Drug Kits and OMDs

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Drug Kits

Part and parcel of the practice of EMS

Virtually synonymous with ALS care in the field

Still confusing and controversial …

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Virginia Board of Pharmacy

Come under the responsibility of the Virginia Board of Pharmacy (BOP)

The BOP regulates purchasing, distribution, storage, prescribing, dispensing and administration of medications in the Commonwealth

http://www.dhp.virginia.gov/Pharmacy/default.htm

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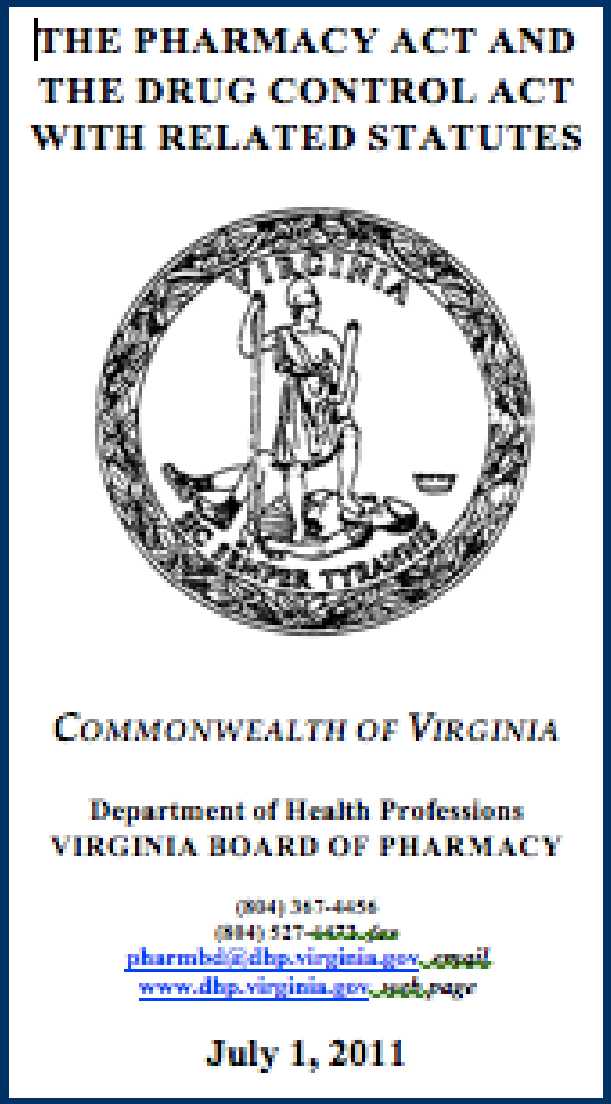
THE PHARMACY ACT AND
THE DRUG CONTROL ACT
WITH RELATED STATUTES

COMMONWEALTH OF VIRGINIA

Department of Health Professions
VIRGINIA BOARD OF PHARMACY

(804) 367-4456
(804) 527-4422 fax
pharmbd@dhp.virginia.gov email
www.dhp.virginia.gov web page

July 1, 2011

The drug laws of Virginia are available though the BOP on-line:

http://www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm

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Schedules

- Prescription medications have been divided into schedules
  - The Controlled Substances Act (CSA) was enacted as part of the Comprehensive Drug Abuse and Prevention Control Act of 1970
  - Created 5 schedules of prescription drugs
  - Drugs are generally added to schedules by the DEA and the FDA

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Schedule I

High potential for abuse, no accepted medical use in the U.S.

Schedule II

High potential for abuse, accepted for medical use in the U.S., abuse may lead to severe psychic or physical dependence

Schedule III

Potential for abuse is less than above, accepted medical use, abuse may lead to moderate or low physical dependence or high psychic dependence

Schedule IV

Low potential for abuse relative to III, accepted medical use, limited physical or psychological dependence

Schedule V

Low potential for abuse relative to IV, accepted medical use, limited physical or psychological dependence relative to IV

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The Commonwealth further defines Schedule VI:

§ 54.1-3455. Schedule VI.

The following classes of drugs and devices shall be controlled by Schedule VI:

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.

2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.

3. Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____." (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

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- The DEA therefore defines Schedules I-V
  - Any medication not specified is then considered "unscheduled" by the DEA (Federal Government)
- Virginia further specifies Schedule VI, which includes all medications that the DEA considers "unscheduled"
  - These medications and supplies are thus considered "controlled" in Virginia

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Examples of commonly used drugs in EMS and their schedules:

- Schedule II
  - Injectable narcotics such as morphine, fentanyl
- Schedule III
  - Ketamine
- Schedule IV
  - Injectable benzodiazepines

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- The majority of the medications used in EMS practice are therefore “unscheduled” by the DEA
- They are almost always Schedule VI under Virginia BOP regulations
  - Examples include IV fluids and supplies, albuterol, nitroglycerine, D50, anti-arrhythmic drugs, vasopressors, etc.
- One exception is epinephrine, which may by personally possessed by providers certified as an EMT or above, by a specific Virginia law

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Participation by pharmacies in an EMS drug kit program is governed by Virginia BOP regulations

The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

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2. The drug kit is sealed in such a manner that it will deter theft or loss of drugs and aid in detection of such.

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3. Drugs may be administered by an emergency medical technician upon an oral order or written standing order of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the technician and shall be signed by a medical practitioner. Written standing orders shall be signed by the operational medical director for the emergency medical services agency. The emergency medical technician shall make a record of all drugs administered to a patient. This administration record shall be signed by the medical practitioner who assumes responsibility for the patient at the hospital. If the patient is not transported to the hospital or if the attending medical practitioner at the hospital refuses to sign the record, a copy of this record shall be signed and placed in delivery to the hospital pharmacy who was responsible for that kit exchange by the agency's operational medical director within seven days of the administration.

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4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year.

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5. The record of the drugs administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

6. Intravenous solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the drug kit.

http://lis.virginia.gov/cgi-bin/legp604.exe?000+reg+18VAC110-20-500

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One-for–one exchanges

- When the agency exchanges or obtains a replacement for a prescription drug in the ED without going through the pharmacy
  - The drug kit is resealed by the provider/agency
  - Allowed for schedule VI drugs only
    - Federal (DEA) law/regulation does not allow exchange of Schedule II-V drugs
  - Requires a CSRC because the agency is considered to be “in possession” of the drugs when they re-seal the drug kit without the pharmacy’s involvement

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- Virginia BOP regulations allow for the storage of IV solutions and associated supplies, such as IV tubing and catheters, outside of the sealed drug kit
  - These supplies must still be secured while on EMS units, and stored securely when not in use/on units

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Controlled Substances Registration Certificate (CSRC)

- Application is available through the Virginia Board of Pharmacy
  - http://www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm#csr
  - CSRC's are location and agency specific
  - They require an inspection by the BOP prior to being issued
  - The BOP may re-inspect the agency at any time

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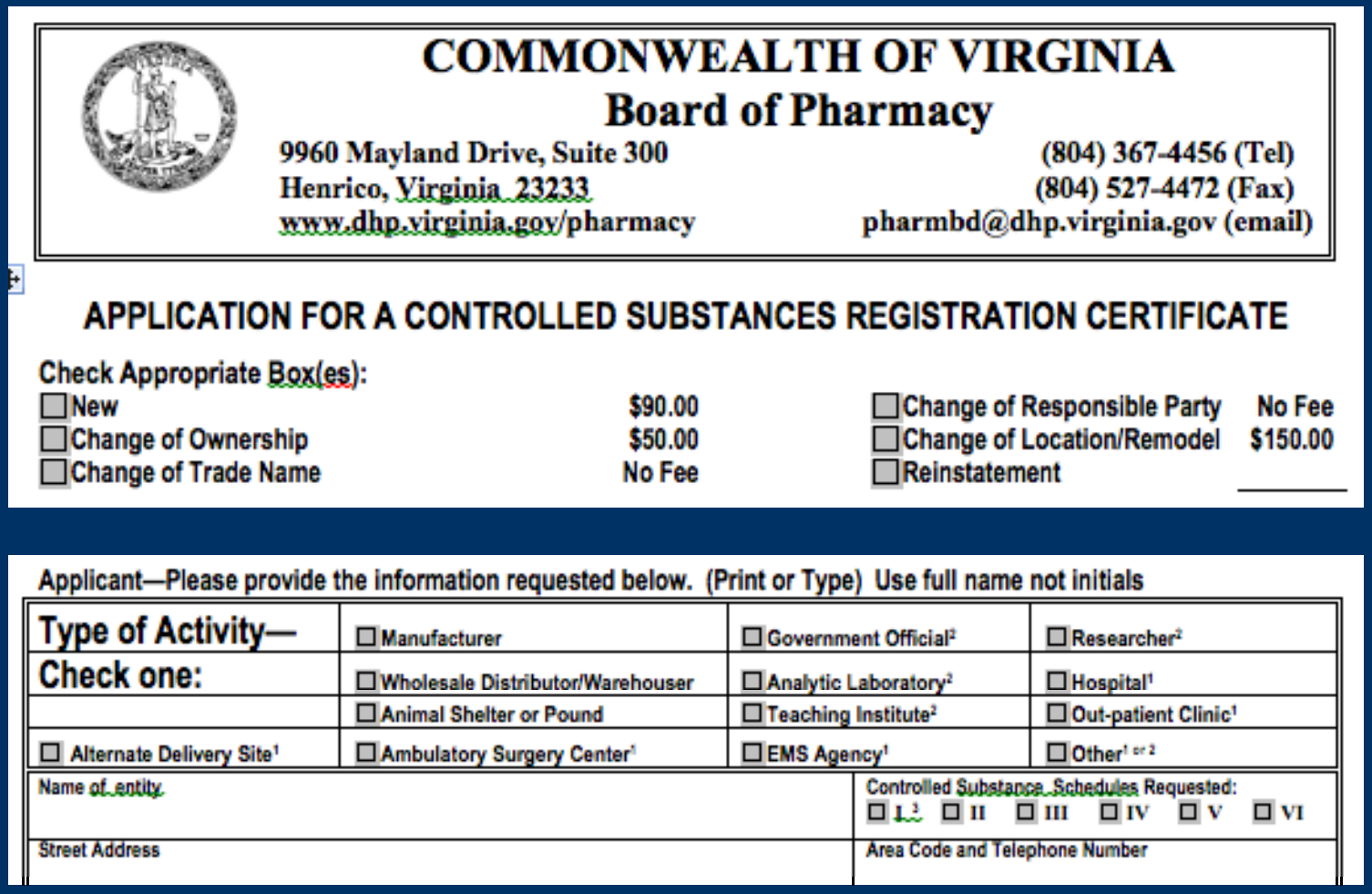

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
www.dhp.virginia.gov/pharmacy

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)
pharmbd@dhp.virginia.gov (email)

APPLICATION FOR A CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Check Appropriate Box(es):

☐ New	$90.00	☐ Change of Responsible Party	No Fee
☐ Change of Ownership	$50.00	☐ Change of Location/Remodel	$150.00
☐ Change of Trade Name	No Fee	☐ Reinstatement	_____

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials

Type of Activity—	☐ Manufacturer	☐ Government Official[2]	☐ Researcher[2]
Check one:	☐ Wholesale Distributor/Warehouser	☐ Analytic Laboratory[2]	☐ Hospital[1]
	☐ Animal Shelter or Pound	☐ Teaching Institute[2]	☐ Out-patient Clinic[1]
☐ Alternate Delivery Site[1]	☐ Ambulatory Surgery Center[1]	☐ EMS Agency[1]	☐ Other[1 or 2]

Name of entity	Controlled Substance Schedules Requested: ☐ I[3] ☐ II ☐ III ☐ IV ☐ V ☐ VI
Street Address	Area Code and Telephone Number

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FOR BOARD USE ONLY: Acknowledgement of Inspection Request	
Assigned Inspection Date[5]:	

1. **Entities applying under this activity code must submit a description of the processes/business practices for which this registration is being sought, and must have a supervising practitioner as follows:**
   A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:
   - ☐ In a hospital without an in-house pharmacy, a pharmacist shall supervise.
   - ☐ In an emergency medical services agency, the operational medical director shall supervise
   - ☐ For any other person or entity approved by the board, a practitioner of pharmacy, medicine, osteopathy, podiatry, dentistry, or veterinary medicine whose scope of practice is consistent with the practice of the person or entity and who is approved by the board shall provide the required supervision.
2. **Persons applying under this activity code must submit, with the application, a protocol which specifically names the controlled substances to be used and provides details as to the intended use of these controlled substances within the work. Additionally, persons applying under this activity code must provide documentation showing competence (curriculum vitae, educational credentials, professional licensure, training documentation) to use the controlled substances within the scope of this activity.**
3. **Schedule I must be approved by DEA prior to Board approval.**
4. **If supervising practitioner is a pharmacist, give DEA number of the provider pharmacy supplying drugs.**
5. **A 14-day notice is required for scheduling an opening or change of location inspection.**
   An inspector will call the responsible party prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at (804) 367-4612 to verify the inspection date with the inspector.

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DEA numbers

A DEA number is required of all practitioners who will prescribe, purchase, store and/or sell controlled drugs

- From the DEA perspective, “controlled” is anything on Schedules I-V
- From the Virginia BOP perspective, “controlled” is anything on Schedules I-VI

http://www.deadiversion.usdoj.gov/faq/general.htm#rx-2

http://www.deadiversion.usdoj.gov/drugreg/faq.htm

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EMS Medical Directors should seriously consider having separate DEA numbers if they have agencies that are purchasing and storing medications that are on the DEA schedule

- If they are only purchasing/storing medications and supplies that are unscheduled by the DEA (Virginia schedule VI) then separate DEA numbers are probably not as much of an issue

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If the provider has a single DEA number that is used for clinical practice as well as EMS activities, and there is as issue that results in action related to that number, such as suspension, it could then affect all aspects of the medical directors practice(s).

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Theft or loss of drugs

Virginia BOP requirements

http://www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm#DEA

from Code of Virginia, Drug Control Act
§54.1-3404

...

E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs. Within thirty days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

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Drug Kits
Theft or loss of drugs
Virginia BOP requirements

Please use the attached DEA 106 form for the complete reporting of theft or loss of drugs. Distribute copies and keep a copy as follows:

1 Copy: **Virginia Board of Pharmacy**
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
804/367-4456

2 Copies: **Drug Enforcement Administration**
Techworld Plaza
ATTN: Drug Diversion
800 K Street, N.W., Suite 500
Washington, DC 20001
202/305-8888

1 Copy: **To be maintained at location of drug stock for your records**

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Theft or loss of drugs

DEA requirements

http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

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Theft or loss of drugs

DEA requirements

https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp

Although the paper version is still available, DEA encourages registrants to use the updated electronic version. A registrant can still receive a paper copy of the updated form by writing to DEA Headquarters, Attn: Registration/ODR, P.O. Box 2639, Springfield, VA 22152.

- **DEA Form 106 On-line** -
  Data will be entered through a **secure connection** to the online application system. **Your web browser must support 128-bit encryption.**
  - See Federal Register Notice - **Reports by Registrants of Theft or Significant Loss of Controlled Substances** for more information.
- **Letter detailing change in reporting requirements**

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- Purchase of Schedule II medications requires additional record keeping
  - Form 222 must be completed by the distributor and the recipient of the medications, and a copy sent to the DEA
    - Records must be kept documenting the ordering and receipt of Schedule II drugs including package size, number of units, and strength/concentration
  - Information:
    - http://www.deadiversion.usdoj.gov/faq/dea222.htm
  - Forms:
    - https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp

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Electronic signatures

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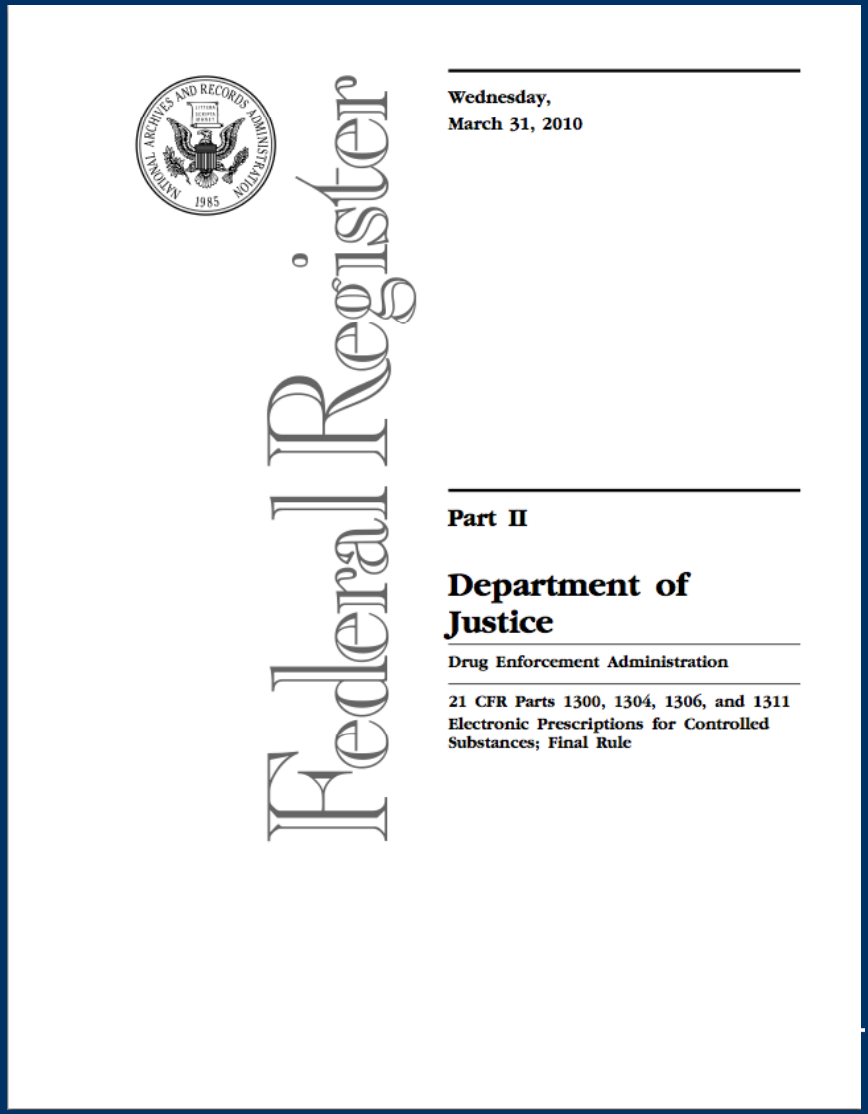
Electronic signatures

http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf



Federal Register

Wednesday,
March 31, 2010

Part II

Department of Justice

Drug Enforcement Administration

21 CFR Parts 1300, 1304, 1306, and 1311
Electronic Prescriptions for Controlled Substances; Final Rule

Drug Kits

At this point in time:

- Electronic signatures can be used when the software platform used meets Federally specified levels of security to guarantee the legitimacy of the signature
- The Pharmacist in Charge (PIC) of a particular pharmacy has the ability to choose whether or not to accept electronic signatures

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Check List for Drug Storage

- Make sure that your responsibilities for drug purchasing and storage are reflected in your agency contract
  - Make sure that the agency insurer also specifically acknowledges that medications will be purchased and stored by the agency
- Ensure that there is a secure, environmentally controlled area for storage
  - Access and entry should be controlled
    - Preferably, individual access should be identified – electronic access versus a single combination for everyone
- Ensure that the agency has an identified position responsible for the purchasing/storage/security of prescription drugs

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Check List for Drug Storage

- Ensure that the wholesaler/supplier that the agency will use is licensed to sell prescription drugs in Virginia
- The purchasing of drugs for the agency will require a DEA number
  - It is strongly encouraged that the OMD acquire a separate DEA number for each EMS agency that is purchasing/storing/distributing drugs on the DEA schedule, and not use their primary practice DEA number
- Ensure that the agency has CSRC permits for the storage locations
  - These permits are location specific
  - Multiple storage sites would require separate permits

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