

## Roadblock on the health IT superhighway: E-prescribing and the controlled substances act

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### ABSTRACT

*Electronic prescribing technology enables healthcare providers access to more complete information regarding patient's medication history including prescriptions written by other healthcare providers. President Bush has put forth the goal of electronic health records for most Americans by 2014. Yet, regulatory roadblocks may be preventing further progress toward achieving these goals. The Drug Enforcement Agency (DEA) must modify the Controlled Substances Act (CSA) to keep pace with technology. It is time to move from discussions and hearings to piloting e-prescribing of controlled substances.*

*Key words: Controlled Substances, e-prescribing, Health Information Technology, prescription diversion*

Electronic prescribing (e-prescribing) is the direct computer-to-computer transmission of prescription information from physician offices to pharmacies. E-prescribing has the potential to improve the safety, quality, and efficiency of healthcare.<sup>1</sup> All but one state (Alaska) has regulations permitting this form of prescriptions.<sup>2</sup> As of 2006, 95 percent of software systems used by US pharmacies had been certified on at least one "highway" connecting physician offices to retail pharmacies.<sup>2</sup> More than two thirds of pharmacies are "live" (ready to receive e-prescriptions) and an estimated 150,000 physicians possess the software for e-prescribing.<sup>2</sup> Despite having the capability, the vast majority of those 150,000 physicians use the e-prescribing software to send faxes to pharmacies, circumventing the potential for reduction of errors and reducing the efficiencies of e-prescribing.<sup>3</sup> Why should this be? A recent study pointed to physicians' confusion in the regulations regarding what types of prescriptions may be e-prescribed.<sup>3</sup> In a large, multistate project to evaluate standards for e-prescribing transactions conducted in 2006, physicians noted their frustration with the need for multiple prescribing methods owing to the inability to e-prescribe controlled substances.<sup>4</sup> Many

preferred to forgo true computer-to-computer e-prescribing in favor of one method (faxing by computer) that covered all prescribing needs.

We consider this a barrier to adoption of e-prescribing. We review recent literature on the public health concerns underlying the need for revision of the Controlled Substances Act (CSA),<sup>5</sup> provide historical perspective on how the CSA has changed in response to other technological advances, and then consider e-prescribing in light of recent changes to monitoring prescription medication abuse and diversion.

### PRESCRIPTION DRUG ABUSE

Distribution of narcotic analgesics for medical use has increased in recent decades while showing substantial state-to-state variation in consumption per capita.<sup>6,7</sup> The narcotic analgesic combination of hydrocodone and acetaminophen accounts for more prescriptions than any other drug product in the United States.<sup>8</sup> According to the Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Abuse Warning Network (DAWN), an estimated 1.5 million drug-related emergency department visits occurred in the United States in 2005.<sup>9</sup> Forty-nine percent involved prescription medications. Indeed, 22 percent of the community dwelling Medicare beneficiaries use at least one medication with abuse potential.<sup>10</sup> Prescription drug diversion occurs from manufacturing and distribution supply chain insecurity, from deceived or dishonest prescribers, and by theft, forgery, and illegal importation.<sup>11</sup> More recently, the Internet has contributed substantially to the illegal distribution of controlled substances.<sup>12</sup>

Diversion and inappropriate use of controlled substances is an important public health concern. The Drug Enforcement Administration (DEA) and various health organizations have formally recognized the difficulty of achieving balance between appropriate use of narcotics and prevention of diversion and misuse.<sup>13</sup> Programs aimed

at curbing inappropriate use of controlled substances began in the 1910s. States began instituting prescription monitoring programs (PMPs) that generally required prescribers to write prescriptions for schedule II medications in duplicate or triplicate using government-issued forms.<sup>14</sup> Pharmacists were responsible for sending a copy to the assigned state agency for compilation and review. DEA policy states that controlled substances (in Schedules II-V) have legitimate medical use and should be prescribed for patients in need. Unfortunately, inconsistent and misinformed interpretation of controlled substances statute and regulations by regulatory boards and practitioners has perpetuated physicians' fear of disciplinary action regarding prescriptions of controlled substances.<sup>15</sup> Ironically, the actual risk of disciplinary action for prescribing controlled substances is quite low and is usually the result of inappropriate behaviors such as self-prescribing, prescribing for nonpatients, and keeping inadequate records.<sup>16</sup> Nevertheless, evaluations of these programs have shown decreased use of controlled substances in states with established multicopy PMPs, due in part to inappropriate substitution of noncontrolled drugs.<sup>17-19</sup>

#### **HISTORICAL PERSPECTIVE: HOW CSA HAS RESPONDED TO EMERGENT TECHNOLOGY**

Instituted in 1970, the CSA<sup>5</sup> fell under the jurisdiction of the DEA after the agency's creation (through presidential reorganization) in 1973.<sup>20</sup> At the time this was enacted into law, technology as a means of communication between healthcare professionals and community pharmacies was limited. In the early 1970s, prescriptions were manually tracked through paper recording systems, often with the assistance of a typewriter. Further, communication between pharmacists and physicians transpired via telephone, in-person conversation, or written prescription (often presented to the pharmacist by the patient or the patient's representative). In the 1980s, vast changes occurred in retail pharmacies with the introduction of the microcomputer. Initially, the microcomputer was viewed in retail pharmacies as a means to improve record keeping but soon was evaluated to determine the potential benefits in terms of patient safety and monitoring (i.e., assisting the pharmacist in evaluating medication interactions).<sup>21</sup> The potential for interfacing fax and computer technology began to be recognized within the medical community as a means to improve communication between providers in different sectors of the healthcare system.<sup>22</sup> The role of fax machines had become increasingly clear as a means of improving efficiency within hospital settings,<sup>23</sup> which later trickled into the realm of community pharmacy. A major advance in the practice of community pharmacy arose with the inclusion of fax machines as a method to receive orders for prescription medications. The improvements in efficiency

realized through the implementation of fax technology were deemed to outweigh the risks including problems with legibility, transmission security, and cost.<sup>24-26</sup> Finally, modification of the CSA<sup>20</sup> in 1994 allowed the facsimile transmittal of controlled substances (in schedules II-V, with some caveats applying to the transmission of those in schedule II).

More than 20 years later, the reality is that prescriptions can be transmitted between physicians and community pharmacies via computer interface (electronic prescribing); yet, to date the CSA has not been modified to allow the transmission of controlled substances despite the potential for reductions in handwriting errors and decreasing the prevalence of "fake" written prescriptions. Electronic prescribing is more secure than paper-based and oral prescription systems, and incorporates technology to decrease medical errors and drug diversion by providing utilization and formulary information at the point of care.<sup>27</sup> This "front-end" information allows prescribers to closely monitor medication use and for potential diversion. In 2001, the DEA assured the public that regulations regarding the transmission of controlled substances via e-prescription would be put forth.<sup>28</sup> In 2002, the DEA released a written statement authorizing electronic transmission of controlled substances albeit they must be treated as oral prescriptions,<sup>29</sup> reducing many of the potential benefits in efficiency afforded by e-prescription of controlled substances. Despite advancing in technology, the DEA is yet to modify the CSA to be responsive to the public's needs for electronic transmission of controlled substances. Will history repeat itself? Will it take another decade for the CSA to keep pace with technology?

#### **RECENT ADVANCES IN PRESCRIPTION DRUG MONITORING**

On August 11, 2005, President Bush signed into law the National All Schedules Prescription Electronic Reporting (NASPER) Act.<sup>30</sup> The purpose of NASPER is to provide funding and best-practice guidelines for states to use to implement PMPs for all schedules of controlled substances, and unlike previous federal funding mechanisms, requires minimum standards for funding eligibility.<sup>31,32</sup> Today's programs aim to efficiently and effectively build data collection and analysis systems, and facilitate the exchange of prescription data across jurisdictions.<sup>31</sup> There are currently 32 state programs in effect. States make data from PMPs available to various stakeholders, including healthcare and regulatory agencies, law enforcement, and, in some states, health professionals.<sup>32</sup> The availability of PMP data has worsened fears of disciplinary action among some. In one state, the vast majority of queries to the PMP were by physicians with law enforcement, pharmacists, and licensure boards making up a small minority.<sup>32</sup>

There are important shortcomings of current PMPs that limit their clinical utility. In their current form, PMPs are tools designed primarily for regulators for use intrastate. Despite the initiatives associated with NASPAR, state-to-state linkage is incomplete. Prescriptions received in one state may not be recorded in a neighboring state's PMP and will miss potentially important cases of abuse or diversion. Similarly, some states do not collect information on schedule III and IV substances. There are growing problems of inappropriate use and diversion of schedule III and IV substances, especially because prescriptions for these agents may be transmitted by facsimile or orally and are allowed refills. In states that collect data on only schedule II drugs, clinicians will have no information of misuse or diversion of these medications. Furthermore, not all states have instituted a PMP and fewer states allow access by health providers. In states that do allow health provider access, physicians have been unhappy with the time it takes to receive reports making it difficult to incorporate PMP information into clinical encounters.<sup>33</sup>

## SUMMARY

Electronic prescribing technology enables healthcare providers access to more complete information regarding patient's medication history including prescriptions written by other healthcare providers. Indeed, the availability of medication history based on retail pharmacy transactions also may be of use to NASPER initiatives. President Bush has put forth the goal of electronic health records for most Americans by 2014. Yet, regulatory roadblocks may be preventing further progress toward achieving these goals. The DEA must modify the CSA to keep pace with technology. It is time to move from discussions and hearings to piloting e-prescribing of controlled substances.

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