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E-Prescribing in a Changing Legal Environment

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I. INTRODUCTION

[1] Perhaps nothing permeates modern American society as much as prescription drugs. Evidence of this exists not just in television and magazine ads extolling the promises of Viagra and Nexium, but also in a few statistics. First, forty-six percent of Americans use at least one prescription drug daily.[1] Further, in 2001, 3.1 billion prescriptions were issued in the United States at a cost of $132 billion.[2] That amount is projected to increase to $414 billion by 2014.[3] Such numbers explain the intensity of the recent political and legal debates surrounding prescription drugs, such as the importation of American pharmaceuticals from Canada and the issuance of prescriptions online without visiting a physician.[4] During the 2004 presidential campaign, President Bush touted his Medicare Modernization Act, a significant component of which concerned

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[1] Greg Critser, *One Nation, Under Pills*, L.A. TIMES, Dec. 15, 2002, at M.6, *available at* http://www.namiscc.org/News/2003/Winter/PharmaceuticalStatistics.htm.

[2] *Id*.

[3] *Id*.

[4] *See, e.g.*, Ronald L. Scott, *Cybermedicine and Virtual Pharmacies*, 103 W. VA. L. REV. 407, 410-11, 421 & 482-83 (2001).

coverage of prescription drugs for senior citizens.[5] On the business front, the issue most in the news is the high cost of brand-name pharmaceuticals compared to generics, and the high profit margin of pharmaceutical companies.[6]

[2] Another issue that does not receive the same headlines but has an enormous impact upon the delivery of health care is the increasing incorporation of high technology into the writing of prescriptions, more commonly referred to as electronic prescribing, or e-prescribing. The nation's 473,000 office-based physicians write the bulk of those 3.1 billion prescriptions, which somehow need to get from the physician to the pharmacy.[7] Increasingly, more and more physicians are choosing to transmit their prescriptions electronically.[8] Numerous e-prescribing system providers ranging from A (A4 Health Systems) to Z (ZixCorp) have fueled this growth, including SureScripts, which certifies retail pharmacies for receipt of transmissions and functions as a sort of technical distributor for e-prescribing.[9] Despite initial implementation costs, e-prescribing has the potential to reduce health care costs by improving efficiency, security, and patient safety.[10]

[3] Although much potential exists, the legal environment within this field presents numerous challenges. The first of these challenges is the inconsistency in regulatory schemes. The transmission of prescriptions is regulated by state law, and there are currently fifty different approaches,

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[5] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C.A. § 1395w-101 (Sup. 2005).

[6] *See, e.g.*, Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II*, 34 J. HEALTH L. 657, 661 (2001).

[7] *See* Joseph Goedert, *Electronic Prescribing: Is It Just What the Doctor Ordered?*, HEALTH DATA MGMT., June 2002, *available at* http://www.healthdatamanagement.com/HDMSearchResultsDetails.cfm?DID=12100.

[8] *Compare id*. (writing that e-prescribing increased from two to four percent of physicians in 2000 to six percent in 2001), *with* Ken Terry, *Expanding Clinical Connections: Prescriptions*, MED. ECON., Oct. 8, 2004, *available at* http://www.memag.com/memag/article/articleDetail.jsp?id=127292 (claiming that, by 2004, e-prescribing was as high as eighteen percent).

[9] SureScripts, About SureScripts, http://www.surescripts.cm/coBack.htm (last visited April 5, 2006).

[10] *E.g.*, Michelle Stowell, *Transmitting Prescriptions Electronically: A Benefit or a Burden?*, 32 MCGEORGE L. REV. 742, 750 (2001); Terry, *supra* note 8.

ranging from a lack of recognition of e-prescriptions to language that specifies technical standards and tries to accommodate trends.[11] Because controlled substances are regulated by the Drug Enforcement Administration, federal law transcends state.[12] Unfortunately, the DEA has not yet promulgated regulations for e-prescribing, so the states differ in their interpretation of the acceptability of electronic transmission of prescriptions for controlled substances.[13] This uncertainty is heightened by the legislative process and regulatory language, neither of which can adequately account for the rapid evolution of the technologies involved in e-prescribing.[14] Even political pressures come into play, such as the requirement in the Medicare Modernization Act for an e-prescribing technical standard by 2008.[15]

[4] These legal issues are a pressing concern as e-prescribing emerges as an increasingly important part of health care. Attorneys for the companies that create and maintain these systems, for the doctors and pharmacists who use these systems, for the agencies that regulate these systems, and for the managed care and insurance providers that can reduce costs with these systems must stay abreast of a legal environment framed by uncertainty, conflict, and rapid change. Although some recent legal scholarship has dealt with e-prescribing, the focus has been on the impact to federal law, such as HIPAA and E-Sign, or on practices that violate existing laws, such as ordering drugs without a prescription via the

[11] *Compare* 49 PA. CODE § 27.20 (2005) (allowing for facsimile transmission of prescriptions but making no mention of electronically-generated prescriptions), *with* 105 MASS. CODE REGS. 721.030 (2004) (providing precise standards for electronic technical security and e-signatures and accommodating potential changes to federal law regarding controlled substances).
[12] *See* 21 C.F.R. §§ 1300 – 1316 (2005).
[13] *Compare* 22 TEX. ADMIN. CODE § 291.34(b)(4) (2004) (allowing Schedule III-V substances to be transmitted electronically), *with* Memorandum from William Black, Wis. Dep't of Reg. & Licensing, to Wis. Pharmacy Examining Bd. (Mar. 16, 2004), *available at* http://drl.wi.gov/boards/phm/pap/RXSignatures3-16-04.pdf (last visited January 8, 2005) (interpreting federal regulations as requiring electronically-generated prescriptions for Schedule III-V substances to be received via facsimile equipment and then orally verified with the prescriber).
[14] Marsha N. Cohen, *RX by Email—Bad Medicine for a Chronic Rulemaking Illness*, ADMIN. & REG. L. NEWS 10, 11 (Fall 2003).
[15] 42 U.S.C.A. § 1395w-104(e) (Supp. 2005).

Internet.[16] As Ridgely and Greenberg point out in their article, however, those who undertake e-prescribing ventures must understand statutes and regulations that vary widely from state to state.[17] This essay will explore the e-prescribing laws of the three most populous states: California, Texas, and New York, as well as the DEA regulations that overlay state law to uncover the most typical legal problems encountered with the implementation and use of e-prescribing systems. It will then offer ways to avoid, account for, or even change these problems. First, though, it will examine e-prescribing in general and the impact of e-prescribing systems.

II. E-PRESCRIBING IN GENERAL

A. TRADITIONAL VERSUS E-PRESCRIBING

Traditional Prescription Methods and Their Drawbacks

[5] Most people are familiar with the traditional methods for getting and filling a prescription. A patient must first visit a physician, who after an examination determines whether certain medications are necessary for treatment. The physician then writes the medication order on a prescription pad for the patient to deliver to the pharmacy, or the physician personally phones the order into the pharmacy or, in more recent times, sends it by facsimile.[18] The patient then visits the pharmacy, either to pick up an order sent by phone or fax, or to present the prescription form to a pharmacist for filling.

[6] These traditional methods present several problems. First, they are inefficient because of time wasted transcribing information for oral orders, re-entering data required for state and federal reporting, and calling

[16] M. Susan Ridgely & Michael D. Greenberg, *Pharmacy, Facsimile, and Cyberspace: An Examination of Legal Frameworks for Electronic Prescribing*, 13 ALB. L.J. SCI. & TECH. 1 (2002); Scott, *supra* note 4.
[17] Ridgely & Greenberg, *supra* note 16, at 40-41.
[18] In many states, prescriptions for some controlled substances require a special form printed and distributed by the state for security and tracking purposes. *See, e.g.*, N.Y. PUB. HEALTH LAW § 3332(2) (Consol. 2005); CAL. HEALTH & SAFETY CODE § 11161.5 (West 2005).

doctors to clarify illegible handwriting.[19] This inefficiency increases the labor costs for both doctors' offices and pharmacies.[20] It also wastes the patient's time because of the delay between presenting and filling a written order.[21] Other major concerns about traditional methods include potential medication errors due to illegible handwriting, the need to transcribe prescriptions multiple times, and possible adverse drug interactions.[22] Medication errors arising from the traditional methods of prescribing medication lead not only to wasted time and extra hospital visits, they cause an estimated 7,000 deaths annually.[23]

E-Prescribing and Its Perceived Drawbacks

[7] E-prescribing is "the use of an automated data entry system to generate a prescription, rather than writing it on paper."[24] In many ways, the core process is the same: the patient visits a physician, who, following an examination, determines if medications are necessary for treatment, and then writes a prescription.[25] The key difference is the manner of transmitting the prescription: in e-prescription, the physician generates the prescription using a computer or a hand-held device such as a Blackberry, then transmits the prescription to an appropriate pharmacy. Several companies offer software and related services that allow physicians to e-prescribe by, for example, using a stylus or mouse to point and click his or her way through the patient's record and to select the appropriate

[19] Stowell, *supra* note 10, at 747.
[20] One doctor estimated that by switching from traditional methods to e-prescribing, his practice saved at least fifteen minutes of nurse overtime per day, and daily calls from pharmacies dropped from twenty to two, which translated to about $11,000 in one year. Terry, *supra* note 8.
[21] Stowell, *supra* note 10, at 747.
[22] *Id*.
[23] *Id*. at 742.
[24] Ridgely & Greenberg, *supra* note 16, at 3 (quoting Peter Kilbridge, *E-Prescribing*, I-HEALTH REPORTS 5, Nov. 2001, http://www.chcf.org/documents/ihealth/Eprescribing.pdf).
[25] E-Prescribing *could* provide a means for obtaining and filling prescriptions without any patient-doctor face-to-face interaction. Barbara J. Williams, *On-Line Prescriptions and Drug Sales: An Overview of Emerging Issues*, 1 HOUS. J. HEALTH L. & POL'Y 147, 147–48 (2001). However, many states explicitly forbid dispensing drugs based on a prescription where no valid patient-physician relationship exists, such as when the only interaction has been via the Internet. *See, e.g.*, 22 TEX. ADMIN. CODE § 291.34 (b)(1)(B) (LEXIS 2004).

medication.[26] After the doctor generates an electronic prescription, e-prescription software routes the prescription through the provider's secure server to the pharmacy (and even the patient's insurance provider, if so desired), where the prescription arrives as either electronic data or as a printed fax.[27] In this way, e-prescription software is able to automatically create and store electronic records for the physician, the pharmacy, and even the insurance provider.[28]

[8] As with any new technology, there are some concerns about the limitations and shortcomings of e-prescription technology. For example, electronic systems that transmit data over the Internet are susceptible to interference by computer hackers.[29] One possible consequence of hacker interference is diversion, whereby hackers use the system to illegally acquire prescription drugs by simulating authentic prescriptions.[30] Another possible consequence is access to confidential information. Since patient data accompanies the e-prescription, patients could be less likely to provide their physicians with important private information for fear of it being intercepted by hackers.[31] Another concern about e-prescriptions is that these electronic systems will be inefficient since pharmacists may be required to reduce to writing all electronically transmitted prescriptions for record-keeping purposes.[32] Finally, high technology often means high cost, and not only do e-prescription systems require start-up costs and

[26] Aside from companies such as Allscripts and ZixCorp, which are major providers of e-prescription software and services, at least twenty-five different companies and organizations have some type of e-prescribing system. SureScripts, *supra* note 9.
[27] *See, e.g.*, Kilbridge, *supra* note 24, at 10. For pharmacies that have neither fax nor electronic capability, the physician's office could simply print the prescription for the patient, who then takes the script to the pharmacy in person.
[28] The various e-prescribing system providers' websites provide more thorough descriptions of this process. *See, e.g.*, PocketScript, ZixCorp, http://www.zixcorp.com/caredel/eprescribing.php (last visited Jan. 17, 2006).
[29] In an attempt to thwart hackers, one e-prescription service has licensed biometrics technology to ensure that the user of its e-prescription service is a licensed physician or pharmacist. Steve Gold, *Site Employs Biometrics for E-Prescription Security*, COMPUTERUSER.COM, Apr. 18, 2000, http://www.computeruser.com/news/00/04/18/news6.html.
[30] Stowell, *supra* note 10, at 743, 748.
[31] *Id.* at 749. Of course, hacker access to a patient's personal information creates the potential for identity theft.
[32] *Id.* at 746. Some states require pharmacies to maintain hard copies of prescriptions for a specific amount of time for, among other reasons, law enforcement. *Id.*

ongoing service fees for physicians and pharmacies, but also state officials may experience increased regulatory and enforcement costs.[33]

B. THE BENEFITS OF E-PRESCRIBING FAR OUTWEIGH THE DRAWBACKS

[9] These fears may have seemed reasonable a decade ago, but advancements in technology and changes in the law have rendered them virtually null. E-prescribing is not only more secure than traditional methods, it can increase efficiency and lower costs.[34] Although the benefits are separated for convenience, note that they actually interrelate. For example, improved efficiency leads to lower physician and pharmacy costs and to fewer patient medical errors; fewer medical errors leads to reduced insurance costs as well as less medical provider liability.

Increased Security

[10] Two changes have made e-prescribing more secure than traditional methods regarding patient confidentiality and diversion. First, anyone who handles patient information—health care professionals, e-prescribing system providers, and insurance companies—must now meet HIPAA standards for confidentiality and security.[35] Second, improvements in technology—such as minimum 128-bit encryption, passwords to log in to the systems, and automatic log-outs for periods of inactivity—have made interception more difficult and therefore less likely.[36] Although dedicated hackers can still intercept electronic data, consider that thieves can more easily steal and forge prescription pads.[37]

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[33] *Id.*

[34] *See* eHEALTH INITIATIVE, ELECTRONIC PRESCRIBING: TOWARD MAXIMUM VALUE AND RAPID ADOPTION 73-74 (2004), http://www.ehealthinitiative.org/assets/documents/eHIFullReport-ElectronicPrescribing2004.pdf.

[35] Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 45 C.F.R.).

[36] *See* PocketScript, *supra* note 28.

[37] eHEALTH INITIATIVE, *supra* note 34, at 73.

Better Patient Care

[11] E-prescribing can improve the effectiveness of health care by reducing errors. For example, the elimination of hand-written prescriptions and transcriptions by office staff reduces errors caused by illegible writing or incorrect transcribing.[38] Also, e-prescribing systems allow easy access to patient records and to computerized drug formularies, and they display warnings to the physician about patient allergies and adverse drug interactions.[39] These factors can significantly reduce the estimated 2.1 million adverse drug events that lead to 190,000 hospitalizations and thousands of deaths each year. [40]

Greater Efficiency and Reduced Costs for Physicians and Pharmacists

[12] This decrease in medication errors is the result of an increase in efficiency. E-prescribing increases efficiency because the data needs to be entered only once, eliminating transcriptions by nursing and secretarial staff and reducing the need for call backs since nothing is handwritten.[41] Further, the pharmacy can fill the order before the patient arrives, saving the patient time.[42] Because the information is already stored electronically, refills are easier for all parties involved.[43]

[13] This increase in efficiency means a reduction in labor and costs for physician offices and pharmacies. For example, reductions in callbacks from pharmacies saved one four-doctor office about $11,000 in overtime pay to nurses in one year.[44] Fewer call-backs, the elimination of transcriptions, and shortened refill times saved one eight-doctor office about 3,000 total hours in one year.[45] Even with initial start-up costs and

[38] Stowell, *supra* note 19 at 747.
[39] Terry, *supra* note 8.
[40] EHEALTH INITIATIVE, *supra* note 34, at 28.
[41] Stowell, *supra* note 19 at 747.
[42] *Id*.
[43] Terry, *supra* note 8.
[44] *Id*.
[45] Jack Beaudoin, *Study: E-Prescribing Cuts Labor Costs by 50 Percent*, HEALTHCARE IT NEWS, Sept. 7, 2004, http://www.healthcareitnews.com/NewsArticleView.aspx?ContentID=1464.

ongoing service charges, e-prescribing systems could pay for themselves in less than a year.[46]

[14] Finally, e-prescribing offers a partial solution in the debate over tort reform and medical malpractice insurance. Two percent of all adverse events lead to the filing of a medical malpractice claim, and the more severe the damage, the more likely a claim.[47] E-prescribing could therefore eliminate up to 4,000 claims per year, easing the burden on health care providers, insurers, and the courts.[48]

The Business Impact of E-Prescribing

[15] Currently, physicians write 3.1 billion prescriptions annually, which is more than ten for each American.[49] Many of these prescriptions are made in hospital, hospice, and institutional settings, although approximately 473,000 physicians work in private office settings and could make use of e-prescribing systems.[50] Only five to eighteen percent of these physicians currently use e-prescribing, so a huge growth potential exists.[51]

[16] The start-up costs average approximately $2,000 per physician in the first year, and much less thereafter.[52] This average accounts for implementation and software fees from the service provider, hardware such as the handheld device, wireless connectivity in the office, and data carrier fees.[53] After initial installation, the physician must pay ongoing software and support fees to the e-prescribing service provider.[54]

[46] Terry, *supra* note 8.
[47] David A. Hyman, *Medical Malpractice and the Tort System: What Do We Know and What (If Anything) Should We Do about It?* 80 TEX. L. REV. 1639, 1643 (2002).
[48] *Id.*; *see* eHEALTH INITIATIVE, *supra* note 34, at 28.
[49] Critser, *supra* note 1.
[50] Goedert, *supra* note 7.
[51] Terry, *supra* note 8.
[52] *Id.*
[53] *Id.*
[54] *Id.*

[17] Despite these costs, health insurers, encouraged by the federal government, have begun to promote e-prescribing.[55] For example, WellPoint has dedicated $40 million to provide hardware and a one-year subscription to either Allscripts or ZixCorp for its 19,000 network physicians, and both Blue Cross Blue Shield of Massachusetts and Tufts Health Plan offer a free, one-year subscription to PocketScript for 3,400 high-prescribing physicians.[56]

[18] Health plans promote e-prescribing for one simple reason: the potential long-term savings far outweigh costs. Increased patient safety adds to a healthier bottom line. Cutting the 190,000 hospitalizations that result annually from the 2.1 million adverse drug events could equal a savings of between $39 and $79 per employee per year in employer health plans.[57] These numbers do not even address the savings for medical malpractice insurers because of the reduction in tort liability. Although these figures do come from studies sponsored by the e-health industry and should be viewed guardedly, the truth is that more physicians are using e-prescribing, more health plans are promoting e-prescribing, and more state laws are changing to accommodate e-prescribing.

III. THE LEGAL ENVIRONMENT FOR E-PRESCRIBING

A. DEA REGULATIONS

[19] The federal government regulates controlled substances through the Drug Enforcement Agency (DEA).[58] Substances are listed as controlled because of their potential for abuse or addiction.[59] Controlled substances are further classified by the DEA into five schedules, which are based on their medicinal value, potential for abuse, and safety or dependence liability.[60] Schedule I substances (LSD, mescaline, marijuana) have no

[55] *Id.*
[56] *Id.*
[57] eHEALTH INITIATIVE, *supra* note 34.
[58] *See* 21 C.F.R. §§ 1300 – 1316 (2005).
[59] 21 U.S.C. § 802(6) (2000).
[60] *Prescription Drugs, State Monitoring Programs May Help to Reduce Illegal Diversion: Testimony Before the Subcomm. on Health, Comm. on Energy and Commerce*, 108th Cong. 4 (2004) (statement of Marcia Crosse, Director, Public Health and Military Health Care Issues).

acceptable medical use and therefore may not be prescribed.[61] Schedule II substances (Ritalin, Demerol, opiates) have medical uses but an extremely high potential for abuse.[62] Prescriptions for Schedule II substances are the most restricted: they must be written (except for emergencies) and manually signed, the dosage is limited, and most of them cannot be refilled without a new prescription.[63] Schedule III-V substances (anabolic steroids, anti-anxiety medications, narcotic cough syrups) have less potential for abuse.[64] Prescriptions for these substances may be oral or written and manually signed, and they may be refilled for up to six months.[65] Pharmacies must maintain records for all controlled substances dispensed and report these to the DEA on a regular basis.[66] These federal regulations are the minimum standards that all states must follow. Although the DEA has no explicit regulations for electronic transmission, it currently treats e-prescriptions as oral prescriptions, so that Schedule III-V substances may be transmitted electronically as long as the pharmacist verifies the prescription.[67]

B. CALIFORNIA

[20] California regulates e-prescribing and is one of the most e-friendly states because it has few specific limitations. State regulations establish the requirements for the content of an e-prescription.[68] California has no explicit technical requirements. Instead, the state has an open-ended definition of e-prescriptions that allows for different and emerging technologies.[69] The content requirements for controlled substances are in a different code section but essentially the same.[70] California even has a code provision that would allow for the electronic transmission of

[61] *Id.*; *See* 21 C.F.R. § 1308.11 (2005).
[62] Crosse, *supra* note 60; *see* § 13.08.12.
[63] Crosse, *supra* note 60; *see* § 1306.11.
[64] Crosse, *supra* note 60; *see* §§ 1308.13 – 1308.15.
[65] Crosse, *supra* note 60; *see* § 1306.21.
[66] Crosse, *supra* note 60; *see* §§ 1304.01 – 1304.33.
[67] Cohen, *supra* note 14.
[68] CAL. CODE REGS. tit. 16, § 1717.4 (Westlaw through 2005).
[69] *Id.*; *see* CAL. BUS. & PROF. CODE § 4040(a), (c) (West 2005) (defining an electronic data transmission prescription as "any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy").
[70] CAL. HEALTH & SAFETY CODE § 11164(b)(1), (3) (West 2005).

Schedule II substances if and when the DEA regulations change.[71] Although state law allows pharmacists to substitute a generic for a prescribed brand-name drug, physicians may prevent such substitution on an e-prescription.[72] Finally, out-of-state physicians may e-prescribe as long as they are licensed in their home state.[73]

C. TEXAS

[21] Texas also allows for e-prescribing, although its approach differs from California because Texas has more extensive and explicit regulations. For example, Texas has thirteen different content requirements for e-prescriptions, including a statement that the prescription is "electronically transmitted to:" the recipient.[74] The regulations for controlled substances are the same as for non-controlled.[75] Technical requirements are also listed, though no technical standards are specified. Thus, for e-prescriptions, data must not be altered during transmission, and confidential patient information must be kept in accordance with federal and state law, but the means for achieving these two requirements are not given.[76] Physicians may prevent generic substitution using e-prescribing.[77] If the brand drug is medically necessary and the patient will receive Medicaid reimbursement, however, the physician must provide a written prescription order within thirty days.[78] E-prescriptions from out-of-state physicians are acceptable, but for controlled substances, the out-of-state physician must be registered under the Texas Controlled Substances Act.[79]

[71] *Id.* § 11164.5(a).
[72] CAL. BUS. & PROF. CODE § 4073(a), (b) (West 2005).
[73] CAL. HEALTH & SAFETY CODE § 11150 (West 2005); CAL. BUS. & PROF. CODE § 4005 (West 2005).
[74] 22 TEX. ADMIN. CODE § 291.34(b)(6)(B)(ix) (West 2005).
[75] *See id.* § 291.34(b)(6)(B)(iii).
[76] *Id.* § 291.34(b)(4)(A)(ii)(I)-(II).
[77] *Id.* § 309.3(c)(3)(A)-(C).
[78] *Id.* § 309.3(c)(3)(C).
[79] *Id.* § 291.34(b)(4)(C)(ii).

D. NEW YORK

[22] New York has the least progressive and most confusing e-prescription regulations of the three states, although changes are pending. New York allows e-prescriptions, except for controlled substances, which are not allowed but not expressly prohibited.[80] E-prescriptions must meet three technical requirements: an electronic signature; electronic encryption that will prevent access, alteration or use by an unauthorized person; and the ability to be reproduced in hard copy by the pharmacist.[81] Further, the State Board of Pharmacy requires that e-prescribing systems have passwords, PINs, or other authentication of the prescriber.[82] Regarding generic substitution, the prescription form must contain the words "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW," as well as meet other font, placement, and design requirements.[83] Thus, the initials "d a w" ("dispense as written") must be handwritten, which is of course impossible electronically.[84] For Medicaid patients, the state further requires that the physician handwrite "brand medically necessary" or "brand necessary" in addition to "d a w."[85] Finally, the laws themselves are difficult to track and decipher. Not only must an attorney consult various code titles, he or she must also refer to the Education statutes for the generic substitution requirement.

[23] Recently enacted legislation should make e-prescriptions more feasible in the near future. New York has redefined "prescription" to include electronic prescriptions in the context of controlled substances.[86] Also, the state legislature has empowered the Commissioner of Health to

[80] N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(a)(7)(i) (Westlaw through 2005); *see* N.Y. State Educ. Dep't Office of the Professions, *Electronic Transmittal of Prescriptions: Questions & Answers* ¶ 14, http://www.op.nysed.gov/pharmqa.htm (last visited Nov. 7, 2005).
[81] N. Y. COMP. CODES R. & REGS. tit. 8, § 63.6(a)(7)(ii)(a)-(c) (Westlaw through 2005).
[82] *See* N.Y. State Educ. Dep't Office of the Professions, *supra* note 70 at ¶ 6.
[83] N.Y. EDUC. LAW § 6810(6)(a) (Consol. 2005).
[84] *Id.*
[85] N.Y. SOC. SERV. LAW § 361-a(9)(c) (Consol. 2005).
[86] N.Y. PUB. HEALTH LAW § 3302(31) (Consol. 2005).

create regulations regarding the use and transmission of e-prescriptions, including changes for Medicaid patients and out-of-state physicians.[87]

IV. PROBLEMS AND CHALLENGES FOR E-PRESCRIBING

[24] As this sample of regulations demonstrates, much variation exists in the limits of e-prescribing in a given state. Even where allowed, restrictions on form and content could cause an e-prescribing system that is valid in one state to be invalid in another. Affecting all of this is uncertainty about the limits of e-prescribing controlled substances under federal regulations. The following are the most common problems that attorneys in health care fields encounter.

A. THE LACK OF FEDERAL STANDARDS

The Questionable Permissibility of E-Prescribing for Controlled Substances

[25] Many commonly prescribed drugs are controlled substances: anti-anxiety medications like Ativan, sleep aids like Ambien, the attention-deficit disorder medication Ritalin, even cough syrup with codeine.[88] For maximum efficiency, therefore, most health care professionals want e-prescribing laws to allow for transmission of these substances.[89] Currently, the DEA, which has ultimate authority over all controlled substances, has promulgated no regulations regarding e-prescribing. The DEA is still conducting a pilot program using digital signatures and Public Key Infrastructure (PKI) technology, which, although initiated in 1999, has yet to result in regulation.[90]

[26] In the meantime, the DEA has chosen to treat e-prescriptions of controlled substances as oral orders.[91] This position has not been posted

[87] *Id*. §§ 21, 3308(5)-(6).
[88] 21 C.F.R. § 1308.12 – 1308.15 (2005).
[89] *See* Cohen, *supra* note 14, at 10.
[90] DEA Diversion Control Program, Electronic Transmission of Prescriptions: Electronic Order Forms, http://www.deadiversion.usdoj.gov/ecomm/e_ordrs/ (last visited Jan. 16, 2006).
[91] *See* SureScripts, SureScripts Partner & Provider Issue Bulletin #1: Transmission Methods Approved by the Drug Enforcement Administration (DEA) for Controlled

as official policy, which continues to be that e-prescriptions of controlled substances are not valid.[92] Rather, a 2002 letter from the Chief of the Liaison and Policy Section of the Office of Diversion Control to a maker of e-prescribing systems explaining this position has circulated widely, so that many state regulators and health care professionals assume that e-prescriptions for controlled substances are acceptable under federal law.[93] Marsha Cohen calls this informal law process a response to "regulatory ossification," which basically means that the official lawmaking process has not kept pace with technology and industry.[94] Although she favors e-prescriptions, Cohen has criticized this response because it is outside of the notice and comment rulemaking process.[95] Attorneys are put in the awkward position of giving legal advice that is correct based upon informal regulatory practice but that could become incorrect when the official regulations are approved—creating problems for all e-prescribing system providers, the health care professionals who use them, and even state officials who may need to rewrite their regulations.

[27] These federal regulations are also problematic because they merely represent the minimum standard, so most states can and do have their own controlled substances regulations that are more restrictive.[96] Often, the regulations that flow from these state controlled substance statutes incorporate federal law.[97] On a theoretical level, if the minimum standards are hazy and inexact, then states are building on a flawed foundation. Further, and of more immediate concern for attorneys, is the inconsistency because of states' differing interpretations of the minimal federal standard.[98]

Substance Prescriptions, http://www.surescripts.com/DEADocument.doc (last visited Jan. 16, 2006). This approach defeats one of the primary purposes of e-prescribing: efficiency. Oral orders for controlled substances must be personally verified by the pharmacist. This means that upon receipt of an e-prescription, the pharmacist must call the physician's office, even though the prescription has gone through an encrypted and password-protected system.

[92] Cohen, *supra* note 14, at 10-11.

[93] *Id*. at 11.

[94] Cohen, *supra* note 14, at 11.

[95] *Id*.

[96] *See, e.g.*, CAL. HEALTH & SAFETY CODE § 11164.5(a) (West 2005).

[97] *Id*.

[98] *Compare* 22 TEX. ADMIN. CODE § 291.34(b)(4) (2004) (allowing Schedule III-V substances to be transmitted electronically), *with* Black, *supra* note 13 (interpreting

Technical Inconsistency

[28] A second problem flowing from federal law relates to technology. Although current e-prescribing systems use Electronic Data Interchange (EDI), which features password-protected access and routes data through secure servers, the DEA's test program incorporates Public Key Infrastructure (PKI) technology and digital signatures.[99] With PKI, data is transmitted as complex computer algorithms, the recipient of the data must have both a public and a private "key" to decode the data, and third-party Certification Authorities issue and maintain the keys.[100] Although PKI theoretically offers higher levels of security, privacy, authentication, and non-repudiation than EDI, practically these benefits are nullified by the high cost and difficulty in implementing and maintaining the technology. The result has been that the high expectations of PKI in the 1990s have failed to materialize in this decade.[101]

[29] If the DEA adopts this technical standard, then it would pre-empt laws like those in Texas.[102] Although the California controlled substance e-prescribing statute includes language that accommodates changes in federal law, such changes would still require state approval of systems.[103] Either way, a change in the technical standard at the federal level would invalidate existing systems—costing e-prescribing providers and the health care professionals who have already adopted this technology much expense—and require a more expensive and difficult-to-use technology, without adding any appreciable benefit.

federal regulations as requiring electronically-generated prescriptions for Schedule III-V substances to be received via facsimile equipment and then orally verified with the prescriber).

[99] DEA Diversion Control Program, *supra* note 90.

[100] *See* Jan Lavorn, *The Power of PKI*, HEALTH MGMT. TECH. 20 (Dec. 2001).

[101] Even PKI providers and advocates acknowledge these limitations. *See* ANGELA KEITH, SANS INSTITUTE, COMMON ISSUES IN PKI IMPLEMENTATIONS—CLIMBING THE "SLOPE OF ENLIGHTENMENT" (2003), http://www.giac.org/practical/GSEC/Angela_Keith_GSEC.pdf.

[102] 22 TEX. ADMIN. CODE § 291.34(b)(4) (2004) (treating e-prescriptions for controlled substances as oral prescriptions and therefore requiring no signature).

[103] CAL. HEALTH & SAFETY CODE § 11164.5(a) (West 2005).

[30] A further federal complication is the requirement in the Medicare Modernization Act for a national technical standard by 2009, at least for transmission related to Medicare.[104] Because the DEA is under the Department of Justice and Medicare is under the Department of Health and Human Services, there could be different, even conflicting, standards. Such pending changes, which are years from being finalized, create problems for health care attorneys who must make business and regulatory decisions now.

B. STATE STATUTES & REGULATIONS

A Time of Flux

[31] Perhaps the most important issue regarding state laws is how quickly they change. Although these changes usually work to the benefit of e-prescribing, attorneys who need to give advice based upon the current law face problems when a bill to overhaul e-prescribing is pending in the state legislature, or when a new version of the law will take effect in three months. Consider that, when I first drafted this essay in January 2005, a change in New York laws to allow e-prescriptions for Medicaid recipients did not take effect until April.[105] This ongoing flux is the norm in most states. For example, the Texas requirement that generic substitution could only be prevented by handwriting "brand medically necessary" was changed in 2002.[106] Also, the main California e-prescribing statute had slight numbering and textual changes that took effect January 1, 2005.[107] Finally, e-prescribing stakeholders in New York must sit and wait while the state promulgates regulations regarding controlled substances, Medicaid, and out-of-state prescribers.[108]\

Attention to Details

[32] Attorneys can easily spot major differences among state statutes and regulations, such as whether a state even allows e-prescriptions of

[104] 42 U.S.C.A. § 1395w-104(e) (Supp. 2005).
[105] N.Y. COMP. CODES R. & REGS. tit. 18, § 505.3(b)(5) (2004).
[106] 22 TEX. ADMIN. CODE § 309.3(c)(3)(A) (2004).
[107] CAL. HEALTH & SAFETY CODE § 11164 (West 2005).
[108] N.Y. PUB. HEALTH LAW §§ 21, 3308(5) (McKinney Supp. 2005); N.Y. EDUC. LAW § 6810 (McKinney Supp. 2005).

controlled substances. Often, however, more subtle legal requirements can escape notice. For example, Texas requires that e-prescriptions contain a statement such as "electronically transmitted to:" and the name of the receiving pharmacy.[109] Also, Texas requires the "electronic access number" of the pharmacy to which the prescription is transmitted, yet it does not define this term.[110] It probably means the telephone number for faxes or computer address for EDI, but it may be something else, such as a state-provided account number. Failure to include either one of these could invalidate the entire prescription, or at the least require time-wasting call-backs for verification. Many states have variations on these requirements.

Inconsistency with the Electronic Medium

[33] State laws are often incompatible with e-prescribing. For example, because the state itself must pay the higher cost of brand-name drugs for Medicaid patients, states often have strict guidelines for how a physician can prevent substitution from the brand name drug to a generic equivalent. In Texas, a physician may prevent substitution via an e-prescription, but within thirty days he or she must provide a written prescription drug order.[111] This requirement means a second prescription, thus negating the efficiency goal of e-prescribing.

Inconsistency from State to State

[34] Several states have large metropolitan areas that spill into other states, such as Portland, St. Louis, New York City, and even Texarkana, which has a total population well in excess of 100,000.[112] A person who lives in one state but works in the other could easily have a physician in one state but a pharmacy in the other. A requirement that out-of-state physicians register under the Texas Controlled Substances Act for their controlled substance prescriptions to be valid is a nuisance.[113] The fact

[109] 22 TEX. ADMIN. CODE § 291.34(b)(6)(B)(ix) (2004).
[110] *Id.* § 291.34(b)(6)(B)(x).
[111] 22 TEX. ADMIN. CODE § 309.3(c)(3)(A)-(C) (2004).
[112] Real Estate Center at Texas A&M, *Texarkana Market Overview 2001: Population*, 2002, http://recenter.tamu.edu/mreports01/texarkana1.html (referencing the U.S. Census Bureau).
[113] 22 TEX. ADMIN. CODE § 291.34(b)(4)(C)(ii) (2004).

that New Jersey requires an official state prescription form or oral verification for controlled substances, New York is currently promulgating regulations for controlled substances, and Connecticut requires state approval of e-prescribing systems while it promulgates new regulations is a legal migraine.[114]

V. SOLUTIONS

A. RECOMMENDATIONS

[35] The problems outlined in the previous section make addressing legal concerns, whether in giving advice to a practitioner or providing e-prescribing services that will be valid in every state, incredibly difficult, but not impossible. Some approaches can help ease the problems.

Aim at Maximum Inclusion

[36] E-prescribing system providers can overcome the myriad of specific state requirements by incorporating as many as possible. For example, the requirement in Texas that the prescription be marked as electronically transmitted appears in several other states' regulations.[115] Nothing in the regulations of states that do not have this requirement, however, forbids including the information. Creating a system that makes this electronic transmission tag part of every prescription in every state will therefore ensure that such requirements are met.

Track Legislative and Regulatory Changes

[37] Many state Boards of Pharmacy provide listserv notices or post online newsletters.[116] These services give information about proposed

[114] *Compare* N.J. ADMIN. CODE 13, § 13:35-7.4A(h) (2004), *with* N.Y. PUB. HEALTH LAW § 3308(5) (McKinney Supp. 2005), *and* CONN. GEN. STAT. ANN. § 20-614(d)(3) (West 2004).
[115] 22 TEX. ADMIN. CODE § 291.34(b)(6)(B)(ix) (2004); *see, e.g.*, CONN. AGENCIES REGS. § 20-576-41 (2004).
[116] *E.g.*, Bd. of Pharmacy, Join or Leave the Board of Pharmacy's E-Mail Notification List, http://www.pharmacy.ca.gov/subscriber_page.htm (last visited Jan. 16, 2006); Tex. State Bd. of Pharmacy, Newsletter, http://www.tsbp.state.tx.us/newsletter/NewsletterStart.htm (last visited Jan. 16, 2006).

legislative and regulatory changes, Board meeting times and places, and Q&A sections that clarify how certain regulations are defined and enforced.[117] Also, regulatory officials in some states are excellent about returning phone calls and responding to emails.[118] Finally, West's KeyCite allows attorneys to select particular state statutes—and for larger states their regulations—for notification of changes.[119]

Realize Where the Responsibility Lies

[38] Many states place the responsibility for ensuring the security and validity of an electronic prescription on the physician who transmits and / or the pharmacist who will fill and dispense the medication.[120] Attorneys for health care providers should advise their clients of particular state restrictions or pending changes, while attorneys for e-prescribing system providers should strive for maximum functionality, trusting that health care professionals will follow state law. In other words, the systems themselves should accommodate the most progressive state laws, and health care professionals should know the limit of their particular states' regulations and use only those features which are appropriate.

Drive the Regulations Rather than Being Driven

[39] Although changes in the law seem like a problem, the process of change may actually provide the best solution because it allows an opportunity for action. State governments allow for comment on proposed regulatory changes. For states with restrictive regulations, contact state legislators and the Board of Pharmacy directly. Smaller states should realize that manufacturers are targeting larger states and adopt regulations that follow the trends in larger states.[121] As discussed above, the trend in California, Texas and New York is toward more favorable e-prescribing laws.

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[117] *E.g.*, Tx. State Bd. of Pharmacy, *supra* note 116.
[118] *E.g.*, Telephone Interview with William Black, Legal Counsel, Wis. Dep't of Regulation & Licensing (June 30, 2004).
[119] West, KeyCite, http://west.thomson.com/store/product.asp?product%5Fid=KeyCite (last visited Jan. 16, 2006).
[120] *E.g.*, CAL. CODE REGS. tit. 16, § 1717.4(h) (Westlaw through 2005).
[121] Terry, *supra* note 8 (explaining that the company SureScipts is targeting fifteen large states).

[40] Driving the federal process may be most important. Both the DEA and Medicare are promulgating standards, which state regulations will have to accommodate. Both provide for comment and feedback, so attorneys and state regulators interested in e-prescribing should take advantage.[122]

VI. CONCLUSION

[41] Because of improvements in efficiency and patient safety, e-prescribing should continue to expand. This expansion includes dozens of e-prescribing system providers, regulatory agencies from all fifty states, and every managed care and insurance provider. It affects hundreds of thousands of health care professionals, and it will mean billions of dollars both in costs to implement and maintain and in savings from efficiency and safety. The non-business side means reduced, or even eliminated, adverse drug reactions, which means fewer hospitalizations and deaths, which leads to better patient care. Attorneys in health care fields will be challenged to stay abreast of a rapidly changing legal environment as state and federal laws develop to accommodate this technology.

[122] Notice of Intent To Conduct Performance Verification Testing of Public Key Infrastructure Enabled Controlled Substance Orders, 67 Fed. Reg. 1,507 (Jan. 11, 2002); 42 U.S.C.A. § 1395w-104(e)(4)(B) (Supp. 2005).