

EMS Scheule II-V Record Keeping Requirements

Information contained in this document is based on the **Protecting Patient Access to Emergency Medications Act of 2017**. The DEA final rule supporting the act is pending. Then language contained is based on Federal Register/Vol. 85, No. 193/Monday, October 5, 2020/Proposed Rules

DEA	Virginia Board of Pharmacy CSR/OEMS
Maintain records of the EMS personnel whose state licensure or certification gives them the ability to administer controlled substances CII-V in compliance with their state laws.	Documents which describe the conditions and extent of the responsible party's authorization to dispense controlled substances for each EMS provider employed by or practicing at an EMS agency holding a CSR. Such documents shall be maintained in a readily retrievable manner and be available for inspection and copying by authorized agents of the board. Examples of such documentation include but are not limited t protocols, practice guidelines or practice agreements.
Schedule II-V records are required to be maintained for at least 2 years from the date of such inventory or records.	Schedule II-V records are required to be maintained for at least 2 years from the date of such inventory or records.
Schedule II records shall be maintained separately from Schedule III-V.	Inventories of Schedule II shall be maintained separately from all other records and shall be kept in chronological order by the date of administration.
Initial inventory: Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances,. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.	Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory. An inventory taken by use of an oral recording device shall be promptly reduced to writing and maintained in a written, typewritten or printed form. Such inventory shall be made either as of the opening of business or as of the close of business on the inventory date.
Biennial Inventory: After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.	After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.
	Records of all controlled substances that are received, administered or otherwise disposed of,
Require maintenance of records of deliveries of controlled substances CII-V between all locations of the agency.	Records of deliveries of controlled substances between all locations of an EMS agency or regional EMS council pursuant to the controlled substance registration.
Records maintained, either electronically or otherwise, at each registered and designated location of the agency	All records shall be maintained at the same location as listed on the CSR registration, or if maintained in an off-site database, retrieved and made available for

<p>where CII-V involved are received, administered or otherwise disposed of</p>	<p>inspection or audit within 48 hours of a request by the board of an authorized agent.</p>
<p>EMS personnel who administers or disposes of CII-V substances to a patient in the course of providing emergency medical care must record the name of the CII-V substance and detailed information surrounding the administration of the substance (name of the substance, date, identification of patient)</p>	<p>A record for each dose of drug in Schedule II-VI administered and destruction or partially administered drugs in the course of providing emergency medical services must be maintained. Destruction of partially used Schedules II-V must be maintained. Destruction of partially used Schedules II-V drugs shall be accomplished by 2 persons, one of whom shall be the EMS provider and the other shall be a second EMS provider, pharmacist, nurse, prescriber, or pharmacy technician. Documentation shall be maintained in the EMS agency or designated location of an EMS agency or regional council for a period of 2 years from the date of destruction</p>
<p>Maintain records of CII-V substances delivered between registered and designated locations of the agencies. These records, for example, should include the name of the controlled substance(s), finished form, number of units in the commercial container, date delivered and the address of the EMS agency location where the controlled substances were delivered.</p>	<p>For each delivery of a drug in Schedules II-VI between a designated location and a registered location: name of the drug, finished form of the drug, number of units, date of delivery, name and address of the designated location to which the substance is delivered.</p>
<p>In the event of theft or loss of CII-V substances, registrants must report such occurrence in accordance with the theft and loss reporting requirements of 21 CFR part 1304.</p>	<p>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.</p> <p>Within 30 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.</p>
<p>Designated locations of an EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response.</p>	<p>Designated locations of an EMS agency must notify the registered location of their EMS agency within 72 hours of receiving Schedule II-V medications from a hospital for the purpose of restocking an EMS vehicle following an emergency response or from another designated location of the same agency.</p>

References:

<https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFR9944e94ba5f1eb0/section-1304.11>

