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Privacy and Security Solutions for Interoperable Health Information Exchange

Report on State Prescribing Laws: Implications for e-Prescribing

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EXECUTIVE SUMMARY

Background and Purpose

This report is one of a series produced under RTI International's contract with the Agency for Healthcare Research and Quality (AHRQ). The contract, entitled Privacy and Security Solutions for Interoperable Health Information Exchange, is managed by AHRQ and the Office of the National Coordinator for Health Information Technology (ONC). In the first phase of this project, 33 states and 1 territory (collectively referred to as states or state teams) conducted an assessment of variation in business practices, policies, and laws that might be perceived as barriers to electronic health information exchange, suggested possible solutions to these barriers, and prepared plans to implement these solutions. In doing so, the states focused on a number of different scenarios, including treatment, health information exchange, payment, research, and public health.[1] As a result, the states identified a number of state laws and policies addressing the limitations on disclosure of health information between health care providers and third parties that may impede electronic health information exchange.

A related state-focused project, the State Alliance for e-Health, funded by ONC and managed by the National Governors Association, has recommended that states give high priority to electronic prescribing (e-prescribing), as they begin to adopt electronic health information exchange.[2] E-prescribing from physicians (or other practitioners) to pharmacies offers the potential to improve patient care by making the prescription process more rapid, accurate, and cost-efficient.[3]

As a general rule, state laws govern the prescribing and dispensing of prescription drugs by licensed health care professionals as well as the practice of pharmacy. Federal law sets standards for prescribing, transmitting, and dispensing controlled substances. The federal government has proposed amending its rules governing controlled substances to permit e-prescribing. However, state laws also regulate the transmission of prescriptions for

[1] Dimitropoulos, L. (2007, July). *Privacy and Security Solutions for Interoperable Health Information, Exchange Assessment of Variation and Analysis of Solutions*.

[2] State Alliance for e-Health (2008). *Accelerating Progress: Using Health Information Technology and Electronic Health Information Exchange to Improve Care*.

[3] Electronic prescriptions offer multiple advantages over written or oral prescriptions: (1) fewer medical errors due to illegible handwriting or mispronounced or misunderstood drug names provided over the phone; (2) early alerts to drug interactions or patient allergies (by linking the electronic prescriptions to other medical records); and (3) reduced processing time at the pharmacy, callbacks to practitioners, and waiting time for patients. See Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances; Proposed Rule,* 73 Fed. Reg. 36722, 36723, 36763 (June 27, 2008).

controlled substances. Providers and pharmacists must comply with these state laws so long as the state provisions do not affirmatively conflict with federal law. [4]

In addition to regulating the acceptable means by which prescriptions may be transmitted, states also have laws designed to curtail health care costs by encouraging the use of generic drugs. Virtually every state has a drug substitution law that generally permits or requires a pharmacist to dispense an equivalent lower-priced generic drug when a brand-name drug is prescribed. States also encourage prescribing generic drugs by capping Medicaid reimbursement payments for brand-name drugs where a generic equivalent is available, through the Federal Upper Limit (FUL) program and state Maximum Allowable Cost (MAC) programs. State laws allow physicians to override these generic substitution or reimbursement caps by transmitting, along with the prescription, a message that the brand name is medically necessary in a means dictated by law, (e.g., handwriting "dispense as written" or "brand necessary" or a similar phrase on the face of a prescription). Federal Medicaid regulations, which used to require that brand necessary be handwritten on the face of a prescription, have recently been amended to expressly permit this certification to be electronically transmitted.

The regulatory framework described above creates many legal complexities for implementing e-prescribing on a national basis. This report is intended to further the initial work of this project, as well as work done by the State Alliance for e-Health, by analyzing some of these relevant state prescription laws and identifying their potential impact on the adoption of e-prescribing. In light of the recent proposed and actual changes in federal law with respect to controlled substances and brand necessary requirements, this report focuses on state laws that may overlap federal law in these areas.

Findings

Prescription Transmission and Retention Requirements for Noncontrolled and Controlled Substances

Nearly every state has statutory or regulatory provisions that allow e-prescribing of noncontrolled substances (which represent approximately 90 percent of all U.S. prescriptions; see Section 1.1.1 below). Thus, lack of authority to e-prescribe generally is not an issue with respect to noncontrolled substances under state law.

Rather, state laws meant to implement e-prescribing may actually complicate its adoption. Some of the more common issues state laws present include

[4] The Controlled Substances Act explicitly contemplates a role for state regulation. See 21 U.S.C. § 903 (2009) providing: No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

- contradictory prescription requirements across different sets of statutes and regulations;
- pharmacy recordkeeping requirements mandating that electronic prescriptions and other pharmacy records be maintained in hard copy (rather than electronically);
- direct transmission requirements for e-prescribing that may interfere with employing an electronic data intermediary; and
- patient consent requirements for the electronic transmission of a prescription.

These provisions, and others like them, may impede the adoption of e-prescribing.

Few states currently expressly authorize e-prescribing of controlled substances. A handful of states expressly permit e-prescribing of controlled substances "as permitted by federal law," and, as a result, the state law remains flexible to accommodate changes to federal controlled substance regulations. Most state laws, however, do not take this approach. Rather, they expressly reiterate verbatim current federal law that requires written prescriptions for certain controlled substances, and written, oral, or fax prescriptions for less harmful controlled substances. When the federal rules permitting controlled substances to be electronically transmitted become final, these state laws will need to be amended to reflect current law.

Brand Necessary Requirements in Generic Substitution and Medicaid Reimbursement Laws

Many state generic substitution laws (non-Medicaid specific) generally accommodate e-prescribing through provisions that allow a provider to ensure that a brand-name drug is dispensed by either (1) expressly permitting providers to electronically designate brand necessary or (2) generically permitting providers to indicate this instruction. However, a similar number of states have legal provisions that require the provider to either handwrite brand necessary or make another handwritten notation on the prescription to avoid generic substitution. Laws in this latter category may make it difficult for a provider to readily exercise choice in prescribing when using an electronic system. Such a restriction may deter providers for whom such choice is an important consideration from e-prescribing.

Few state Medicaid laws expressly permit providers to certify brand necessary electronically. This finding held true both for Medicaid laws that require generic substitution and for Medicaid laws that cap reimbursement for brand-name drugs unless the provider certifies that the brand name is medically necessary. To the contrary, most state laws in both of these categories require that brand necessary be handwritten on the prescription. For the most part, state Medicaid laws continue to reflect the pre-2007 federal Medicaid requirement for a handwritten certification of brand necessary to override reimbursement limits.

Recommendations

On the basis of our findings, we recommend that states take the following actions:

- Review prescribing statutes and regulations to identify and remove inconsistencies.
- Eliminate requirements for hard copies of electronic prescriptions and other duplicative paper records.
- Revise prescription provisions to clarify that electronic data intermediaries may be employed.
- Decide whether patient consent is required for e-prescribing.
- Consider promoting e-prescribing through medical licensure requirements.
- Revise state prescription provisions to permit e-prescribing for controlled substances to the extent permitted by federal law.
- Revise brand necessary provisions to permit electronic certification that a brand name is medically necessary.

We also recommend that the Centers for Medicare and Medicaid Services (CMS) issue a letter to state Medicaid Directors informing states of the 2007 amendment, which expressly permits using electronic means to specify that a specific brand of medication is medically necessary, and encouraging them to follow suit. Additionally, the Centers for Medicare & Medicaid Services could volunteer to address the requirements for specifying brand necessary at the next meeting of the National Association of State Medicaid Directors.

1. BACKGROUND AND PURPOSE

In the first phase of this project, RTI International provided oversight to 33 states and 1 territory (collectively referred to as states or state teams) that conducted an assessment of variation in business practices, policies, and laws that might be perceived as barriers to electronic health information exchange, suggested possible solutions to these barriers, and prepared plans to implement these solutions. The states focused on a number of different scenarios, including treatment, regional health information exchanges, payment, research, and public health. The resulting Assessment of Variation and Analysis of Solutions report, an earlier product of this project, presented an overview of the major areas states identified as presenting challenges to the privacy and security of electronic health information exchange.

E-prescribing from physicians and other practitioners (providers) to pharmacies offers the potential to improve patient care by making the prescription process more rapid, accurate, and cost-efficient.[5] These advantages, coupled with an existing infrastructure for e-prescribing, have prompted the State Alliance for e-Health, a project funded by ONC and managed by the National Governors Association, to recommend that states give highest priority to e-prescribing as a potential accelerator for the adoption of electronic health information exchange [State Alliance for e-Health (2008)]. Ongoing work in this area, however, has identified potential legal barriers to e-prescribing.

1.1 Federal Law Overview

1.1.1 Controlled Substances Act

Background

For purposes of this report, prescription drugs may be divided into two categories: controlled substances and noncontrolled substances. Controlled substances are drugs that can cause psychological and physical dependence; these include opiates, stimulants, depressants, hallucinogens, and anabolic steroids, and drugs that are immediate precursors of these classes of substances [73 Fed. Reg. 36722 (June 27, 2008)].

Controlled substances represent only a small fraction (approximately 10 percent) of U.S. drug prescriptions; the remaining 90 percent of U.S. drug prescriptions are for noncontrolled substances [74 Fed. Reg. 15596 (April 6, 2009)]. Notwithstanding the relatively small percentage of prescriptions for controlled substances, these drugs pose a disproportionate public risk because of their potential for abuse and because, historically,

[5] Electronic prescriptions offer multiple advantages over written or oral prescriptions: (1) fewer medical errors due to illegible handwriting or mispronounced or misunderstood drug names provided over the phone; (2) early alerts to drug interactions or patient allergies (by linking the electronic prescriptions to other medical records); and (3) reduced processing time at the pharmacy, callbacks to practitioners, and waiting time for patients. See Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances; Proposed Rule,* 73 Fed. Reg. 36722, 36723, 36763 (June 27, 2008).

prescriptions for these substances have been stolen, altered, falsified, sold, or otherwise diverted for illegal purposes (73 Fed. Reg. 36722, 36725-26). For these reasons, controlled drugs are heavily regulated under federal law through the Comprehensive Drug Abuse Prevention and Control Act of 1970, often called the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act. The federal Drug Enforcement Administration (DEA) administers these laws and publishes the implementing regulations in Title 21 of the Code of Federal Regulations (C.F.R.), pts. 1300 to 1399 (73 Fed. Reg. 37622). States may also regulate controlled substances so long as state law does not affirmatively conflict with the federal standards.[6] Nearly every state has incorporated the federal standards into state law through adoption of the Uniform Controlled Substances Act, which derives from the CSA.[7]

The CSA establishes five ranked schedules (listed in 21 C.F.R. pt. 1308) into which controlled drugs are assigned according to their potential for medical use and illegal abuse. Schedule I drugs—including heroin and PCP—have a high potential for abuse, no currently accepted medical use, and are not available to the public with a prescription. Schedule II drugs include opiates such as hydrocodone and morphine, have accepted medical uses but also have a high potential for abuse, and may lead to severe psychological and physical dependence. Drugs on schedules III through V have successively lower potentials for abuse and dependence, with Schedule V including such drugs as cough syrups with codeine.[8]

Current Law

The CSA and DEA regulations were adopted before the advent of e-prescribing, at a time when most drug transactions, particularly prescriptions, were done on paper (73 Fed. Reg. 36722, 36723). Accordingly, current DEA regulations do not expressly address e-prescribing or electronic prescriptions.

The CSA provides that a controlled substance in Schedule II may only be dispensed by a pharmacy pursuant to a "written prescription," except in emergency situations [21 U.S.C. 829(a); 21 C.F.R. § 1306.11(a)]. For Schedule III-IV controlled substances, a pharmacy may dispense pursuant to a written, signed prescription, a facsimile (fax) of a written, signed prescription, or an oral prescription that has been reduced to writing by the

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[6] The Controlled Substances Act explicitly contemplates a role for state regulation. See 21 U.S.C. § 903 (2009) providing: No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

[7] "Drug Policy in America—A Continuing Debate: Report of the Task Force on the Use of Criminal Sanctions to the King County Bar Association of Trustees," *30 Fordham Urban Law Journal 499*, 506 (Jan. 2003). See Uniform Law Commissioners, *Uniform Controlled Substances Act (1990)*, available at http://www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/ucsa94.pdf.

[8] U.S. General Accounting Office, Prescription Drugs, State Monitoring Programs May Help to Reduce Illegal Diversion. Testimony Before the Subcommittee on Health, Committee on Energy and Commerce, 108th Cong. 4 (2004).

pharmacist [21 U.S.C. 829(b), 21 C.F.R. § 1306.21(a)]. DEA regulations specify that written prescriptions must be signed manually "in the same way the practitioner would sign a check or other legal document" [21 C.F.R. 1306.05(a)].

For recordkeeping, DEA requires the pharmacy to maintain prescription records for Schedule I and II drugs in a "separate prescription file." Prescription records for Schedule III-V substances may be maintained either in a separate prescription file for Schedule III-V substances or in "such form that they are readily retrievable from the other prescription records of the pharmacy" [21 C.F.R. § 1304.04(h)]. If a pharmacy employs an electronic recordkeeping system for prescriptions, it must permit identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled to meet this requirement [21 C.F.R. § 1304.04(h)].

Proposed Regulations

In 2008, the DEA published a Notice of Proposed Rulemaking to amend its regulations to permit e-prescribing of controlled substances in Schedules II-V [73 Fed. Reg. 36722 (June 27, 2008)]. For recordkeeping, the proposed regulations require electronic prescription records for controlled substances to be maintained electronically, although they must be immediately retrievable (73 Fed. Reg. 36722, 36749).

As shown in Section 3.3, some states are better prepared for DEA's updated regulations to permit e-prescribing (with statutes or regulations in place that allow e-prescribing of controlled substances "to the extent permitted under federal law"). Most state laws, however, provide no such conditional authorization for e-prescribing controlled substances. Accordingly, these laws, unless modified, will lack the flexibility to offer practitioners the option of e-prescribing controlled substances when this option becomes available under federal regulation.

1.1.2 Electronic Signatures in Global and National Commerce Act

In 2000, Congress enacted the Electronic Signatures in Global and National Commerce Act (E-SIGN) [Pub. L. No. 106-229, 114 Stat. 464 (2000) (codified at 15 U.S.C. § 7001 *et seq*.)]. The federal law, which established the validity of electronic records and signatures, governs in the absence of a state law or where state law is inconsistent with the federal standards. Most states have adopted the Uniform Electronic Transactions Act (UETA) that essentially requires commercial electronic records and electronic signatures to be given the same legal status as their paper counterparts.[9]

[9] National Conference of State Legislatures, Uniform Electronic Transactions Act. http://www.ncsl.org/programs/lis/CIP/ueta-statutes.htm.

1.1.3 Federal Medicaid Regulations

All states have elected to include in their Medicaid programs prescription drug coverage, an optional service which is eligible for federal matching funds. In an effort to contain health care costs, the federal government, through regulations governing the Federal Upper Limit (FUL) program, caps the amount Medicaid agencies may pay for name brand prescriptions for which therapeutically equivalent generic medications are available.[10] Providers may overcome these reimbursement limitations by certifying that a brand-name drug is medically necessary for a particular patient. Prior to 2007, Medicaid regulations governing the FUL program required that the provider make this certification "in his or her own handwriting" [42 C.F.R. § 447.331 (2007)]. These regulations were amended in July 2007 to also allow the provider to certify that a brand is medically necessary by using "an electronic means approved by the Secretary [42 C.F.R. § 447.512 (2008)].[11] The use of check-off boxes as a means of certifying brand necessary is not acceptable. Otherwise, federal regulations allow state Medicaid agencies to decide what certification form and procedure are used.

1.2 Project Purpose

The purpose of this project was to provide an overview of state statutes and regulations that may impact e-prescribing and a "lay of the land" perspective. For each state, we reviewed the prescription provisions within the various legal codes to determine whether and under what circumstances state laws permitted e-prescribing. We also addressed the question whether states' legal codes facilitated or hindered e-prescribing. In light of recent proposed and final amendments to federal DEA and Medicaid regulations designed to facilitate e-prescribing, we paid particular attention to state laws that potentially overlap with these regulations (i.e., that govern transmitting prescriptions for controlled substances or that specify the means by which a provider may specify that a brand name prescription is necessary to overcome Medicaid reimbursement caps).

[10] Testimony of Dennis Smith, Director, Center for Medicaid and State Operations Centers for Medicare & Medicaid Services on Medicaid Prescription Drug Reimbursement, before the House Energy and Commerce Subcommittee on Oversight and Investigations, December 7, 2004.

[11] 42 C.F.R. § 447.331 was redesignated as § 447.512 at the same time.

2. METHODOLOGY

We used online legal research tools, including Lexis/Nexis, Westlaw, and relevant websites operated by state governments to conduct our research. We reviewed the state statutes and regulations (as well as any relevant interpretive case law identified in case notes in Lexis or Westlaw) pertaining to e-prescribing for all the states and territories. We also reviewed materials under "advance legislative service," which contains statutes not yet codified, and Attorney General opinions, which reflect the state's attorney general's interpretation of the statutes. We did not examine state manuals, such as state Medicaid manuals or pharmacy manuals, for prescription requirements.

2.1 Prescription Transmission and Retention Requirements for Noncontrolled and Controlled Substances

For general prescribing requirements, we used the following search terms:

- *electron! w/25 prescri!*[12]
- *e-prescri!*
- *controlled w/2 substance! or drug!*
- *regulated w/2 drug!*
- *prescri!*
- *dispens!*
- *drug!*

Using these terms, we identified and reviewed prescription requirements within the following areas of the states' statutory and regulatory codes:

- professions and occupations
  - pharmacists/pharmacies
  - medical doctors
- food and drugs
  - prescription drugs
- Medicaid
  - controlled substances

[12] The symbol *!* is used in a search as a wildcard to find variations on a root term. As used here, the term *electron!* will locate statutes and regulations that contain the word *electronic* as well as variations such as *electronically*. Similarly, the term *prescri!* will capture provisions containing the words *prescribe*, *prescription*, and *prescribing*. *W/25* or *w/2* are connector search terms that require the primary search terms be present in a document within 25 or 2 words, respectively, of each other. In this case, the search will produce instances where the terms *electronic* or *electronically* are within 25 words of the term *prescribe*, *prescription*, or *prescribing*.

  - crime
  - public health
  - consumer protection

We varied our search terms depending upon the relative breadth or narrowness of the categories searched (i.e., for narrow categories such as *controlled substances*, we used broader search terms, such as *prescri!*).

In our research, we studied the prescription requirements for a physician's prescription to be filled at an independent pharmacy. We did not address the transfer of prescriptions between pharmacies or prescriptions in hospital or other on-site pharmacy settings. Within the above-specified statutory and regulatory provisions, we identified and collected laws and regulations that set the standards for transmitting or otherwise submitting a prescription for medication to an independent pharmacy/pharmacist. For every provision identified by a Lexis/Nexis or Westlaw search we reviewed the associated statutory or regulatory table of contents to identify other related, relevant provisions. Finally, we analyzed the laws for requirements that might facilitate or impede electronic prescribing (e.g., the requirement that an electronic prescription be printed in hard copy).

2.2 Brand Necessary Requirements in Generic Substitution and Medicaid Reimbursement Laws

For brand necessary provisions, we used the search term: *prescri! & dispens! & brand*.[13] After experimenting with multiple search terms, we found this term to be the most comprehensive and productive. After reviewing the identified provision for relevancy, we reviewed the table of contents associated with the provision to locate other related, relevant laws. Moreover, we reviewed the table of contents in at least the areas listed below for other relevant laws and regulations:

- professions and occupations
  - pharmacists/pharmacies
  - medical doctors
- food and drugs
  - prescription drugs
- Medicaid

We identified and collected laws and regulations that dictate the means by which a provider may override generic substitution and Medicaid reimbursement caps to prescribe a brand-name drug. We analyzed these laws for requirements that might facilitate or impede

[13] The search term *&* identifies statutes and regulations in which all the specified terms are present regardless of their proximity to one another.

electronic prescribing (e.g., the requirement that the provider handwrite brand necessary on the prescription).

3. FINDINGS

3.1 Prescription Transmission and Retention Requirements for Noncontrolled and Controlled Substances

Nearly every state authorizes e-prescribing of noncontrolled substances within one or more provisions of its statutory or regulatory code. The mere presence of an e-prescribing law, however, does not guarantee a smooth path to e-prescribing implementation. Many state codes, while recognizing electronic, computer-based methods as valid means for transmitting prescriptions, also contain:

1. contradictory prescription requirements across different sets of statutes and regulations;
2. pharmacy record-keeping requirements mandating that electronic prescriptions and other pharmacy records be maintained in hard copy;
3. direct transmission requirements for e-prescribing that prohibit any intermediary from accessing prescription information, which may interfere with employing an electronic data intermediary; and
4. patient consent requirements for the electronic transmission of a prescription.

All of these state provisions may impede the adoption of e-prescribing.

For controlled substances, few states expressly authorize e-prescribing. When states do authorize such e-prescribing, the authorization is usually contingent upon what federal law permits for controlled substances.

Most states require prescribers to prescribe Schedule II substances in writing (with limited exceptions) and Schedule III-V substances only in writing, orally, or via facsimile; these requirements essentially reiterate current federal regulatory requirements. In these states, prescribers may still be unable to e-prescribe controlled substances even when the federal rules permitting this activity become final. Absent modification, state law will lock prescribers into outmoded paper-based controlled substance prescription requirements.

Table A-1 provides a brief summary of some state statutory and regulatory prescription transmission and retention requirements for noncontrolled and controlled substances that may impact e-prescribing.

3.2 Noncontrolled Substances

3.2.1 Express Authority to Electronically Transmit Prescriptions

Almost all states have some statutory or regulatory provisions that expressly authorize e-prescribing for noncontrolled substances.[14] However, a few states and territories with prescription provisions appear to simply not address electronic prescriptions [see, e.g., S.D.

[14] See National Association of Boards of Pharmacy, 2009 Survey of Pharmacy Law.

Admin. R. 20:51:05:20 (2008) (pharmacist may only dispense legend drug pursuant to a written prescription, fax of a written prescription37, or oral prescription reduced to writing by the pharmacist); 25 Guam Admin. R. & Regs. § 13108(a)(1)(i) (1997) (describing the prescriptions a pharmacist receives as "oral or written"); V.I. Code Ann. tit. 27, § 141 (2008) (prescription means a "written or oral order for drugs").]. In these jurisdictions, the failure to expressly authorize e-prescribing may create confusion as to whether such prescriptions are permitted.

3.2.2 Contradictory Statutes and Regulations

Individual states often do not address e-prescribing consistently across statutes and regulations. Prescribing requirements may be embedded within multiple titles of a state's legal code such as Professions and Occupations, Food and Drugs, Medicaid, and Controlled Substances. In many states, the various prescription provisions contradict each other, potentially creating uncertainty among practitioners or pharmacies regarding e-prescribing.

State Medicaid and Other State Law[15]

In a number of states, statutes or regulations permitting e-prescribing of noncontrolled substances are contradicted by state Medicaid regulations that require or appear to require a conventional written prescription for Medicaid pharmacy services. This burdens prescribers with different prescription processes for different categories of patients. For example, a prescriber might transmit an e-prescription for a non-Medicaid patient and then be obliged to provide a Medicaid patient with a written prescription for the same drug to be filled at the same pharmacy.

Rhode Island regulations illustrate conflicting prescription requirements. The pharmacy regulations permit a prescription to be transmitted by "electronic means" from the prescriber to the dispensing pharmacy. In contrast, the Rhode Island Medicaid regulations require that physicians prescribe drugs for Medicaid recipients on a specifically identified three-part Medicaid prescription form.[16] Similarly, Illinois pharmacy law permits e-prescribing while the state Medicaid regulations require a prescription form signed "in ink" by the physician.[17]

In other states, the Medicaid regulations appear to implicitly require a written, nonelectronic prescription even though e-prescribing is expressly permitted in that state's pharmacy code or regulations. For example, New Jersey Medicaid regulations require a "written" prescription with no indication that an electronic prescription may be treated as a written

[15] This project did not review, and this analysis does not address, rules contained in state Medicaid manuals to the extent they are not also recorded in statute or regulation.
[16] Compare 14-130-001 R.I. Code R. § 8.43(b) (2009) (pharmacy regulation) with 15-040-004 R.I. Code R. § IX (2009) (Medicaid regulation).
[17] Compare 225 Ill. Comp. Stat. Ann. 85/3(e), (z) (2009) (Pharmacy Practice Act) with Ill. Admin. Code tit. 89, §§ 140.414(a)(2), 140.443(a) (2009) (Medicaid regulations).

prescription [see N.J. Admin. Code § 8:83C-1.5(b) (2009)]. Still other states with pharmacy regulations that permit e-prescribing have Medicaid regulations that speak solely of written, faxed, or oral prescriptions [see 55 PA. Code §§ 1121.52(a) (2009); 13-170-008 VT. Code R. § M800 (2009); 48-130-010 Wyo. Code R. §§ 4(lll), 6(b)(ii) (2009)]. In comparison, New York pharmacy and Medicaid regulations both explicitly authorize electronic prescriptions [N.Y. Comp. Codes R. & Regs. tit. 8, § 63.6(a)(7) (2009) (pharmacy); N.Y. Comp. Codes R. & Regs. tit. 18, § 505.3(b)(6) (2009) (Medicaid)].

Miscellaneous Other Conflicting Laws and Regulations

Medicaid regulations are only one source of problematic provisions relative to e-prescribing. There are many other instances of conflicting state statutes and regulations outside the Medicaid program. For example, in Hawaii, the food and drugs law permits electronic prescriptions, whereas the pharmacy regulations do not. Under Hawaii's pharmacy regulations, a prescription is limited to a written order with an original signature, a facsimile, or a telephone order that the pharmacist reduces to writing.[18] Conversely, in Illinois, the pharmacy statutes permit e-prescribing while the food and drugs statutes define prescription to include only written, facsimile, or verbal orders.[19]

Kentucky presents a noteworthy case. Kentucky pharmacy provisions do not address e-prescribing whereas state public health/controlled substances law permits electronic prescriptions for Schedule III-V substances. This leads to the anomalous situation where there is express authority for an electronic prescription for a controlled substance, but not for an electronic prescription for a noncontrolled substance [see KY Rev. Stat. Ann. § 218A.180(2) (2009) and discussion on controlled substances in Section 3.3].

3.2.3 Patient's Right to Choose Means for Transmitting Prescriptions

A few states require that a patient affirmatively approve the transmission of an electronic prescription (i.e., opt in to e-prescribing) [see Nev. Admin. Code § 639.7105(2)(b)(1) (2008) (practitioner may not transmit a prescription electronically unless patient "consents to the transmission of the prescription electronically"); Wis. Stat. Ann. § 450.11(1m) (2008)]. In several other states, patients are given the right to choose whether their prescription is transmitted to the pharmacy via hard copy or electronically (i.e., opt out of e-prescribing) [see Mo. Code Regs. Ann. tit. 20 § 2220-2.085(2)(D) (2008) (patient has option of having electronically produced prescription sent electronically or provided as hard copy generated from the prescriber's electronic prescribing system); N.H. Rev. Stat. Ann. § 318.47-c(I)(b) (2009) (patient entitled to receive a paper prescription); 14-130-001 R.I. Code R. § 8.43(e) (2009)]. Generally, these laws do not appear to require the practitioner

[18] Compare Haw. Rev. Stat. Ann. § 328-16(c) (2008) (Hawaii Food, Drug, and Cosmetic Act) with Haw. Code R. §§ 16-95-2, 16-95-82 (2009) (pharmacy regulations).

[19] Compare 225 Ill. Comp. Stat. Ann. 85/3(e), (z) (2009) (Pharmacy Practice Act) with 410 Ill. Comp. Stat. Ann. 620/2.36 (2009) (Illinois Food, Drug, and Cosmetic Act).

to obtain the patient's written permission to e-prescribe, which would impose an additional record-keeping burden. However, allowing patient choice as to the means of transmitting prescriptions may, as a practical matter, require pharmacists to continue to process and maintain more paper prescriptions than necessary and slow the overall implementation of e-prescribing within a state.

3.2.4 Content Requirements for Electronic Prescriptions

Typically, state provisions authorizing e-prescribing require that this type of prescription include information required for paper and oral prescriptions. These prescription requirements vary from state to state [see, e.g., 50-018-001 Miss. Code R. Art. XII (2008) (electronically transmitted prescriptions must include age of the patient); Nev. Admin. Code § 639.7105(3) (2008) (at the patient's request, the prescribing physician must include "the symptom or purpose for which the drug is prescribed"); 22 Tex. Admin. Code § 291.34(b)(6)(B) (2008) (electronically transmitted prescriptions must include indications for use, unless the practitioner determines that providing this information is not in the best interest of the patient)].

States have also adopted language from the Model State Pharmacy Act, which has specific requirements for prescriptions electronically transmitted.[20] Such specific requirements include: the time and date of transmission; the transmitter's telephone number; the pharmacy intended to receive the transmission; and the identity of the transmitting agent [see, e.g., 070-00-007 Ark. Code R. § 008(c) (2009); Cal. Code Regs. tit. 16, § 1717.4(c) (2009); 24-2500 Del. Code Regs. §§ 5.10.1.2, 5.10.2 (2009); Kan. Admin. Regs. § 68-2-22(b) (2008)]. Some states have specific requirements for electronic prescriptions in addition to those specified in the Model Act. Wisconsin, for example, requires electronic prescriptions to include the designation "electronically transmitted prescription," or similar language [Wis. Admin. Code [Phar] §7.08(2), (3) (2008)].

3.2.5 Paper-Based Record-Keeping Requirements

Many states that permit electronic prescriptions fail to reap the full benefits of e-prescribing. Instead of permitting pharmacies to maintain electronic prescriptions in electronic form, state law often requires a printout or other hard copy of an electronic prescription for the pharmacy's files.

In Kentucky, for instance, an electronic prescription must be reduced to writing and signed by the pharmacist since "[a] prescription contained in a computer or other electronic format shall not be considered writing" [see KY Rev. Stat. Ann. § 218A.180(6) (2009)]. Similarly, in Connecticut, a pharmacist that receives an electronically transmitted prescription must

[20] Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (2008), available at: http://www.nabp.net/ftpfiles/NABP01/ModelActFINAL.doc.

"record the prescription on a prescription form or computerized printed record" [Conn. Gen. Stat. § 20-614(b) (2008)].

Kansas, too, requires that a prescription transmitted electronically "be maintained in hard copy for the time required" by law [Kan. Admin. Regs. § 68-2-22(g) (2008)]. Likewise, Arkansas mandates that a prescription drug order transmitted electronically be "immediately reduced to a form, by the pharmacist, that may be maintained for the time required by law or rules" [070-00-007 Ark. Code R. § 07-00-0008(c)(1) (2009)]. Alaska,[21] Montana,[22] Nevada, [23] New York, [24] and Ohio[25] are other examples of states that require hard copies of electronic prescriptions.

It is unclear whether these paper-based record keeping requirements have been impacted by the terms of the federal E-sign Act and states' UETA that essentially require commercial electronic records and electronic signatures to be given the same legal status as their paper counterparts.[26]

In contrast, California's pharmacy law permits a pharmacy to retain an electronic prescription in electronic form provided that it has the ability to produce a hard copy of the prescription if necessary [Cal. Bus. & Prof. Code § 4070(b) (2008)]. Rhode Island, too, permits a pharmacy receiving an electronic prescription to retain the prescription electronically if it has the "capacity to retrieve a hard copy of the prescription from the pharmacy's computer memory" [14-130-001 R.I. Code R. § 8.43(d) (2009)].

Apart from specific hard-copy documentation requirements for electronic prescriptions, more general requirements regarding documentation of computerized pharmacy records may also limit a pharmacy's ability to reduce paper records through electronic prescriptions. For instance, in Alabama, a pharmacy with a computerized record-keeping system must produce a weekly printout covering all new and refill prescription activity and keep it in a separate binder for 2 years [Ala. Admin. Code r. 680-X-2-.15(1)(h) (2008)]. In Delaware, a pharmacist who dispenses a prescription must either hand-sign the prescription or hand-sign a daily prescription printout or log book attesting to the correctness of the prescription information [24-2500 Del. Code Regs. § 5.2.3 (2009)]. Similarly, in North Carolina, pharmacists must document the correctness of prescription entries in their automated data

[21] Alaska Admin. Code tit. 12, § 52.450 (2009) (pharmacy must retain for 2 years a "plain paper version" of a prescription drug order received by electronic transmittal).
[22] Mont. Admin. R. 24.174.523(4)(e) (2009) (pharmacy must retain for 2 years a "printed, non-fading copy of an electronically transcribed [sic] prescription").
[23] Nev. Admin. Code § 639.7105(4)(a) (2008) (pharmacist must print copy of an electronic prescription on paper of sufficient quality to last for 2 years).
[24] N.Y. Comp. Codes R. & Regs. tit. 8, § 63.6(a)(7)(ii)(c) (2009) (pharmacist must produce and retain for 5 years a "permanent hard copy of an electronically transmitted prescription").
[25] Ohio Admin. Code 4729-5-21(F)(2) (2009) (hardcopy of an electronic prescription "must be printed to document the dispensing").
[26] Abood, R. (2005). *Pharmacy Practice and the Law*, pg.104. Boston: Jones and Bartlett.

processing systems by manually signing a daily printout, log book, or separate file [21 N.C. Admin. Code 46.2304(3) (2008)].

In contrast, New Jersey allows pharmacists who fill a prescription to place their initials or other personal identifier directly into the pharmacy's electronic data processing system instead of requiring them to produce and sign a paper record [N.J. Admin. Code § 13:39-7.6(a), (c) (2009)].

Apparently, the above requirements were originally designed for automated data processing systems into which pharmacists, or their assistants, keyed information related to paper and oral prescriptions (see 73 Fed. Reg. 36727). Many of these pharmacy systems have been reprogrammed to be able to capture the data from electronic prescriptions directly (73 Fed. Reg. 36727). However, these automated data processing laws may be worded broadly enough to apply to these new systems, resulting in pharmacists being required to produce paper logs of prescriptions that have been created, transmitted, and recorded electronically.

3.2.6 Direct Transmission Requirements

Many states allow practitioners to use intermediaries—e-prescribing networks—to route prescriptions to pharmacies [see, e.g. Conn. Gen. Stat. § 20-614(d) (2008) (electronic data intermediary may transfer electronically transmitted data between prescribing practitioner and pharmacy)].[27] Intermediaries may serve to reformat a practitioner's prescription so that the receiving pharmacy can read and process it, while assuring the transmission's authenticity, security, and confidentiality [see 73 Fed. Reg. 36722, 36728 (June 27, 2008)].

At least one state, Indiana, requires that practitioners use an intermediary for all electronic prescriptions [Ind. Code Ann. § 25-26-13-25.5 (2009) (prescription may be transmitted electronically from a practitioner to a pharmacy only through the use of an approved electronic data intermediary)]. Although the use of an intermediary is fairly standard in the current environment, in the future other means of e-prescribing may make such a requirement obsolete. Thus, state laws that require the use of an intermediary lack the necessary flexibility to accommodate a quickly evolving field.

In other states, the wording of the e-prescribing provisions may raise a question whether the use of intermediaries is permitted. Arkansas, as well as other states, requires that electronic prescriptions be sent directly to the pharmacy of the patient's choice "with no intervening person having access to the prescription drug order" [070-00-007 Ark. Code R. § 0008(c)(2)(A) (2009)].[28] Intermediaries, however, generally must have access to the prescription to reformat it for the receiving pharmacy [see 73 Fed. Reg. 36722, 36728 (June 27, 2008)].

[27] Accord G.A. Comp. R. & Regs. 480-27-.04(5)(a) (2009); Neb. Rev. Stat. Ann. § 38-2870(4) (2009); N.D. Admin. Code 61-04-05-02 (2008); W.Va. Code Ann. § 30-5-12c(b) (2008).

[28] Accord 24-2500 Del. Code Regs. § 5.10.1.1 (2009); Okla. Admin. Code § 535:15-3-15.1(a)(1) (2007); Wash. Rev. Code Ann. § 69.41.055(1) (2009).

Some provisions permit a practitioner's designated "agent" (e.g., a nurse in the practitioner's office) to transmit the prescription in lieu of the practitioner. However, these provisions do not appear to encompass transmission from a practitioner to an intermediary to a pharmacy [see, e.g., 18 Va. Admin. Code § 110-20-285 (2008) (incorporating Va. Code Ann. § 54.1-3408.01(C)) ("authorized agent" permitted to transmit an electronic prescription is an "employee of the prescriber who is under his immediate and personal supervision" or an individual licensed to administer and dispense drugs who is directed by the prescriber)].[29]

In contrast, Georgia's electronic prescription provision is worded to provide the option of direct electronic transmission between a practitioner and a pharmacy or with the help of an intermediary: "Electronically transmitted prescription drug orders shall be transmitted directly by the prescribing practitioner or indirectly utilizing intervening electronic formatters as permitted under Georgia law… to the pharmacy of the patient's choice with no other intervening person or intermediary having access to or retaining information contained in the prescription drug order" [G.A. Comp. R. & Regs. 480-27-.04(5)(a) (2009)]. Similarly, prescription provisions in New Mexico and Vermont indicate that the prohibition against an "intervening person" accessing or altering electronic prescription content does not apply to the format modification done by approved prescribing networks [N.M. Code R § 16.19.6.23(F)(1)(e) (2009); accord 04-030-230 VT. Code R. § 19.3.1.5(A) (2009)].

3.3 Controlled Substances

E-prescribing for controlled substances faces the obstacles discussed above for noncontrolled substances and presents additional challenges because these substances are regulated at both the federal and state level. In light of the proposed DEA amendments to permit e-prescribing of controlled substances, this section focuses on some areas where state law overlaps with the proposed amendments.

3.3.1 Express Authority to Electronically Transmit Prescriptions

In an attempt to establish consistent controlled substance laws among states and between states and the federal government, nearly every state has adopted the Uniform Controlled Substances Act, which is based on the federal CSA [Drug Policy in America (2003)]. It is, therefore, not surprising that many state laws mirror the current federal requirements for transmitting prescriptions for controlled substances: they require (1) a written prescription for Schedule II drugs (subject to certain limited exceptions) and (2) written, faxed, and oral prescriptions for Schedule III-V controlled substances [see, e.g., 070-00-007 Ark. Code R. § 07-04-0001(a) (2009); 070-00-007 Ark. Code R. § 07-00-0001(c)(1) (2009); Del. Code

[29] Another state requirement that may raise a question regarding the use of an intermediary is that a prescription be transmitted to a pharmacist "exactly as transmitted by the prescriber." See Kan. Admin. Regs. § 68-2-22(b)(1) (2008). This language may not allow format changes made by an intermediary.

Ann. tit. 16, § 4739 (2009) 856 Ind. Admin. Code 2-6-7(a) (2008); 856 Ind. Admin. Code 2-6-12(a) (2008); 856 Ind. Admin. Code 1-31-2(4) and (8) (2008)]. Because they essentially reiterate current federal standards, these state provisions do not provide, as the proposed DEA regulations do, express authorization to e-prescribe controlled substances. Absent state action, these restrictive state laws will remain in place after the DEA finalizes its regulations to permit e-prescribing. Thus, the state laws will retain the barriers to e-prescribing that the federal regulation will remove once finalized.

Even some state laws that permit e-prescribing of controlled substances are nonetheless more restrictive than the proposed DEA regulations. Some states permit e-prescribing of Schedules III-V substances, but not of Schedule II substances [see, e.g., Nev. Admin. Code § 639.7105(1) (2008); N.D. Admin. Code 61-04-05-03(1), (2) (2008) 49 PA. Code § 27.201(b) (2009); 22 Tex. Admin. Code § 291.34 (b)(4)(C) (2008)]. In contrast, the proposed federal regulations allow e-prescribing of Schedule II substances.

Some state laws treat electronic prescriptions like oral prescriptions. In these states, prescriptions for Schedule III-V drugs may be electronically transmitted provided that they are reduced to hard copy by the pharmacist filling the prescription [see Cal. Health & Safety Code § 11164 (2008); Mo. Code Regs. Ann. tit. 19, § 30-1.062(2) (2008)]. In addition, some states authorize electronic prescriptions for Schedule II drugs in emergency situations, provided that specified conditions are met, such as the delivery of a written drug order within a mandated period of time [see Kan. Admin. Regs. § 68-20-10a(e)(5) (2008); 247 Mass. Code Regs. 5.03 (2008)]. Although these provisions recognize the utility of e-prescribing, the requirement that an electronic prescription be reduced to hard copy is an impediment to e-prescribing that is not required by the proposed DEA regulations.

Several states have structured their laws to be more flexible and simply include a reference to applicable federal law related to e-prescribing of controlled substances (see *Proposed Regulations* in Section 1.1.1). These states permit e-prescribing of controlled substances to the extent such prescribing is authorized by (or consistent with) federal law [see e.g., 18 Va. Admin. Code § 110-20-285(A) (2008) (Schedule II-V controlled substance prescriptions may be transmitted electronically if they comply with state and federal law)].[30]

However, other states that have attempted to anticipate changes to federal law by allowing e-prescribing for controlled substances, have not necessarily done so universally throughout their laws. Iowa, for example, has provisions in its public health/controlled substances code that permit e-prescribing for a controlled prescription if permitted by federal law, while the pharmacy regulations expressly exclude “orders for controlled substances” from those prescription drug orders that may be sent by electronic transmission [compare Iowa Code

[30] See also 105 Mass. Code Regs. 721.030(A) (2008) (controlled substance prescription may be transmitted electronically if it is validated and authenticated in accordance with state law, as well as state and federal regulations).

Ann. § 124.308(5) (Public Health/Controlled Substances law) (2008) with Iowa Admin. Code r. 657-21.8 (2008) (pharmacy regulations)]. In North Dakota, the pharmacy regulations permit Schedule III-V controlled substance prescriptions to be received via computer, while the state's food and drugs law requires a written prescription or an oral prescription reduced to writing on a new prescription blank.[31] Similarly, Kansas pharmacy regulations permit the electronic transmission of a prescription for a Schedule III-V controlled substance, yet the state's Public Health/Controlled Substance law requires a "written or oral prescription," and does not expressly address electronic prescriptions.[32] Other examples of states with conflicting controlled substance prescription provisions are Georgia,[33] New Jersey,[34] New Mexico,[35] Pennsylvania,[36] and Vermont.[37] Conflicting laws within a state may easily generate provider confusion and concerns about potential liability. Providers may be reluctant to engage in e-prescribing for controlled substances when such behavior, while permitted by one statutory or regulatory provision, appears to violate another.

3.3.2 Paper-Based Record-Keeping Requirements

Even if state laws were modified to permit e-prescribing for controlled substances, paper-based record-keeping requirements in some states may still impede e-prescribing [see Ala. Admin. Code r. 680-X-2-.15(1)(c)(1), (h) (2008) (pharmacies that use a computerized record-keeping system to note refills of prescriptions for Schedule III-V substances must document the correctness of the refill information by a signed and verified daily printout or a daily statement in a bound log book or separate file); Haw. Code R. § 23-200-18(b)(3)

[31] Compare N.D. Admin. Code 61-04-05-03(1) (2008) (pharmacy regulations) with N.D. Cent. Code § 19-03.1-22(3) (2009) (food and drugs law).

[32] Compare Kan. Admin. Regs. § 68-20-10a(d) (2008) (pharmacy regulations) with Kans. Stat. Ann. § 65-4123(c) (2007) (Public Health/Controlled Substances law).

[33] Georgia's pharmacy regulations permit the electronic transmission of a prescription for a Schedule III-V controlled substance whereas Georgia's Crimes and Offenses/Controlled Substances law provides that a Schedule III-V controlled substance may not be dispensed without a written or oral prescription (presumably reduced to writing by the pharmacist). Compare Ga. Comp. R. & Regs. 480-22-.07(1)(d) (2009) with Ga. Code Ann. § 16-13-41(d)(1) (2008).

[34] New Jersey pharmacy regulations permit an electronic prescription for a Schedule III-V controlled substance if federal law permits, but New Jersey food and drugs law and controlled dangerous substances regulations require a "written or oral prescription" and do not address e-prescribing. Compare N.J. Admin. Code § 13:39-7.11(i) (2009) with N.J. Stat. Ann. § 24:21-15(b) (2009) and N.J. Admin. Code § 8:65-7:13(a), (b) (2009).

[35] New Mexico pharmacy regulations authorize electronic prescriptions for controlled substances to the extent permitted by federal law, but the state Controlled Substances law requires written prescriptions for Schedule II controlled substances and written or oral prescriptions for Schedule III-IV controlled substances. Compare N.M. Code R. § 16.19.6.7(C) (2009) with N.M. Stat. Ann. § 30-31-18(A), (C), (G) (2008).

[36] Pennsylvania pharmacy regulations permit electronic prescriptions for Schedule III-IV controlled substances, whereas the state Controlled Substance, Drug, Device and Cosmetic Act requires a written or oral prescription and does not address e-prescribing. Compare 49 PA. Code § 27.201(b) (2009) with 35 PA. Stat. Ann. § 780-111(b) (2008).

[37] Vermont pharmacy regulations permit the electronic transmission of a prescription for a Schedule III-V controlled substance, but state food and drugs law requires a written prescription or an oral prescription that is reduced to writing by the pharmacist. Compare 04-030-230 VT. Code R. § 19.3.1.1 (2008) with VT. Stat. Ann. tit. 18, § 4215(a) (2007).

(2009) (pharmacies may maintain prescriptions for Schedule III-V controlled substances in a computerized data base that provides a daily printout of the prescriptions); Minn. R. 6800.3950(2)(D) (2008) (pharmacies that use electronic data processing equipment to store prescription information must produce a hard-copy daily summary of controlled substance transactions); Okla. Admin. Code § 535:15-3-21(d) (2007) (pharmacies that use automated data processing systems to maintain prescription files must either produce nightly signed reports of controlled substance prescriptions or maintain a bound log book or separate file of daily statements signed by dispensing pharmacists attesting to the correctness of the refill information entered into the computer)].

Although the proposed DEA regulations also require prescription logs, these logs need not be printed out in paper. Under the proposed rules, electronic prescription systems must, on a monthly basis, provide the practitioner with an electronic log, readily viewable by the user of the system of all electronic prescriptions for controlled substances that were issued during the previous month (see 73 Fed. Reg. 36777).

3.3.3 Out-of-State Prescriptions

A few states limit the ability of pharmacists to fill prescriptions for controlled substances from out-of-state providers, whether the prescription is in paper or electronic format. For example, under Michigan's public health code a pharmacist may not dispense a prescription for a controlled substance that was issued by a physician licensed in another state unless the physician resides adjacent to the land border between Michigan and an adjoining state or resides in Illinois or Minnesota. [Mich. Comp. Laws § 333.17763(e) (2009)]. Such restrictions impede interstate e-prescribing and raise interstate commerce issues.[38]

3.4 Brand Necessary Requirements in Generic Substitution and Medicaid Reimbursement Laws

In an effort to contain health care costs, virtually every state[39] has a generally applicable drug product selection law that permits or requires pharmacists to offer generic equivalents[40] to patients with prescriptions for brand-name drugs ("generic substitution laws").[41] Similarly, state Medicaid programs have mandatory generic substitution policies requiring that generic drugs be dispensed whenever a generic version of the drug is available. Under federal and state law, Medicaid agencies also cap payment for brand-name

[38] See Texas Op. Att'y Gen. JM-555 (1986) (discussing whether requiring licensing by the board of out-of-state pharmacies established an unconstitutional burden on interstate commerce). Available at: http://www.oag.state.tx.us/opinions/opinions/47mattox/op/1986/htm/jm0555.htm.

[39] This report uses the term *states* as encompassing states and territories. Our research did not reveal drug substitution laws in Northern Mariana Islands or Puerto Rico. However, access to the regulations of these territories was limited.

[40] Many states define *generic drug* or *drug product equivalent* as a drug product designated as therapeutically equivalent drug by the Food and Drug Administration.

[41] Cheng, J. (2008, October). "An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry." *Columbia Law Review, 108*, 1471–1481.

drugs that have therapeutically equivalent generic medications available (Smith testimony, 2004).

Providers are generally able to override these generic substitution and reimbursement limitations by specifying that substitution is not acceptable in accordance with legally mandated requirements. The terminology that a provider must use to ensure that generics are not substituted varies from state to state and includes such phrases as: "dispense as written," "DAW," "brand necessary," "brand medically necessary," "no substitution," and "allergic to the inert ingredients of the drug" (collectively referred to in this report as "brand necessary provisions").[42] State laws also require differing means by which a provider may convey that the brand name must be dispensed. Some state provisions require that the provider handwrite the phrase on the face of the prescription while others merely require that the provider in some manner *indicate* these instructions. Many states have brand necessary provisions throughout various provisions of their state laws, with differing requirements.

State laws that do not allow providers to specify brand necessary electronically may be perceived as potentially interfering with a provider's ability to efficiently exercise his or her professional judgment. As a result, providers subject to such restrictions may be less willing to adopt e-prescribing.

Section 3.4.1 discusses state statutory and regulatory brand necessary provisions in state generic substitution laws that apply to most general prescriptions. State statutes and regulations that specifically apply to state Medicaid programs are discussed in Section 3.4.2.

An overview of these provisions is presented in Table A-3. Table A-4 summarizes the pertinent text of these state statutory and regulatory requirements.

3.4.1 General Generic Substitution Laws

Every state has a generally applicable drug product selection law that permits or requires pharmacists to offer generic equivalents to patients with prescriptions for brand-name drugs (generic substitution laws). These laws permit the provider to override generic substitution by certifying that the brand name is necessary (or by specifying that the pharmacist must "dispense as written" or some similar terminology). State law provisions that permit generic substitution override generally require the provider to convey this instruction by

- electronically specifying,
- indicating (generally—no specific method required),
- handwriting, or
- including brand necessary or the equivalent in conjunction with the prescription.

[42] Federal Medicaid regulations require the use of brand necessary. See 42 C.F.R. § 447.512 (2008).

Electronically Specifying Brand Necessary

Over 20 states have statutory or regulatory provisions that expressly permit a provider to denote brand necessary in conjunction with an electronically transmitted prescription (see Table A-2). For example, Hawaii's food and drug code provides that generic substitution is overridden if a prescription is… electronically ordered and the provider or authorized employee of the provider indicates "brand medically necessary" [Haw. Rev. Stat § 328-92(b) (2008)]. Similarly, Wisconsin pharmacy laws allow a provider to designate "in electronic format the phrase 'no substitutions' or words of similar meaning" [Wis. Stat. Ann. § 450.13(2) (West 2009)].

A few states have drafted their laws to encourage the e-prescribing provider to select the appropriate drug on a case-by-case basis. North Dakota, for example, requires the provider to take specific overt action to include the brand necessary language with electronic transmission; overt action includes, for example, the provider's agent typing out brand necessary letter by letter [N.D. Admin. Code 61-04-05-03 (2009)]. Michigan and Minnesota prohibit providers from maintaining "dispense as written" or "D.A.W." as a default on all prescriptions [Mich. Admin. Code. r. 338.479b (2009); Minn. Stat. Ann. § 151.21(2)(3) (2009)]. These provisions facilitate e-prescribing by allowing providers to continue to exercise their professional judgment to appropriately designate that a specific brand is necessary.

Indicating Brand Necessary

Sixteen states have provisions that, while not expressly addressing e-prescribing, generally permit the provider to, in some manner, "indicate" or "state expressly" that the prescription is to be dispensed as communicated (see Table A-2). Arkansas pharmacy laws for example, provide that in the case of a prescription other than one in writing, the provider may "expressly indicate" that the prescription is to be dispensed as communicated [Ark. Code Ann. § 17-92-503(b) (2009); 07-00-007 Ark. Code R. § 07-00-0007 (2009)]. See also Maryland's pharmacy laws, allowing a pharmacist to substitute a generic if the provider does not state expressly the prescription is to be dispensed as directed [Md. Code Ann., Health Occ. § 12-504(c) (2008)].

Others are more expansive. Kentucky's food and drug statutes, for example, permit the provider to indicate the brand is necessary in the manner of his choice except that the indication cannot be preprinted on the prescription [Ken. Rev. Stat. Ann § 217.822(1), (3) (2008)].

Handwriting Brand Necessary

Twenty-three states have laws that require a provider to make some handwritten notation (signature, check-box, description) for the pharmacist to prescribe the brand-name drug (see Table A-2). New Mexico's food and drug laws, for example, allow a provider to prohibit

drug substitution "by writing with his hand the words 'no substitution'… on the face of a prescription" [N.M. Stat. Ann. § 26-3-3 (2009)].

Some states require (or permit) prescriptions to be written on prescription forms, specifically formatted to allow a provider to designate whether generic substitution is permitted. States with these forms generally require the provider to mark brand necessary or the equivalent phrase in his or her own handwriting. Delaware, for example, requires all prescriptions to include the preprinted statement, ''In order for a brand name product to be dispensed, the provider must handwrite 'Brand Necessary' or 'Brand Medically Necessary' in the space below'' along with a line for the provider to so designate the prescription [Del. Code Ann. tit. 24, § 2549 (2009)]. Illinois similarly requires the provider to place a mark in his or her own handwriting beside the words "may not substitute" and sign in his or her own handwriting to authorize the issuance of the prescription [225 Ill. Comp. Stat. Ann. 85/25 § 25 (2008)]. The statute expressly prohibits the use of "preprinted or other rubber stamped marks, or other deviations from the prescription format (listed in the statute)" [225 Ill. Comp. Stat. Ann. 85/25 § 25 (2008)].

At least one state allows providers to indicate brand-name preference on this type of required form, but does not require that the provider do so in his or her own handwriting [Idaho Admin. Code r. 27.01.01.188 (2009)].

The states appear evenly divided on their approach to requirements for specifying brand necessary. The number of states with legal provisions expressly requiring handwritten notations approximates the number of states with provisions expressly permitting electronic designation of brand necessary. A number of states take both approaches simultaneously, requiring handwritten notation of brand necessary in some laws while permitting electronic designation in others (see Table A-2).

3.4.2 Medicaid Generic Substitution Laws

At least 39 states require that the generic version of a drug be dispensed to Medicaid beneficiaries when available (Smith testimony). Our review of state statutes and regulations identified at least 25 states with statutes or regulations dictating requirements for specifying brand necessary to overcome these requirements (see Table A-3).[43] Although in most states these provisions are found in Medicaid-specific provisions of state statutes and regulations, in nine states, such provisions for Medicaid prescriptions are found outside of the Medicaid Code, most often in the pharmacy laws or food and drug laws. Some of these provisions explicitly reference requirements when a "prescription is filled under the Medicaid program" [see Indiana food and drug statutes, Ind. Code Ann. § 16-42-22-10 (2008)];

[43] This figure underreports states that have such provisions because this project conducted a limited review of state statutes and regulations and did not review state Medicaid manuals due to time and budget constraints and the fact that these manuals are not uniformly readily available to the general public.

while others generally apply the relevant statute "to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments" [see Arizona pharmacy statutes, Ariz. Rev. Stat. § 32-1963.01 (2009)].

Similar to generally applicable state generic substitution laws, state Medicaid laws that allow the provider to override generic substitution by specifying that such substitution is not acceptable generally require the provider to convey this instruction by

- electronically specifying,
- Indicating (generally—no specific method required),
- Handwriting, or
- Including brand necessary or the equivalent in conjunction with the prescription.[44]

Electronically Specifying Brand Necessary

In contrast to generally applicable generic substitution laws, only a few state Medicaid statutes or regulations expressly permit providers to denote brand necessary in an electronic transmission, including California, Connecticut, Hawaii, and Indiana (see Table A-3). California providers can indicate there shall be no generic substitution for an electronic prescription by "indicat[ing] 'Do not substitute' or words of similar meaning, in the prescription as transmitted by electronic data" [Cal. Bus. & Prof. Code § 4073(b), (d) (2008); see also Haw. Rev. Stat § 328-92(b) (2008)] (providing that the pharmacist shall not substitute an equivalent generic drug product if a prescription is electronically ordered and the provider indicates "brand medically necessary" or other similar words or phrases).

Connecticut law is less clear. Both the pharmacy code and the Medicaid code permit the designation of brand medically necessary electronically for Medicaid recipients. The pharmacy code expressly requires a provider who electronically specifies brand medically for a Medicaid prescription to send written certification of brand medically necessary in the provider's own handwriting to the dispensing pharmacy within 10 days [Conn. Gen. Stat. § 20-619(c) (2008)]. In contrast, the Medicaid statute's 10-day handwritten certification requirement applies to telephone prescriptions, but does not reference electronic transmissions [Conn. Gen. Stat. §17b-274(b) (2009)].

Indicating Brand Necessary

We identified six states with statutes and regulations that allow the provider to prevent generic substitution for a Medicaid recipient if the provider indicates brand necessary. Some provisions were very general ("unless the provider directs otherwise on the form or attached signed certification of need, the generic form of the drug… shall be used to fill the prescription" [Md. Code Ann., Health-Gen § 15-118(a)(1) (2008)]); while others were more

[44] The override provisions for Medicaid reimbursement caps can be similarly categorized.

specific (generics dispensed "except when the provider personally indicates on the prescription order "dispense as written" [10A N.C. Admin. Code 220.0118(b) (2009)]).

Handwriting Brand Necessary

Of the 25 states we identified as having brand necessary clauses specifically applicable to Medicaid, 16 have restrictive provisions requiring handwritten instructions to prevent a generic drug from being dispensed (see Table A-3). Generally, the statutory or regulatory language requires the provider to sign on a "dispense as written" signature line or personally handwrite the notation directly on the prescription [see e.g., Kan. Admin. Regs. § 30-5-92(a) (2009); 15-040-004 R.I. Code R. § IX(D)(7) (Weil 2009)]. Some states explicitly impose handwritten certification on Medicaid prescriptions while setting more lenient standards for other prescriptions. For example, Kentucky allows the provider to indicate there shall be no generic substitution in a manner of his choice *unless* it involves prescriptions under the Kentucky medical assistance plan, in which case the physician must indicate this preference in his own handwriting [Ky. A.G. 77-223 (1977)].[45] See also [50-018-001 Miss. Code R. art. X(1) (2008)]; (see Table A-4).

Some state laws that require (or permit) prescriptions to be written on prescription forms specifically formatted to allow a provider to designate whether generic substitution is appropriate expressly apply to Medicaid prescriptions [see, e.g., Del. Code Ann. tit. 24, § 2549 (2009)]. Maine provides that "written" prescriptions may be issued on such prescription forms or by electronic transmission. However, the provisions that allow a provider to overcome generic substitution appear to address only hard-copy prescriptions, requiring the provider "to handwrit[e] on the prescription form, along with the provider's signature, 'dispense as written,' 'DAW,' 'brand,' 'brand necessary' or 'brand medically necessary'" [Me. Rev. Stat. Ann. tit. 32, § 13702-A (2008); §13781 (2008)]. Massachusetts generally permits a provider to indicate brand necessary without requiring handwriting, but also requires that the prescription form include the specific statement that "Interchange is mandated unless the practitioner indicates no substitution in accordance with law [Mass. Gen. Laws ch. 112, § 12D (2008)]; (see Table A-4).

Texas takes a somewhat similar approach. The state permits electronic transmission of Medicaid prescriptions. However, to prohibit substitution on a Medicaid electronic prescription drug order, the provider is required to fax a copy of the original prescription drug order that complies with the requirements of a written (i.e., handwritten) prescription drug order within 30 days [22 Tex. Admin. Code § 309.3(c)(4)(C) (2009)]; (see Table A-4). Notably, the state provision refers to 42 C.F.R. § 447.331, the federal regulation, which has since been amended, that required handwritten certification of brand necessary.

[45] Interpretation confirmed by Attorney General opinions based on general pharmacy code provision, Ky. Rev. Stat. § 217.822, and Medicaid regulations adopted to conform to federal requirements.

These statutes accommodate hard-copy prescriptions as well fax transmissions, but, at least facially, do not facilitate the electronic transmission of prescription data. State laws that require handwritten provisions appear to be superseded by E-SIGN, and, in most states, the UETA, which essentially requires commercial electronic records and electronic signatures to be given the same legal status as their paper counterparts (see Section 1.1.2). However, it is not completely clear whether this is the case, and if so, how familiar pharmacists and their regulators are with these general electronic commerce statutes.

3.4.3 Medicaid Reimbursement Caps

In an effort to contain health care costs, the federal government and the states, through the FUL program and state MAC programs, cap the amount Medicaid agencies pay for brand-name prescriptions for which therapeutically equivalent generic medications are available (Smith testimony). Providers may overcome these reimbursement limitations by certifying that a brand-name drug is medically necessary for a particular patient.[46] Prior to 2007, Medicaid regulations governing the FUL program required that the provider make this certification "in his or her own handwriting" [42 C.F.R. § 447.331 (2007)]. These regulations were amended in July 2007 to also allow the provider to certify that a brand is medically necessary by using "an electronic means approved by the Secretary" [42 C.F.R. § 447.512 (2008)].[47] The use of check-off boxes as a means of certifying brand necessary is not acceptable. Otherwise, federal regulations allow state Medicaid agencies to decide what certification form and procedure are used. State MAC programs have similar brand necessary requirements and exceptions.

We identified 25 states with statutes and regulations that permit providers to overcome Medicaid reimbursement caps on brand-name prescriptions by certifying that the brand-name drug is medically necessary.[48]

Electronically Specifying Brand Necessary

We identified only one state, Alaska, with a Medicaid reimbursement provision that expressly allows an electronic specification of brand necessary. Alaska's provision requires the provider to "write [] on the prescription 'brand-name medically necessary drug' or 'allergic to the inert ingredients of the generic drug'" and permits the information to be "submitted electronically or telephonically" [Alaska Admin. Code tit. 7, 43.590(b)(7) (2009)]. Given the requirement for "writing on the prescription," it is not clear whether this provision was intended to apply to computer-to-computer electronic prescriptions.

[46] This report does not address other state restrictions on prescribing brand-name drugs, such as requiring authorization from the state Medicaid agency prior to writing such a prescription.
[47] 42 C.F.R. § 447.331 was redesignated § 447.512 at the same time.
[48] This number is understated because we did not review state Medicaid manuals. We have not broken out FUL programs versus MAC since the state requirements often cover both programs.

Indicating Brand Necessary

Six states have provisions where, in order to override the reimbursement cap for a Medicaid prescription, the provider needs to *indicate* the brand-name drug is medically necessary (see Table A-3). Mississippi Medicaid regulations, for example, provide that the program will not reimburse "for brand-name drugs if a generic equivalent is available with the exception of when the provider indicates brand name medically necessary" [13-000-011 Miss. Code R. § 31.11 (2008)].

Handwriting Brand Necessary

Of the states we identified with brand necessary reimbursement exceptions, most state Medicaid statutes and regulations (17 out of 25) require the provider to handwrite brand medically necessary or sign the "dispense as written" line on the face of the prescription in order to be reimbursed at the brand-name cost (see Table A-3). For example, Texas physicians may override state MAC reimbursement caps only by handwriting brand necessary on the face of the prescription [1 Tex. Admin. Code § 355.8546(a) (2009)].

For the most part, state laws continue to reflect the pre-2007 FUL standard that required a handwritten certification of brand necessary to override reimbursement limitations. None have clearly incorporated the July 2007 amendment that expressly allows certifying brand necessary electronically.

4. CONCLUSION AND RECOMMENDATIONS

4.1 Conclusion

Virtually all states authorize e-prescribing for the majority of prescription drugs (noncontrolled substances) in one or more statutory or regulatory provisions. Nonetheless, at present, states are unable to achieve full implementation of e-prescribing because of various state legal impediments. The use of e-prescribing in many states is made difficult by the following issues:

1. contradictory prescription requirements across different sets of statutes and regulations (some state provisions permit e-prescribing; others preclude e-prescribing);
2. pharmacy record-keeping requirements mandating that electronic prescriptions and other pharmacy records be maintained in hard copy (rather than electronically);
3. direct transmission requirements for electronic prescriptions that may interfere with employing an electronic data intermediary (a number of states require direct transmission of an e-prescription between a practitioner and a pharmacy and prohibit any "intervening person having access to the prescription drug order"); and
4. patient consent requirements for the electronic transmission of a prescription (some states require that a patient affirmatively approve an e-prescription or be provided a choice between a conventional written prescription and an e-prescription).

Controlled substances, which represent only a small percentage (approximately 10 percent) of U.S. drug prescriptions, present more difficulties for e-prescriptions than noncontrolled substances. As shown above, most states do not permit e-prescriptions for controlled substances, consistent with current DEA regulations governing controlled substances. Yet, last year DEA proposed regulations authorizing e-prescribing for controlled substances; these regulations are being finalized. Some states have anticipated the new federal regulations with state provisions authorizing prescriptions for controlled substances "to the extent allowed by federal law and regulation." But most state provisions flatly prohibit controlled substance e-prescriptions without such conditional language. Absent state action, these restrictive state laws will remain in place after the DEA finalizes its regulations to permit e-prescribing. Thus, the state laws will retain the barriers to e-prescribing that the federal regulation will remove once finalized.

State statutory and regulatory requirements on the means by which a provider must specify brand necessary to override state generic substitution requirements and reimbursement caps may adversely affect the adoption of e-prescribing. State generic substitution laws that are generally applicable are the most accommodating of e-prescribing. Some 20 states have provisions that expressly permit electronically designating brand necessary to override generic substitution. Seventeen states have provisions that merely require the provider to *indicate* that the brand name is medically necessary without specifying a particular means of doing so. Laws in both of these categories would appear to allow a provider to retain

flexibility in the drugs they prescribe electronically. However, 20 states have legal provisions that require the provider to either handwrite brand necessary or make another handwritten notation on the prescription to avoid generic substitution. Laws in this latter category may make it difficult for a provider to readily exercise choice in prescribing when using an electronic system. Such a restriction may deter providers for whom such choice is an important consideration from e-prescribing.

Few state Medicaid laws expressly permit providers to certify brand necessary electronically. This finding held true both for Medicaid laws that require generic substitution and for Medicaid laws that cap reimbursement for brand-name drugs unless the provider certifies that the brand name is medically necessary. To the contrary, most state laws in both of these categories require that brand necessary be handwritten on the prescription. For the most part, state Medicaid laws continue to reflect the pre-2007 federal Medicaid requirement for a handwritten certification of brand necessary to override reimbursement limits.

4.2 Recommendations

On the basis of our findings, we recommend that states take the actions outlined in the following sections.

4.2.1 Review Prescription Statutes and Regulations to Identify and Remove Inconsistencies

States would be well-served by conducting a comprehensive review of the totality of their statutes and regulations addressing drug prescriptions. Such a review will (1) identify inconsistencies within state law on e-prescribing, and (2) begin the process necessary to remove these inconsistencies. Our research found that prescription requirements may be embedded within the states' statutory and regulatory codes for professions and occupations (pharmacy board, medical board); food and drugs; Medicaid; controlled substances; crime; consumer protection; and public health as well as other subject areas.

4.2.2 Eliminate Requirements for Hard Copies of Electronic Prescriptions and Other Duplicative Paper Records

States may want to consider following the model of California and Rhode Island by allowing electronic prescriptions to be retained electronically so long as they can be retrieved in hard copy if needed (see Section 3.2.5). Electronic prescribing is a "green" technology that can potentially eliminate the need for many paper records, while saving the time and expense involved in filing and storing those records. Yet, in a number of instances, states that permit electronic prescribing have gone only partway in replacing written prescriptions. When prescribers transmit electronic prescriptions that the pharmacy must print out for filing, the state is losing an important benefit of e-prescribing (i.e., a paper-free system) without enhancing patient care. The proposed DEA regulations appear to acknowledge this

advantage and permit pharmacies to retain electronic prescriptions for controlled substances in electronic form (see Section 1.1.1).

4.2.3 Revise Prescription Provisions to Clarify that Electronic Data Intermediaries May be Employed

States wishing to permit electronic data intermediaries to transmit electronic prescriptions may need to clarify that prescription provisions denying access to "any intervening person" do not apply to such intermediaries. Georgia, New Mexico, and Vermont prescription regulations offer examples of clarifying language (see Section 3.2.6).

4.2.4 Decide Whether Patient Consent is Required for Electronic Prescribing

A few states require patient consent for electronic prescribing; most do not address the question (see Section 3.2.4). It is probable that practitioners and pharmacies will ask whether the state requires such consent. Patient consent for e-prescribing is not required by federal law. States should resolve whether patient consent is required for such transactions.

4.2.5 Permit Out-of-State Electronic Prescriptions

To the extent some states restrict out-of-state electronic prescriptions, they may wish to permit pharmacies to fill such prescriptions in the same manner that an in-state prescription may be filled.

4.2.6 Consider Promoting Electronic Prescriptions through Medical Licensure Requirements

Massachusetts law contains a unique feature designed to encourage e-prescribing. Applicants for medical licensure are required to show competency in e-prescribing (as well as in the use of electronic health records and other forms of health information technology) [see Mass. Gen. Laws Ann. ch. 112, § 2 (2009)]. In addition, e-prescribing competency is an eligibility requirement for a Massachusetts program offering repayment assistance for medical school loans [see Mass. Gen. Laws Ann. ch. 111, § 25N(a) (2009)]. While the other recommendations listed above are designed to create a legal environment that permits and is hospitable to e-prescribing, states may wish to take additional steps, as Massachusetts did, to actively encourage e-prescribing.

4.2.7 Revise State Prescription Provisions to Permit e-Prescribing for Controlled Substances to the Extent Permitted by Federal Law

In light of DEA's published announcement that it intends to finalize its proposed regulations permitting electronic prescriptions for controlled substances (see Section 1.1.1), states may wish to modify their prescription provisions to permit such electronic prescriptions "to the extent allowed by federal law and regulation" as other states have done (see Section 3.3). States need not entirely revamp their prescription provisions; they merely need to add

language that allows electronic prescriptions as an optional mode of prescribing. In fact, this is the approach that DEA has taken in its proposed regulations [see 73 Fed. Reg. 36722 (June 27, 2008)].

4.2.8 Revise Brand Necessary Provisions to Permit Electronic Certification that a Brand Name is Medically Necessary

To reflect evolving technology, states should revise their general drug product selection laws to allow providers to override generic substitution by electronically specifying that the brand-name drug is necessary. As some states have demonstrated, these laws may be structured to encourage providers to select the appropriate drug on a case-by-case basis, by ensuring that 'brand necessary" is not the default setting in an e-prescribing system.

Similarly, states should evaluate their Medicaid-specific statutes and regulations to expressly permit providers to certify brand necessary electronically. Most of these state laws continue to reflect outdated federal Medicaid requirements that were amended in 2007. To encourage states to update their laws, CMS could issue a State Medicaid Director Letter informing states of the 2007 amendment, which expressly permits using electronic means to specify that a specific brand of medication is medically necessary, and encouraging them to follow suit. Additionally, CMS could volunteer to address this issue at the next meeting of the National Association of State Medicaid Directors.

APPENDIX TABLES