

Testimony of

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Regarding

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

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## Introduction

Chairman Leahy, Ranking Member Specter, and distinguished members of the Senate Judiciary Committee, thank you for the opportunity to appear today to discuss the Drug Enforcement Administration's (DEA's) ongoing efforts in establishing an appropriate system that allows electronic prescribing to be used for controlled substances while ensuring adequate safeguards are in place to prevent the diversion of controlled substances.

DEA supports the use of technology to reduce medical errors, streamline the medical process and increase efficiency. However, DEA must balance this objective with its legal responsibility to ensure there is a closed system of distribution for controlled substances in order to minimize the risk that these substances will be diverted and used illegally. Therefore, it is extremely important to understand the need for specific requirements when establishing standards for a system that allows electronic prescribing for controlled substances. It is critical that the technology and standards to be employed include adequate security that incorporates authentication, non-repudiation, and integrity in the recordkeeping process. These three security-related elements are necessary to ensure that DEA can fulfill its obligations under the Controlled Substances Act (CSA).

## DEA's Legal Authority and Responsibilities

By delegation from the Attorney General, DEA is responsible for the implementation and enforcement of the CSA. The CSA and its implementing regulations are designed to ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes. The CSA also was established to help prevent the diversion of controlled substances destined for illegal purposes. The CSA mandates that there be a closed system of control for manufacturing, distributing, and dispensing controlled substances. To accomplish this, any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for their corresponding activity.

## Pharmaceutical Controlled Substances

Pharmaceutical controlled substances are drugs that have a legitimate medical purpose, coupled with a potential for abuse and psychological and physical dependence. They include opiates, stimulants, depressants, hallucinogens, and anabolic steroids. These substances are divided into five schedules:

- Schedule I substances have the highest potential for abuse and have no accepted medical use within the United States. These substances may only be used for research, chemical analysis, or in the manufacturing process of other drugs.

- Schedule II - V substances have accepted medical uses and also have potential for abuse and psychological or physical dependence.

Prescriptions for pharmaceutical controlled substances constitute a small percentage of the drugs prescribed in the United States--between 10 percent and 11 percent of all prescriptions written in the United States. Generally, for a pharmaceutical controlled substance to be dispensed legally, a prescription must be written by a practitioner licensed by the state where the practitioner is located and be registered with DEA to dispense these substances.

Although the number of pharmaceutical controlled substance prescriptions is a small portion of the overall total, the importance of ensuring a safe, secure, and accurate method for issuing legitimate prescriptions is increasingly important. According to a May 2007 report by the Kaiser Family Foundation, "From 1994 to 2005, the number of prescriptions purchased increased 71% (from 2.1 billion to 3.6 billion), compared to a US population growth of 9%."<sup>1</sup> Based upon these figures the number of prescription written for controlled substances in 2005 would have ranged from 360 million to 400 million.

With this increase in the number of prescriptions has come a disturbing increase in the abuse of prescription drugs. According to the most recent National Survey on Drug Use and Health (NSDUH), nearly 7 million Americans are abusing prescription drugs--more than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined. That 7 million was just 3.8 million in 2000, an 80 percent increase in just 6 years. Nearly 1 in 10 high school seniors admits to abusing powerful prescription painkillers. In addition, opioid painkillers now cause more drug overdose deaths than cocaine and heroin combined. As we discuss alternative technologies to ensure fewer drug interactions and higher quality, we should not forget that a prescription does not make these substances less dangerous. Additionally, black-market sales for prescription controlled substances are typically five to ten times their retail value. Profits generated from these illegal sales provide a strong incentive for continued diversion.

#### Pertinent Provisions of the CSA and DEA Regulations Pertaining to Prescriptions for Controlled Substances

In enacting the CSA, Congress sought to control the diversion of pharmaceutical controlled substances into illicit markets by establishing a "closed system" of drug distribution governing the legitimate handlers of controlled substances. Any regulatory action DEA takes to permit the electronic prescribing of controlled substances must meet existing statutory requirements and must continue to ensure the integrity of the "closed system" envisioned through the CSA.

The CSA currently mandates two different security standards for the prescribing of controlled substances, depending upon the schedule of the substance. The CSA requires that, except in limited emergency circumstances, a pharmacist may only dispense a schedule II controlled substance pursuant to a written prescription from a practitioner. For schedule III and IV controlled substances, a pharmacist may dispense the controlled substance pursuant to a written or oral prescription from a practitioner.

A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe by the state in which he or she is licensed to practice and is registered, or exempted from registration, with DEA. To be valid, a prescription must be written for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice; a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the CSA, and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Longstanding DEA regulations specify that each written controlled substance prescription contain certain information including the practitioner's manual signature. This manual signature affixed to the prescription by the practitioner serves as formal attestation by the practitioner that the prescription has been written for a legitimate medical purpose

and affirms the practitioner's authority to prescribe the controlled substance in question. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. Further, a corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by DEA regulations.

A prescription may be filled only by a pharmacist acting in the usual course of professional practice who is employed in a registered pharmacy. Except under limited circumstances, a pharmacist may dispense a schedule II controlled substance only upon receipt of the original written prescription manually signed by the practitioner. A pharmacist may dispense a schedule III or IV controlled substance only pursuant to a written and manually signed prescription from an individual practitioner, which is presented directly or transmitted via facsimile to the pharmacist, or an oral prescription, which the pharmacist promptly reduces to writing containing all of the information required to be in a prescription, except the signature of the practitioner.

Every prescription must be initialed and dated by the pharmacist filling the prescription. Under many circumstances, pharmacists are required to note certain specific information regarding dispensing on the prescription or recorded in a separate document referencing the prescription before the prescription is placed in the pharmacy's prescription records.

DEA requires the registered pharmacy to maintain records of each dispensing for two years from the date of dispensing of the controlled substance. However, many states require that these records be maintained for longer periods of time. These records must be made available for inspection and copying by authorized employees of DEA. This system of records is unique in that the prescribing practitioner creates the prescription, but the dispensing pharmacy retains the record.

The signature requirement for written prescriptions for controlled substances provides DEA with reliable evidence needed to enforce the CSA in administrative, civil, and criminal legal proceedings. In criminal proceedings for violations of the CSA, the Government must prove the violation beyond a reasonable doubt. As the agency responsible for monitoring compliance with the regulatory requirements of the CSA, it is essential that DEA have the ability to determine whether a given prescription for a controlled substance was, in fact, signed by the practitioner whose name appears on the prescription. It is likewise essential that DEA have the ability to determine that a prescription that has been filled by a pharmacy was not altered after it was prepared by the practitioner. Further, because DEA relies on the records of these prescriptions in the conduct of investigations, DEA must also know that the prescription has not been altered after receipt by the pharmacy. Vulnerabilities at any point in this chain of custody will certainly compromise the Government's ability to successfully prosecute violations of the CSA.

The elements of the prescription that identify the practitioner (the practitioner's name, address, DEA registration number, and signature) also serve to enable the pharmacy to authenticate the prescription. If a pharmacy is unfamiliar with the practitioner, it can use the registration number to verify the identity of the practitioner through publicly available records. Those same records would indicate to the pharmacy whether the practitioner has the authority to prescribe the schedule of the controlled substance in question.

Requiring that the original documents be maintained in paper form serves to support both the accuracy and integrity of each record and, thus, the accuracy and integrity of the system of records as a whole. The availability of the original written and manually signed prescription provides a level of document integrity or provides physical evidence that the record has been altered: alterations of hard-copy records are usually apparent upon close examination. A forensic examination of a prescription can prove that a practitioner signed it or, equally important, that the practitioner did not sign it. The maintenance of the paper record at a pharmacy also ensures that state and local law enforcement agencies have access to records they need for investigations. In addition, the written prescription record ensures there will be a limited number of pharmacy employees who will have annotated the record and can testify that the prescription is, in fact, the prescription they received and dispensed.

All of these elements are present in existing federal law and regulations to ensure that prescriptions are legitimate, to deter the diversion of controlled substances prescriptions and the substances dispensed based on those prescriptions, and to provide federal, state, and local law enforcement with the tools necessary to detect diversion when it occurs. These same elements must be present in any electronic system for the same reasons.

## Other Governing Legislation

Besides the mandates of the CSA, regulations regarding electronic prescribing must be consistent with other statutory mandates and federal regulations. The Electronic Signatures in Global and National Commerce Act of 2000, commonly known as E-SIGN, was signed into law on June 30, 2000. It establishes the basic rules for using electronic signatures and records in commerce. E-SIGN was enacted to encourage electronic commerce by giving legal effect to electronic signatures and records and to protect consumers. E-SIGN provides that, with respect to any transaction in or affecting interstate or foreign commerce, a signature may not be denied legal effect solely because it is in electronic form. However, E-SIGN further provides that, where a statute or regulation requires retention of a record, and an electronic record is used to meet such requirement, federal, state, and local agencies may set performance standards to ensure accuracy, record integrity, and accessibility of records. Such performance standards may be specified in a manner that requires the implementation of a specific technology if such requirement serves an important governmental objective and is substantially related to that objective interest. DEA shares this vision as evidenced by its advance notice of rulemaking.<sup>2</sup>

In 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act, commonly referred to as the MMA. The MMA requires the Department of Health and Human Services (HHS) to develop standards for the transmission of electronic prescriptions for the Medicare Part D program. DEA recognizes that Congress and many in the healthcare industry want to encourage the shift to electronic medical records, including electronic prescriptions.

One of the considerations in support of the implementation of electronic prescriptions is the view that using electronic prescriptions, in lieu of written or oral prescriptions, could reduce medical errors that occur because handwriting is illegible or phoned in prescriptions are misunderstood as a result of similar sounding medication names. Another consideration is that, if prescription records are linked to other medical records, practitioners can be alerted at the time of prescribing to possible interactions with other drugs the patient is taking or allergies a patient might have. Electronic prescribing systems also can link to insurance formulary lists to inform the practitioner prior to prescribing whether a drug is covered by a patient's insurance.

As the committee is aware, HHS has finalized initial regulations establishing standards for an electronic prescription drug program under Medicare Part D. The standards were not designed to provide safeguards against the diversion of controlled substances. The responsibility for establishing these regulatory safeguards against diversion of controlled substances falls upon DEA as the agency charged with administering and enforcing the CSA.

### Means by Which Controlled Substances Are Diverted

Understanding the means by which controlled substances are diverted is critical to determining appropriate regulatory controls. One of the factors that contribute to the abuse of prescription controlled substances, as evidenced by the Partnership for a Drug-Free America's Partnership Attitude Tracking Study, is the perception by some members of the public that it is safer to abuse prescription substances than to abuse illicit substances. Diversion of prescription controlled substances can occur in a number of ways, including, but not limited to, the following:

- Prescription pads are stolen from practitioners' offices by patients, staff, or others and illegitimate prescriptions are written and forged.
- Legitimate prescriptions are altered to obtain additional amounts of legitimately prescribed controlled substances.
- Drug-seeking patients may falsify symptoms and/or obtain multiple prescriptions from different practitioners for their own use or for resale. In some cases, organized groups visit practitioners with fake symptoms to obtain prescriptions, which are filled and resold. Some patients resell their legitimately obtained drugs to earn extra money.
- Prescription pads containing legitimate practitioner information (e.g., name, address, DEA registration number) are printed with a different call back number that is answered by an accomplice to verify the prescription.

- Computers and scanning or copying equipment are used to create prescriptions for nonexistent practitioners or to copy legitimate practitioners' prescriptions.

- Pharmacies and other locations where controlled substances are stored are robbed or burglarized.

- Prescriptions are written for other than a legitimate medical purpose.

Some practitioners have been convicted of knowingly writing prescriptions for non-medical purposes. Criminal organizations commonly referred to as "rogue Internet pharmacies" often employ practitioners to issue prescriptions based on on-line questionnaires from patients with whom the practitioner has no legitimate medical relationship.

- Controlled substances have been stolen from a pharmacy by pharmacy personnel. Legitimately dispensed prescriptions may be altered to make the thefts less detectable.

Given the risk of diversion, as well as the increasing extent of prescription controlled substance abuse in the United States, any system allowing the electronic prescribing of controlled substances must have sufficient safeguards to minimize risks and prevent further diversion. With proper controls, DEA believes the risk of diversion can actually be reduced through the use of electronic prescriptions. Among the essential elements of an envisioned system are the assurances that only DEA registrants electronically sign and authorize controlled substance prescriptions and that the prescription record cannot be altered without the alteration being detectable.

Accordingly, a system that fails to provide standards for verification of the registrant's identity and authority to issue controlled substance prescriptions and/or that fails to ensure that alteration of the record is detectable would create new routes of diversion that could be even harder to prevent, detect, and investigate. Further, any system that does not have these safeguards will inhibit the Government's ability to meet its burden of proof in criminal, civil, and administrative proceedings. Systems lacking adequate controls would provide a plausible defense for a practitioner who would choose to divert these dangerous substances by simply denying that they authored and approved a prescription for a controlled substance. The Government's ability to refute their claim would be circumstantial or non-existent--hence the critical need for authentication, non-repudiation, and integrity of the record. In fact, without these standards we would create new avenues of diversion of pharmaceutical controlled substances and would place more Americans at risk for abuse, addiction, and even death.

#### DEA's Regulatory Activities Regarding Electronic Prescribing

The CSA and DEA's regulations were originally adopted at a time when most transactions--particularly prescriptions--were completed on paper. The CSA mandates that many controlled substance prescriptions must be written; DEA regulations require that written prescriptions must be manually signed by the practitioner prescribing the controlled substance. In 1999, in response to requests from the regulated community, DEA began to examine how to revise its regulations to allow the use of electronic systems within the limits imposed by the statute and mindful that the records must be admissible in legal actions.

There is a strong foundation for electronic prescriptions that has been developed by HHS' Centers for Medicare and Medicaid Services (CMS) and industry. The challenge is building from this foundation a secure system for electronic prescriptions of controlled substances.

After an exhaustive review of current industry practices at the time, including practitioners' and pharmacies' use of computer technology, diversion concerns, and other issues, DEA developed three standards which it believed, and continues to believe, are critical in any electronic prescribing of controlled substances:

- Authentication: The system must enable a recipient to positively identify the signer and subsequently demonstrate to a third party, if needed, that the signer was properly identified.

- Nonrepudiation: The system must ensure that strong and substantial evidence is available to the recipient of the signer's identity, sufficient to prevent the signer from successfully denying having signed the data. This criterion includes the ability of a third party to verify the origin of the document.

- Record integrity: The system must ensure that the recipient or a third party can determine whether the document has been altered following signature.

Because the law requires tighter controls for controlled substances than for other prescription drugs, an effective and secure electronic prescription system for controlled substances must minimize authentication concerns and maintain record integrity.

DEA is committed to its responsibilities under the CSA, as well as its obligations to issue regulations for the use of electronic prescriptions for controlled substances. DEA will continue our efforts to move the rulemaking for electronic prescriptions of controlled substances through the clearance process for submission to OMB pursuant to Executive Order 12866.

#### Conclusion

DEA is keenly aware that pharmaceutical controlled substances are vital tools for the medical community. DEA also is aware that various public and private entities are striving to leverage modern-day technology to streamline its business practices. DEA supports the responsible adoption of electronic prescriptions for controlled substances in a manner that will meet statutory obligations and minimize the risk of diversion. However, in the absence of appropriate controls, allowing electronic prescriptions for controlled substances would certainly exacerbate a growing epidemic of prescription drug abuse in the United States. It is essential that the rules governing the electronic prescribing of controlled substances do not undermine the ability of federal, state, and local law enforcement to identify and prosecute those who engage in diversion and put our citizens at risk.

1 Kaiser Family Foundation, Prescription Drug Trends, May 2007 p. 2

2 Federal Register: March 5, 2001 (Volume 66, number 43)