this amended proposal. However, this is a positive step in the direction of the DEA rule and a streamlining of e-prescribing into current prescriber and pharmacy workflow.

159. *See id.*

160. *See, e.g.*, D.C. CODE § 48-903.08(a) (2011); FLA. STAT. § 893.04 (2010); GA. COMP. R. & REGS. § 480-22-.04(1), (7) (2009).

West Virginia is another state that has inconsistencies within its own governing statutes and regulations:

> "E-prescribing" means the transmission, using electronic media, of prescription or prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or health plan as defined in 45 C.F.R. §160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms "electronic prescription" or "electronic order" . . . .
>
> . . . . A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules II through V, that is communicated in written form or by E-prescribing. A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, that is communicated orally (including telephone voice communication) or by way of electronic transmission other than E-prescribing.[161]

Although the West Virginia rule seems to allow for e-prescribing of controlled substances in the first sentence it may read to contradict itself in the following sentence.[162] This rule may be confusing, as e-prescribing for controlled substances is currently prohibited in West Virginia pending DEA technology certification and West Virginia's approval.[163] Adding to the complexity, the West Virginia statute was recently amended to allow for e-prescribing of controlled substances, in which the West Virginia Board of Pharmacy states the statute is in concert with all other state and federal authorities.[164]

> Notwithstanding any other provision of this code to the contrary, E-prescribing, as defined in subdivision (15), section one-b of this article, is hereby permitted and electronic prescriptions shall be treated as valid

161. W. VA. CODE R. § 15-1-2.1.18 (2009).

162. *Id.* § 15-1-21.1.1.

163. "At this time, prescriptions for controlled substances cannot be sent electronically and must be written on tamper resistant prescription blanks for Medicaid patients. Hand-signed hard copies of prescriptions for Schedule III through V drugs can be sent using manual fax technologies. Be sure to follow DEA regulations and refrain from sending controlled substance prescriptions electronically." *WVeScript Online Learning: Frequently Asked Questions*, W. VA. BUREAU FOR MED. SERVICES, http://www.wvescript.com/frequently_asked_questions (last visited Jan. 2, 2012).

164. *E-Prescribing and Controlled Substances, FAQs from DEA*, W. VA. BOARD OF PHARMACY NEWS (W. Va. Bd. of Pharmacy, Charleston, W. Va.), Sept. 2010, at 1, *available at* http://www.nabp.net/publications/assets/WV092010.pdf (citing W. VA. CODE § 30-5-12c (2009)). Until recently, West Virginia was not situated to accept e-prescribing for controlled substances, but in this newsletter article, the West Virginia Board of Pharmacy has addressed the regulatory language and is convinced they are appropriately situated for a transition to e-prescribing of controlled substances. *Id.*

> prescriptions orders. E-prescribing of controlled substances shall not be permitted, except as provided by emergency rules promulgated by the board . . . .
>
> . . . . *All electronic prescriptions shall be transmitted in a manner consistent with applicable* federal law, rules and regulations, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1181, as amended, the Medicare Prescription Drug, Improvement and Modernization Act of 2003, 42 U.S.C. § 1395w, as amended, the Controlled Substances Act of 1970, 21 U.S.C. § 801, as amended, the Drug Abuse Prevention, Treatment and Rehabilitation Act, 21 U.S.C. § 1101, as amended, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, 42 U.S.C. § 4541, as amended.[165]

It seems to the outside observer reading these statutes that West Virginia is attempting to allow e-prescribing in section 30-5-12c(c); by allowing the state to apply all applicable federal language.[166] However, section 30-5-12c(1) makes it clear that e-prescribing of controlled substances is not allowed in West Virginia until there is promulgation of emergency rules.[167] The spirit of these two statutes seems to be in direct contradiction. The West Virginia Board of Pharmacy states their rules and statutes are in compliance with the new DEA regulation, which they seem to be.[168] However, with the implementation of technology standards by the DEA, West Virginia will have to promulgate separate emergency rulemaking procedures to exercise e-prescribing of controlled substances.[169] In situations like this, hurried and jumbled language has caused practitioners and pharmacists to give pause when considering regulatory inconsistencies surrounding e-prescribing of controlled substances.[170] Specifically, the timing of e-prescribing implementation is unsettled because practitioners will have to wait for

165. W. VA. CODE § 30-5-12c (2009).

166. *See id.*

167. *See id.* § 30-5-12c(a).

168. *Id.* § 30-5-12c(c). It is also important to note that West Virginia does have several laws on the books that take into account privacy, security, and other issues that relate to the barriers and fears of e-prescribing. *See* W. VA. CODE R. § 15-1-21.1.8.b (2011). It seems the West Virginia Board of Pharmacy and legislature were extremely prospective in their flexible language to comply with all of the pertinent integrity, privacy and security measures at the state and federal level. *Id.*

169. *See* W. VA. CODE § 30-5-12c(a) (2009).

170. Confusing laws always seem to limit or at least make practitioners think twice about moving to a given state. Chris Dimick, *Fear Factor: Ambiguities in State Law Leave Some Providers Hesitant to Adopt EHRs*, J. AHIMA, Nov.-Dec. 2009, at 50, 50; *see also* Jonathan Gill, *Tough Laws, High Insurance Drive Doctors Away from West Virginia*, L.A. TIMES, Jan. 7, 1990, at A10.

emergency rules.[171] Even when the CII prescription is allowed e-prescribing status, West Virginia prescribers and pharmacists receive no benefit from the practice because the subsequent regulation requires a paper prescription for all CII medications.[172] Currently:

> If a CII prescription is given over the phone or via e-prescribing in an emergency situation which is allowed, "the orally communicated prescription is immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission is immediately reduced to a hard copy."[173]

The contradictions within West Virginia's statutes and rules seem to mean that a prescriber can send a CII prescription via e-prescribing, but the electronic prescription must be reduced to writing. This negates many of the potential workflow efficiencies, paper-less benefits, and potential security measures offered by e-prescribing.[174]

The West Virginia legislative and regulatory confusion brings to light an obvious but overlooked sentiment by states: the need to protect from prescription drug diversion.[175] The DEA addressed this in the background of the rule and within their response to rule commentators.[176] The DEA reasoned e-prescribing would likely cut down on diversion by patients and

171. *See* W. VA. CODE § 30-5-12c(a).

172. W. VA. CODE R. § 15-1-21.1.6.

173. *Id.* § 15-1-21.1.6.b.

174. EHEALTH INITIATIVE, *supra* note 10, at 2-3; Jason Harris, *Going Paperless: EHRs Offer Challenges, Benefits*, HEMONCTODAY (Aug. 10, 2010), http://www.hemonctoday.com/article.aspx?rid=67420. Ultimately the paperless system will enhance cohesive health delivery, create a "greener" health care environment, and increase portability of medical records. *See* Mark Singh, *Benefits of Paperless Record Systems in Hospitals*, CLINICORE HEALTH SOLUTIONS (Apr. 8, 2010, 6:28 PM), http://clinicore.blogspot.com/2010/04/benefits-of-paperless-record-systems-in.html.

175. Prescription drug diversion is the deflection of prescription drugs from medical sources into the illegal market. PILAR KRAMAN, COUNCIL OF STATE GOV'TS, DRUG ABUSE IN AMERICA—PRESCRIPTION DRUG DIVERSION 4 (2004) *available at* http://www.csg.org/knowledgecenter/docs/TA0404DrugDiversion.pdf. West Virginia's laws have been established to reduce oral and electronic prescriptions to writing and to confirm those prescriptions with a hard-copy from the prescriber to prevent diversion. W. VA. CODE R. § 15-1-21.1.2 (2011). The American Pharmacists Association (APhA) has expressed the sentiment that there is an increased security benefit of e-prescribing to reduce forgeries of prescriptions for controlled substance because e-prescribing patients will not have an opportunity to manipulate a paper prescription. *Electronic Prescribing of Controlled Substances: Addressing Health Care Law and Enforcement Policies: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 2 (2007) [hereinafter APhA's Senate Statement] (statement of The American Pharmacists Association (APhA)).

176. *See* Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236, 16,244-45 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311).

those outside of the health delivery model.[177] By not allowing patients to have physical contact with the prescription, when taking it from the prescriber to the pharmacy, there is less chance for the document to be tampered,[178] altered or copied for the purpose of abuse.[179] However, the risk for internal diversion and diversion through technological means is still of great concern.[180] There is an increased risk of computer hacking or manipulation of data through the technology intermediaries that manage the e-prescribing software.[181]

The two-factor authentication is the DEA's answer to internal diversion issues. Although this will deter agents in a prescriber's office or hospital from forging controlled substance prescriptions, states and experts alike are skeptical.[182] Many times computer consoles stay logged-in allowing a prescriber easy access, but this opens up an opportunity for potential abuse.[183] There may also be opportunities for an office employee to observe a physician entering a password to use later for diversion purposes, a two-factor authentication should limit this problem.[184] Additionally, these same security pundits find cause for concern about the security of the network itself, through hacking.[185] Could an enterprising computer expert or hacker gain access to an e-prescribing system and then write prescriptions that look legitimate? The answer may be yes.[186] There are

177. *Id.*; APhA's Senate Statement, *supra* note 175, at 2; Barlas, *supra* note 127, at 626. Diversion of controlled substances is "a relatively simple task in the current paper-based environment." Kathryn Foxhall, *HHS, DEA Still at Odds Over E-Prescribing*, DRUG TOPICS (Aug. 21 2006), http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=365721.

178. *See Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (Statement of Joesph T. Rannazzisi, Deputy Assistant Director, Office of Diversion Control, Drug Enforcement Administration), *available at* http://www.justice.gov/dea/pubs/cngrtest/ct120407.html.

179. *See* Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,244.

180. *Id.* at 16,244-45.

181. *See id.* at 16,243; AM. COLL. OF PHYSICIANS, ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES—A NEW OPTION 1, http://www.acponline.org/running_practice/technology/eprescribing/dea.pdf.

182. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,249-250.

183. *Id.* at 16,240.

184. *Id.* at 16,249.

185. *Id.* at 16,242.

186. *See, e.g.*, Press Release, Drug Enforcement Administration, Statement for the International Day Against Drug Abuse and Illicit Trafficking (June 27, 2008), http://www.justice.gov/dea/pubs/pressrel/pr062708.html ("DEA Deputy Assistant Administrator for the Office of Diversion Control, Joseph Rannazzisi, said 'Our goal is to put in place an electronic prescribing system that is efficient, medically beneficial to patients and prescribers, and provides security from hackers and others who might seek to engage in fraudulent prescribing

several e-prescribing technology intermediaries that facilitate the transmission from the prescriber to the pharmacy.[187] The DEA has promulgated language that denotes any change to the content of a prescription during transmission, including truncation or removal of data, will render the electronic prescription invalid.[188] As noted above, the DEA is working on appropriate technological standards for e-prescribing and soon a timeline and implementation of the technology will be outfitted for market use.[189] However, until that time states may see fit to prepare themselves for the new technology through changes in their own statutes and regulations.

The DEA notes the two-factor authentication and additional computer security measures will deter hacking.[190] Also, prescribers are required to print and observe monthly logs of their controlled substance prescriptions, which encourage oversight and security.[191] Computer software developers have initiated a "hard-stop" in the e-prescribing software that would automatically log-out a prescriber after a controlled substance prescription is authorized.[192] Additionally, the two-factor authentication is needed for every controlled substance prescription.[193] In actuality, internal diversion can occur with or without e-prescribing software and it is up to prescribers, insurance companies, and pharmacists to police the transmission of those prescriptions.[194] It can be argued that a stolen prescription pad from a doctor's office is just as dangerous as a breached e-prescribing system.[195]

Finally there is a third subset of states that have not adopted e-prescribing of controlled substances language. The Nebraska Board of Pharmacy has determined that until the DEA certifies the systems used by

activities."); *see also* Jill Wechsler, *Health IT Gains Momentum*, MANAGED HEALTHCARE EXECUTIVE (Jan. 1, 2008), http://managedhealthcareexecutive.modernmedicine.com/mhe/News+Analysis/Health-IT-Gains-Momentum/ArticleStandard/Article/detail/482403. *But see* CTR. FOR HEALTH TRANSFORMATION, *supra* note 40, at 12.

187. DEA eRx, *supra* note 39; MD. HEALTH CARE COMM'N, E-PRESCRIBING: AN INFORMATION BRIEF 2-3 (2008), *available at* http://mhcc.maryland.gov/electronichealth/eprescribing/PharmacyBoardReport062408v2.pdf. It is important to note that both SureScripts and RxHub have never reported an incident of hacking or breach in their e-prescribing network. CTR. FOR HEALTH TRANSFORMATION, *supra* note 40, at 12.

188. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,288.

189. *See supra* text accompanying notes 200-06.

190. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,242.

191. *Id.* at 16,262.

192. Ann Carrns, *Special Health IT Report: Electronic Prescribing Increasing Despite Glitches*, KAISER HEALTH NEWS (June 29, 2009), http://www.kaiserhealthnews.org/Stories/2009/June/29/eprescribe.aspx.

193. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,249.

194. *Id.* at 16,261.

195. ELECTRONIC PRESCRIBING INITIATIVE, EHEALTH INITIATIVE, ELECTRONIC PRESCRIBING: TOWARD MAXIMUM VALUE AND RAPID ADOPTION 73 (2004).

prescribers and pharmacies.[196] Nebraska will follow current law, not change laws on the books and not allow e-prescribing for controlled substances.[197] The Nebraska statute currently reads:

> [A] controlled substance listed in Schedule II of section 28-405 shall not be dispensed without the written prescription bearing the signature of a practitioner authorized to prescribe . . . .
>
> . . . . Except as otherwise provided in this subsection or when administered directly by a practitioner to an ultimate user, a controlled substance listed in Schedule III, IV, or V of section 28-405 shall not be dispensed without a written or oral medical order.[198]

Nebraska's Board of Pharmacy's software concerns illustrate certain privacy issues.[199] Additionally, the Nebraska Board of Pharmacy has expressed the use of intermediaries is not ideal, and intermediary services (also known as a "switch") burden providers and pharmacists with extra costs and security issues.[200]

Privacy concerns fall primarily under HIPAA[201] through standards imposed on the prescriber, pharmacy, and other business entities involved in

196. The Board requested that staff gather more information from the DEA before changes to Nebraska statutes and regulations are pursued. The Board mentioned having discussions with the Department regarding changes that may need to be made to the Uniform Controlled Substances Act to allow electronic prescribing in Nebraska. NEB. BD. PHARMACY, MEETING MINUTES MAY 10, 2010, at 2 (2010), *available at* http://dhhs.ne.gov/publichealth/Documents/051010pharmminutes.pdf.

197. *Id.*; *see also* NEB. BD. PHARMACY, MEETING MINUTES JULY 12, 2010, at 4 (2010), *available at* http://dhhs.ne.gov/publichealth/Documents/071210pharmminutes.pdf. It is important to note that Nebraska pharmacy leaders are not against e-prescribing of controlled substances, the Board of Pharmacy is simply skeptical about the certification process and functionality of the security features of the e-prescribing systems. *See* EHEALTH COUNCIL, NEB. INFO. TECH. COMM'N, E-PRESCRIBING WORK GROUP REPORT AND RECOMMENDATIONS 5-6 (2009), *available at* http://www.nitc.nebraska.gov/eHc/plan/reports/EprescribingRecommendations.pdf.

198. NEB. REV. STAT. § 28-414(2)(a) (2009).

199. *See* Gilman & Cooper, *supra* note 5, at 283-84; Sarah Rubenstein, *Privacy Advocates Sound Alarm About Electronic Prescribing* WALL ST. J. HEALTH BLOG (July 29, 2008, 9:02 AM), http://blogs.wsj.com/health/2008/07/29/privacy-advocates-sound-alarm-about-electronic-prescribing/; *see generally* EPRESCRIBING DATA USE TASK GRP., EPRESCRIBING DATA USE PROBLEM STATEMENT 4-5 (2009) (discussing various issues surrounding privacy and e-prescribing).

200. EHEALTH COUNCIL, *supra* note 197, at 4.

201. *See* Health Insurance Portability and Accountability Act (HIPAA) of 1996 Pub. L. 104-191, § 264, 110 Stat. 2033, 2033-34 (codified as amended at 42 U.S.C. § 1320d-2). "HIPAA privacy and security standards still exert influence over several aspects of the prescribing process, including storage of and access to related records, as well as the communication of records between providers." Greenberg et al., *supra* note 111, at 463. "The kind of system integration and data sharing that offers greatest promise for improving

electronic health care information.[202] Providers and pharmacies have adapted to HIPAA standards well but at a significant cost,[203] which may lead e-prescribing users with an impression that they will be able to adapt quickly to any privacy concerns. However, state privacy laws may impede the adoption of the e-prescribing process too.[204] E-prescribing and EHR systems will ideally allow the free flow of patient data to all parties that require the electronic medical information.[205] With data becoming more accessible the danger is that more privacy violations under HIPAA or state privacy law may appear.[206]

It seems these concerns may be over-emphasized. With the computerization of patient health information ("PHI") health care entities have been able to adequately adapt and change their operations to meet both state and federal laws.[207] But if necessary, could EHR and e-

clinical prescribing practice is also the most challenging aspect of e-Rx under HIPAA and the privacy regulations." *Id.* at 465.

202. Greenberg et al., *supra* note 111, at 465.

203. *Id.* at 463.

204. "The ultimate goal [is]…to obtain appropriate privacy protections while facilitating the development of fully functional, network-based e-Rx systems. Achieving this goal also could involve some marginal tailoring of federal pre-emption of state privacy laws." *Id.* at 467. States may have a multitude of different privacy regulations concerning the medical community; Iowa for example released a report discussing HIPAA preemption and Iowa Privacy laws. *See* IOWA HIPPA SNIP, IOWA HIPAA PREEMPTION ANALYSIS: A REPORT ON THE RELATIONSHIP BETWEEN HIPAA'S PRIVACY RULE AND IOWA STATUTORY LAW vi (2003), *available at* http://www.iowamedical.org/documents/legal/IowaHIPAAPreemptionAnalysis.pdf. The HIPAA preemption and individual state laws are beyond the scope of this article but it will be important for states to address privacy laws as a possible barrier to e-prescribing adoption. Greenberg et al., *supra* note 111, at 465-66.

205. "An interoperable system of HIE [health information exchange]—that is, one in which various parties can share and exchange data among them—will have difficulty accommodating the current range of variation in policy requirements." Linda Dimitropoulos & Stephanie Rizk, *A State-Based Approach to Privacy and Security for Interoperable Health Information Exchange*, 28 HEALTH AFF. 428, 428-29 (2009).

206. An excellent resource to delve into the privacy concerns of EHR and e-prescribing is RTI International and their work with National Health Information Security and Privacy Collaboration (HISPC). *See* Press Release, RTI Int'l, RTI International to Support National Health Information Security and Privacy Collaboration (Oct. 12, 2005), http://www.rti.org/page.cfm?objectid=0AD0F1AC-B38F-4286-92481FDE5E224511. RTI International has contracted with 34 states to investigate and consolidate privacy laws in states that serve as barriers to EHR, Health Information Exchange (HIE), and e-prescribing adoption. LINDA L. DIMITROPOULOS, PRIVACY AND SECURITY SOLUTIONS FOR INTEROPERABLE HEALTH INFORMATION EXCHANGE—IMPACT ANALYSIS 3-2 (2007), *available at* http://www.rti.org/pubs/phase2_impactanaly.pdf; *see also* Greenberg et al., *supra* note 111, at 462.

207. Greenberg et al., *supra* note 111, at 462. Surescript's statistics note an 181% increase in e-prescribing and over 25% of all office based physicians are e-prescribing. SURESCRIPTS, *supra* note 27, at 8, 10.

prescribing laws provide a more comprehensive, uniform approach to assessing privacy issues? Too heavy a burden is being placed on national health care entities to adhere to a multitude of different state regulations. With the exchange of information becoming a national endeavor[208] and health care entities stretching through all fifty states,[209] there must be a growing trend for states to consolidate uniform standards for e-prescribing and privacy. New, flexible regulations or statutes must be entertained if not adopted.

The inconsistent regulatory scheme nationwide remains a significant barrier to e-prescribing for controlled substance adoption. As mentioned above, technology pilot studies and tests are ongoing and will soon be mimicked to allow for a full functioning, secure e-prescribing system.[210] One of the few remaining barriers to e-prescribing is the passive resistance of state statutes and regulations. The inconsistent language provided by the majority of the states leaves practitioners, pharmacists, and technology intermediaries waiting for state legislative action. There needs to be a conscious and focused effort to implement regulatory amendments to accelerate this slow adopting but extremely beneficial health delivery tool. With only the technological barriers of DEA certification remaining, state regulatory language is one of the final barriers e-prescribing advocates must tear down.

V. IS MODEL LANGUAGE A SOLUTION?

Adoption rates of e-prescribing are growing[211] but considering the federal, state, and private initiatives[212] already in place, it is argued that the adoption rates of e-prescribing remain sluggish.[213] Model language could

208. *See* Gilman & Cooper, *supra* note 5, at 287; SURESCRIPTS, *supra* note 27, at 11.

209. *See* NAT'L GOVERNORS ASS'N, *supra* note 10, at 5; Press Release, Walgreens, Electronic Prescriptions Soar at Walgreens (Apr. 13, 2009), http://news.walgreens.com/article_print.cfm?article_id=5176; Press Release, CVS Caremark, CVS Caremark Announces e-Prescribing Agreement with Allscripts (Jan. 7, 2010), http://investor.cvs.com/phoenix.zhtml?c=99533&p=irol-newsArticle&ID=1372549&highlight=.

210. DEA eRx, *supra* note 39; *see also* AGENCY FOR HEALTHCARE RESEARCH & QUALITY, AHRQ PUBL'N NO. 07-0047-EF, FINDINGS FROM THE EVALUATION OF E-PRESCRIBING PILOT SITES v (2007), http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_8969_227460_0_0_18/Findings%20From%20The%20Evaluation%20of%20E-Prescribing%20Pilot%20Sites.pdf.

211. *See* SURESCRIPTS, *supra* note 27, at 10-11.

212. *See, e.g.*, *eRx Incentives*, *supra* note 32; CTR. FOR HEALTH TRANSFORMATION, *supra* note 40, at 16-24; CMS ePrescribing Incentive Program, AM. MED. ASS'N, http://www.ama-assn.org/ama/pub/physician-resources/health-information-technology/incentive-programs/cms-eprescribing-incentive-program.page.

213. JOY M. GROSSMAN, CTR. FOR STUDYING HEALTH SYS. CHANGE, ISSUE BRIEF NO. 133, EVEN WHEN PHYSICIANS ADOPT E-PRESCRIBING, USE OF ADVANCED FEATURES LAGS 1 (2010),

be the key to clarifying and quashing many of the barriers e-prescribing needs to overcome.[214] Significant merit must be given to the DEA rule and other e-prescribing initiatives that have spent years on analysis and implementation of e-prescribing standards. But DEA rules may not address many of the state regulatory concerns that plague e-prescribing implementation.[215]

Historically, model language has been created and used by state legislatures and agencies to foster change in the regulatory scheme.[216] Model language has been a successful tool throughout the legal community for many years,[217] for example model language has been drafted for use in the health law sector,[218] electronic transactions,[219] and business code in state law.[220] E-prescribing model language may allow for a uniform transition from old state rules to newer and more current forms of rules. It could provide uniformity to all of the stakeholders of e-prescribing from the practitioners, to regulators and third-parties.

available at http://www.hschange.com/CONTENT/1133/1133.pdf; *see also* Nathan, *supra* note 54 at 203.

214. "The work of the ULC simplifies the legal life of businesses and individuals by providing rules and procedures that are consistent from state to state—a consideration that has become more critical as new technology wears away geographical borders and matters of law implicate more than one state." *Frequently Asked Questions*, NAT'L CONF. OF COMMISSIONERS ON UNIFORM STATE LAW, http://www.nccusl.org/Narrative.aspx?title=Frequently%20Asked%20Questions (last visited Jan. 3, 2012) [hereinafter NCCUSL].

215. The DEA rule seems to be silent on state privacy laws, state anti-kickback legislation, and separate state licensure of prescribers and pharmacies. *See* Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311).

216. *See* NCCUSL, *supra* note 214 (stating "[s]ince the ULC first convened in 1892, it has produced more than 250 uniform acts focusing on such areas as commercial law, family or domestic relations law, estates, probate and trusts, real estate, implementation of full faith and credit, interstate enforcement of judgments, and alternate dispute resolution").

217. *See id.*; *see also ALI Overview*, AM. L. INST., http://www.ali.org/index.cfm?fuseaction=about.overview (last visited Jan 3, 2012); CORNELL UNIV. L. SCHOOL, *Uniform Commercial Code Locator: Uniform Law*, LEGAL INFO. INSTITUTE, http://www.law.cornell.edu/uniform/uniform.html (last visited Jan. 3, 2012). One author even goes so far as to entertain uniformity of the prescriber's licensing process. Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospective of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. & POL'Y 87, 114 (2011).

218. *See, e.g.*, UNIF. HEALTH-CARE INFO. ACT § 1-102 (1986), *available at* http://www.law.upenn.edu/bll/archives/ulc/fnact99/1980s/uhcia85.pdf (providing an example of model language in the health law sector).

219. *See, e.g.*, UNIF. ELEC. TRANSACTIONS ACT § 2 (1999), *available at* http://www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/ueta99.pdf (providing an example of model language in electronic transactions).

220. *See* NAT'L CONF. OF COMM'RS ON UNIF. STATE LAW, UNIFORM COMMERCIAL CODE, http://www.nccusl.org/Update/ActSearchResults.aspx (last visited February 1, 2011).

Model language can also be a source of expertise;[221] not all states have the time and money to spend on legislative drafting and model language can bring in nationally renowned experts to help implement language.[222] Not to mention draft a flexible, forward-thinking uniform rule that would accommodate changes in the legal and health delivery environments.[223] Model language takes the burden of drafting off of the states while allowing them to implement either the whole or parts of a specific plan.[224]

On the other hand, one risk of model language use is that certain sub-sections of a state's population would not be accommodated.[225] Model language "brushes with broad strokes" and as such may not be specific enough for states with outlying population groups.[226] Additionally, by virtue of the drafting process interest groups will undoubtedly have input drafting rules or statutes.[227] This may create biases.[228] Finally, model language may take too long or be too involved. If the language is too cumbersome states may choose not to adopt because they fear increased bureaucracy, enforcement issues, or incidental cost.[229]

As illustrated above, states' e-prescribing concerns include diversion and privacy issues specifically in the realm of computer security and security at the point of the prescriber. State boards of pharmacy or medicine may fear they will be inundated with increases in diversion at the physician's office and the burden to investigate and protect against computer hacking—both areas that have been traditionally beyond the scope of their regulating expertise. Additionally, states may worry about anti-kickback legislation or implications within their own fraud and abuse regulations. State language

221. Bruce H. Kobayashi & Larry E. Ribstein, *The Non-Uniformity of Uniform Laws*, 35 J. CORP. L. 327, 328, 343 (2009) [hereinafter *Non-Uniformity*].

222. *See* Lawrence J. Bugge, *Commercial Law, Federalism, and the Future*, 17 DEL. J. CORP. L. 11, 19 (1992); Larry E. Ribstein & Bruce H. Kobayashi, *An Economic Analysis of Uniform State Laws*, 25 J. LEGAL STUD. 131, 140 (1996) [hereinafter *Economic Analysis*].

223. Bugge, *supra* note 222, at 18-19.

224. *Non-Uniformity, supra* note 222 at 330; *Economic Analysis, supra* note 222 at 140.

225. *Economic Analysis*, *supra* note 222, at 142.

226. *Id.*

227. "Interest groups can influence uniform law drafters even if these drafters are appointed on a nonpolitical basis rather than elected . . . . [Uniform law makers] invite[] 'advisers' representing the groups to attend and participate in drafting and annual meetings. Advisers can most influence those commissioners who lack independent knowledge that would enable them to take positions that are not advocated at the meetings." *Id.* Although it would seem special interest groups are a "necessary evil" to get buy-in and appropriate expertise involved in the drafting process. *See* Kathleen Patchel, *Interest Group Politics, Federalism and the Uniform Laws Process: Some Lessons From the Uniform Commercial Code*, 78 MINN. L. REV. 83, 100 (1993).

228. *Economic Analysis*, *supra* note 222, at 143.

229. *See generally Economic Analysis*, *supra* note 222, at 135-37.

should be consistent. Rules and statutes need to align and guidance by boards of pharmacy, medicine and nursing need to be clear.

Model language has the ability to address specific concerns and resolve state privacy barriers, security issues, and inconsistent language. Sections of model language should explicitly address each of these issues while taking into account that some states may not adopt a given section. If this occurs, model language would not only have to stand as a cohesive work but each section should be well-drafted to stand on its own. An organization of model language may look like this (including but not limited to the following sections):

1) *Model Act for E-prescribing*
    a) *§1 Definitions*
        i) *Electronic Prescribing*
        ii) *Electronic Transmission*
        iii) *Prescription*
        iv) *Valid Signature*
        v) *Valid, eligible Prescriber*
        vi) *Eligible Pharmacy (Resident or Non-Resident)*
        vii) *Eligible Third Party Intermediaries*
    b) *§2 Requirements of an Electronic Prescription (e-prescription)*
        i) *Eligible Prescribers and Agents of Prescribers*
            (1) *DEA Licensure/Approval*
            (2) *State Controlled Substance Licensure*
        ii) *Eligible Pharmacies*
            (1) *DEA Licensure*
            (2) *State Licensure*
        iii) *Eligible Software and Systems Management Stakeholders*
            (1) *DEA and/or State approval*
            (2) *Third party certification*
            (3) *Certified Biometrics, Hard Token, Password Specifics*
        iv) *Scope of Medication that may be prescribed*
            (1) *CII-CV*
            (2) *Address CI Research Issues*
            (3) *May have the option to limit or line item certain medications*
        v) *Information Required (Prescription and Label information)*
            (1) *Patient Identifiers*
            (2) *Drug Identifiers*
            (3) *Prescriber Information*
            (4) *Prescription Information (Refills, Quantity, Drug, Dose, etc. . .)*
            (5) *Standardized drug nomenclature and instructions for use*

- *vi) Training*
  - *(1) Physicians*
  - *(2) Pharmacists*
  - *(3) Pharmacists Technician*
- *vii) Software Uniformity*
  - *(1) Similar Alerts and Warnings*
  - *(2) Similar construction of the software*
  - *(3) Reasonable Safety Measures Implemented*
  - *(4) Standardized drug names and terms*
- *viii) Requirements of written prescriptions removed. Paperless system*

c) §3 Security Measures

- *i) Two-factor authentication*
  - *(1) Password*
  - *(2) Hard Token*
  - *(3) Biometrics*
- *ii) Agent of Prescriber*
  - *(1) Can agents assist in prescriptions (only ministerial duties)*
- *iii) Software and technology measures (ascertained/unascertained)*
  - *(1) Valid eSignature*
  - *(2) What is a signature*

d) §4 Recordkeeping

- *i) Monthly Logs*
- *ii) Maintaining Records*
- *iii) Record storage*

e) §5 Feedback Measures

- *i) Insurance, physician, and pharmacist's feedback loop*
- *ii) What are the required functions and connectivity that must be incorporated*

f) §6 Privacy Concerns, Safe Harbors, Tax Incentives

- *i) Addressing HIPAA and state privacy laws*
- *ii) Access to data*
- *iii) Verification and validation either through the DEA or other State agency*
- *iv) Modification and Amendments to State Anti-kickback laws*

g) §7 Emergency Measures

- *i) Emergency prescription uses*
- *ii) Long Term Care, Hospice*
- *iii) Public Health emergencies*

h) §8 Penalties and Remedies

- *i) Criminal Offense for diversion*
- *ii) Inappropriate billing (fraud)*
- *iii) Medical malpractice, tort issues*

Model language would need to address conflicting definitions while leaving ambiguity for changing prescribing practices and innovative health technology. For example, language should address but not limit the scope of computer transmissions, PDA or mobile e-prescribing, and physician agent transactions. Model language should encompass all forms of prescribers, such as physicians, dentists, nurse practitioners, optometrists, and pharmacists with collaborative practice agreements. To encompass all of the ascertained and unascertained stakeholders, any type of model language should be flexible to unforeseen changes in the healthcare landscape; for example, the advent of new prescribing professionals. Beyond the overall intention of proposed model language, the definitions, terms, or technological assertions should be given specific meaning. For example, the term "electronic transmission" has a different meaning in Iowa[230] than it does in West Virginia.[231]

When attempting to draft uniform laws, drafters must respect non-adoption by the states. Any uniform law must walk the fine line between all-encompassing versus uselessly ambiguous language. Giving substantial meaning to terms and language must be considered at all possible avenues. There is a significant danger for model language to become un-manageable if states need to qualify or add statutory clauses. Ambiguous model language would just require states to do more work to clarify, guide, and coax stakeholders into implementing e-prescribing.

Model language could also encompass and override conflicting regulations and state codes.[232] Allowing state legislatures to pass a law that removes conflicting regulations in their own state would add significant consistency within a single state. If the model language were to gain widespread adoption it would also benefit those health care entities that reach beyond one or two states. Uniformity amongst the states could increase e-prescribing transactions and increase companies reach from a regional to a national level. Giving states the tools required to pass comprehensive rules would allow clarification for state regulators,

230. IOWA ADMIN. CODE r. 657-21.1 (2009).

231. "'E-prescribing' means the transmission, using electronic media, of prescription or prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or health plan as defined in 45 C.F.R. § 160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms 'electronic prescription' or 'electronic order.'" W. VA. CODE R. § 15-1-2.1.18 (2009).

232. As illustrated in the West Virginia example above, where the statutes seem inconsistent with each other and the Board of Pharmacy guidance seems to allow e-prescribing. W. VA. CODE § 30-1-12c(a), (c) (2009).

prescribers, management, and other shareholders in public and private health care entities.

A proposed uniform law or regulation would reduce time and effort needed by legislators and their aides.[233] However, any proposed model language should include wide discretion at the state's agency level (professional boards) to maintain and endorse state autonomy in the delivery and regulation of health care. Maintaining the state's traditional power to regulate health care[234] will keep intact the core principles between federal and state authority.[235] Additionally, it should be noted that model language would be the jumping-off point of e-prescribing rules. States may be in a better position to tailor any language to their needs after the basic underpinnings of e-prescribing are adopted through a uniform law. If a state requires additional protective measures the uniform law should not discourage customization. However, it would behoove drafters to think of issues and potential solutions prior to a state's individual adoption of any uniform law. Uniform law adoption is rarely universal. Many states will change or alter certain clauses for the benefit of their specific situation, but if model language can set base-line understandings and definitions it will have assisted in e-prescribing adoption.

The next steps to increase the adoption of e-prescribing of controlled substances should be to establish a taskforce with the all of the major stakeholders at the drafting table (Appendix A). The taskforce should include groups from payors, providers, patient groups, regulators, and other third-party intermediaries with an emphasis on unbiased drafting that could result in adoption by a majority of the states. Enlisting a taskforce of state regulators, healthcare parties, and patient advocacy groups seems like a monumental task. But so are the savings and benefits that e-prescribing can bring the health care delivery system.

VI. CONCLUSION

States, private health care entities and providers will shoulder the burden when it comes to implementation of e-prescribing on a large scale. Model language or a set of standards may accommodate and encourage rapid adoption of e-prescribing. Additionally model language resolves many unaddressed issues including regulatory inconsistency, diversion and privacy. With the implementation of model language much of the burden

233. *Economic Analysis*, *supra* note 222, at 140.

234. *See, e.g.*, NAT'L GOVERNORS ASS'N, *supra* note 10, at 8-10 (illustrating the various e-prescribing initiatives); *see also* Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236, 16,304 (proposed Mar. 31, 2010) (to be codified 21 C.F.R. at pts. 1300, 1304, 1306, 1311).

235. Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. at 16,304.

can be taken off of the state and given to stakeholders and those who are affected by the implementation of e-prescribing. E-prescribing has enormous potential to save lives, money, and time so patients, providers, and payors can benefit.

CHARLES S. HARTIG*

* Charles Hartig is a registered pharmacist in Iowa, Illinois, Wisconsin and Missouri. He plans on graduating with his JD and Health Law Certificate in May, 2012. Charles would like to thank his SLU Law advisor Thomas "Tim" Greaney, Kevin Nicholson and Don Bell for their insight and guidance.

APPENDIX A. LIST OF POTENTIAL STAKE HOLDERS

Providers

Pharmacy Chain Representatives (e.g. Walgreens, CVS, Wal-Mart)
Community Pharmacy Owners
Staff Pharmacists
Family Practice Physicians and Other Physician Groups
Internal Medicine Physicians
Hospitals
Small, Rural Hospitals
Long-Term Care Facilities
Nurses

Special Interest Groups

American Pharmacist Association
American Medical Association
National Association of Board of Pharmacy (representing State Board of Pharmacy)
Institute of Medicine
National Association of Chain Drug Stores
National Community Pharmacists Association
American Hospital Association
Health Care Information and Management Systems Society
American Insurance Association
National Association of Insurance Commissioners
American Health Information Management Association
National Governors Association
National Rural Health Association

Third Party Payors and Intermediaries

Insurance Companies (Blue Cross Blue Shield, WellPoint)
SureScripts
AllScripts
Software Developers

Government Regulators

Center for Medicare and Medicaid Services
Drug Enforcement Administration
Office of the National Coordinator for Health Information Technology

Patient Advocacy Groups

Patient Advocacy Foundation
American Association of Retired Persons
Privacy Rights Clearinghouse
Electronic Privacy Information Center