

**DEA Hearing**  
**July 11-12, 2006**  
**Crystal City Marriott, Arlington, VA**

My name is Danna Droz. I am here today representing National Association of State Controlled Substances Authorities (NASCSA), as Chairman of the Executive Committee.

NASCSA is an independent, non-profit, educational organization. Our membership consists of state agencies from 43 states, which are responsible for the scheduling of controlled substances and administering, or enforcing the state laws related to controlled substances. Many of the agency representatives are also health care professionals.

NASCSA's primary purpose is to prevent and control drug abuse, yet ensure that controlled substances are reasonably available to those persons who have a true medical need for these drugs. NASCSA maintains a working relationship with both the federal Drug Enforcement Administration (DEA) and the Substance Abuse Mental Health Services Administration (SAMHSA) on issues related to the federal and state controlled substances acts.

Today we are here to discuss electronic prescriptions as the concept relates to controlled substances. Every state has laws that regulate prescriptions in general and additional, more stringent requirements for prescriptions for controlled substances. As state regulators, we support the concept of electronic prescriptions. However, we are not convinced that the

standards currently used for electronic prescriptions for non-controlled substances, i.e. legend drugs, are adequate, thus, and should not be extended to electronic prescriptions for controlled substances. We must either strengthen the requirements for all prescriptions or create additional requirements for prescriptions for controlled substances.

Some documents require greater security than other documents.

Businesses often use electronic documents to conduct many aspects of business including contracts, especially since the passage of the e-sign law. But certain documents still have to be on paper. A birth certificate is the gateway to a driver's license, a social security number, or a passport. I have yet to see an electronic birth certificate that is acceptable for getting one of these other documents. That is because the value of the information inherent in a birth certificate is so high that it becomes extremely important that the document be genuine.

Prescriptions for controlled substances are similarly valuable. A prescription is not simply a health record but it is a lawful order for a dangerous drug. The holder of a prescription for Vicodin® or OxyContin® can obtain a product that can be resold for many times its original cost. On the other hand the product can also provide relief from painful medical conditions. As health care professionals, we want patients with legitimate medical needs to be able to get the treatment and relief they deserve. Therefore, it is extremely important to distinguish between genuine prescriptions and forged, altered, or fraudulent documents. We must ensure that the prescriptions used are genuine. Notice that I said "genuine", not "paper".

We need to be able to use electronic prescriptions for controlled substances. However, the requirements for prescriptions for controlled substances need to be more rigorous than those for other prescription drugs because:

- The drugs are different,
- The prescribers are different,
- The record keeping and security are different,
- The liability is different, and therefore,
- The responsibilities are different.

**Controlled substances are not like other prescription drugs.**

Both federal and state laws describe controlled substances in terms of their potential for abuse, either physical or psychological, or their potential to produce addiction. Every drug listed as a controlled substance is reviewed, not only by DEA, but also by HHS, for an assessment of its abuse or addiction liability. Antibiotics, antihypertensives, and antihyperlipidemics, are not subject to such a review because they have never been prone to abuse and no person has ever become addicted to them.

**Prescribers of controlled substances have requirements that are more stringent.**

There are dozens of types of health care professionals. Some are authorized to prescribe drugs but this may or may not include the authority

to prescribe a controlled substance. Even when the authority is granted, sometimes additional restrictions are imposed such as

- A nurse practitioner may be allowed to prescribe certain drugs but not others;
- An optometrist may be limited to prescribing a 24 hour supply of controlled substances; or
- A physician assistant may be able to authorize a refill but may not initiate therapy.

Then, after a state grants the authority under the licensure provisions, that practitioner must obtain a DEA registration. This is just further evidence that prescriptions for controlled substances are not like prescriptions for other drugs such as antidepressants.

**The recordkeeping and security for controlled substances is more stringent.**

Manufacturers, distributors, practitioners, and pharmacists are required to meet security requirements and maintain separate records for every gram of raw material or each dosage unit of a controlled substance that they handle. Even the disposal of the left over raw materials or expired products is highly regulated.

Manufacturers and distributors are required to store controlled substances in a secure location. DEA regulations specify the type of safe or cage surrounding the drugs and they inspect the alarm system every year. The records have to be visually or physically separate from records for other

prescription drugs. The business has to insure that the purchaser is also registered with DEA and must deliver the drugs only to the address that is shown on the purchaser's DEA certificate. Finally, the manufacturer or distributor must report many of the sales to DEA through the ARCOS system. None of this is required for heart drugs or thyroid drugs.

Practitioners and pharmacists who use controlled substances to treat patients have their own set of federal and state laws about security and recordkeeping. The locations where the drugs may be stored is regulated and access to the storage area must be limited. In addition, they must inventory the stock periodically, record every dose and which patient received it. Not only the patient name, but also the patient's address, the date it was given, who authorized it, and the quantity used. Then, they are subject to audit by state or federal authorities. There are no such requirements for security for and accountability of allergy medications.

**The liability is stricter and therefore the responsibilities are more rigorous.**

This responsibility is so important that it is written into federal law and into many state laws, as well. The Code of Federal Regulations states that both pharmacists and practitioners have a corresponding responsibility to insure that every prescription for a controlled substance is issued and dispensed to a legitimate patient, to treat a legitimate medical condition, by a practitioner in a legitimate practitioner-patient relationship. Federal law does not require this for diuretics, cancer chemotherapy, or nuclear pharmaceuticals. Why? Because there is little incentive for a person to

consume those drugs unless they need them. And even then, it is a challenge to get patients to take those drugs as prescribed. There are unpleasant side effects; they are expensive; and the patients sometimes forget. But controlled substances are a different story. There are many people who will consume or at least purchase narcotics, sedatives, or stimulants even when they don't have a medical condition. For them, the undesirable side effects are irrelevant. If the cost is high, they can always sell a few to friends or neighbors. For these reasons and more, the law has always held prescriptions for controlled substances to a higher standard.

**Electronic prescriptions need to be available as an option to prescribers.**

Electronic prescriptions can be a secure and cost effective means of delivering a prescription to a pharmacy. More and more physician offices are utilizing computers to maintain records. The easy availability of the Internet facilitates sending the prescription directly to the pharmacy of the patient's choice, rather than relying on the patient himself or herself to delivery it. In theory, it could eliminate forgery, alteration, and loss.

Electronic prescriptions also nearly eliminate the confusion caused by hand written prescriptions. The need for accuracy in prescriptions has been the subject of a great deal of research even when the results are intuitive.

Since 2000, DEA and NASCSA have been discussing electronic prescriptions for controlled substances. When DEA first raised the topic,

the NASCSA members had concerns about these electronic documents. While there are problems with paper prescriptions, the requirements in place created some relative assurances for the pharmacists.

The pharmacist needs to know certain things from every prescription – who the patient is, who the prescriber is, what drug is prescribed and how should the patient take the drug. But if the prescription is for a controlled substance, the pharmacist must also determine:

- whether the prescriber is authorized by state law;
- Whether he/she has a valid DEA registration;
- Whether the patient has a legitimate medical condition;
- Whether the prescriber is treating within the scope of his/her licensure; and
- Whether the treatment is within the usual course of the prescriber's professional practice.

**Electronic prescriptions for controlled substances need to have additional safeguards beyond what is currently allowed for other prescriptions.**

In the early discussions of electronic prescriptions, the regulators were concerned about electronic prescriptions because of the abuses we had seen with paper and telephone prescriptions for controlled substances. Since DEA regulates paper, telephone, and fax prescriptions, we wanted DEA to ensure that the electronic prescriptions would be at least as reliable as paper prescriptions. We also felt that it was important to have a federal

standard so that the technology companies knew basically what was required, even though individual states may have small differences. Ideally, the federal standard will provide sufficient security that states will not feel the need for additional protection.

While the technology could vary, it is clear that there are some basic requirements for any prescription for a controlled substance.

- Identification of the prescriber – who is sending this prescription?
- Verification of the prescriber's authority – is this a valid DEA # for this prescriber?
- Integrity (No alteration) of the prescription – has there been any change in the prescription while it was in cyberspace?
- Non-repudiation of the prescription by the prescriber – what prevents a dishonest doctor from issuing an electronic prescription and then, if confronted by law enforcement denying, that he/she did so?
- Non-duplication of the prescription i.e. Once a prescription is plucked from cyber space, it can only be filled one time. Thus, the prescription as dispensed should be unique.

There can be multiple technologies used to provide these characteristics to electronic prescriptions. The important thing is that each characteristic accompanies each and every prescription for a controlled substance.

On the surface, one might view standard electronic prescriptions and say that they embody each of the characteristics mentioned. Based on our experience, we expect a larger number and more elaborate scams with

electronic prescriptions unless strict protections are in place. Even then, we merely hope to minimize the number of illegal electronic prescriptions.

Identification of the prescriber – One of the biggest diversion problems in recent years involves ancillary personnel in the pharmacy or in the prescriber's office. We all know that a person who is technologically sophisticated can do amazing things with a computer. Without strict transmission standards, it will be very easy to transmit a document to multiple pharmacies that has the same appearance as one that actually came from the prescriber. Voila! Forged electronic prescriptions.

Verification of the prescriber's authority – State license numbers and DEA registration numbers have specific formats. This information is very easy for dishonest people to obtain either from other prescriptions, from the Internet, or by purchase. Consequently, anyone with a computer can create a very realistic prescription blank for a fictitious prescriber. I once worked a case where a person was creating paper prescription blanks on a home computer. The fakes were so good that even the physician himself could not distinguish the fakes from the one he obtained from a local printing company. Why do we think that electronic prescriptions will be any safer unless it is required?

Integrity of the prescription – Once a prescription leaves the practitioner's hand or mouth, it is available for alteration. With paper or oral prescriptions, there are red flags that indicate to a pharmacist that further validation is needed. A pharmacist is expected to notice multiple ink colors, multiple handwritings, unusual format of a written or oral prescription. With an

electronic prescription, there are no similar warning signals. The pharmacist must be assured that the electronic prescription he or she receives has not been modified in any way since the practitioner created it. Electronic can be another word for invisible. Since any electronic alterations will not be visible, the process of transmitting a prescription for a controlled substance must include assurances of integrity.

Non-repudiation is another term for “positive identification”. I have been involved in investigations of illegal prescriptions where the prescriber simply stated that he/she did not write the prescription, despite other evidence to the contrary. Once a practitioner disavows a prescription, the investigation becomes extremely difficult and expensive. We’ve all had experience with computer viruses that make e-mails appear as though they originated from a trusted source when, in fact, their origin may be a foreign country or a prison. A prescription for a controlled substance is so valuable that once a prescriber authorizes it, that practitioner cannot have the ability to later deny the action. Therefore, an electronic prescription for a controlled substance needs more positive identification than typically accompanies an electronic document. The prescription should be positively linked to the prescriber.

**We need strict federal standards for electronic prescriptions for controlled substances.**

I have been a regulator in three different states. Regulators receive phone calls on a regular basis about electronic prescriptions for controlled substances. The industry has answered the needs of medicine and

pharmacy for electronic medical records, electronic billing records, and electronic business records. It is time to enable the health care professionals to fully utilize the advantages of electronic prescriptions for ALL drugs. But the current technology for electronic prescriptions is not sufficient for prescriptions for controlled substances.

Practitioners and pharmacists should not have to be cops. We need to protect them by setting standards for electronic prescriptions for controlled substances that are as secure as reasonably possible. Health care professionals also need to be assured that regulators and law enforcement can do the job of catching the bad guys so that they can do their job of treating patients.

Federal standards for transmitting prescriptions for controlled substances are overdue. But lax standards are worse than none at all. States have the right to impose criteria that are more stringent than federal law. If the federal standards are less stringent than state law, we will have to protect our citizens by continuing to require adherence to stricter state standards.

Thank you.