NAAMTA Internal Training Material
Controlled Substances

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Glossary

APPENDIX A – COMMON MEDICATIONS IN TRANSPORT DRUG BAGS

Q. What does DEA stand for?

A. The **Drug Enforcement Administration** (**DEA**) is a United States federal law enforcement agency under the U.S. Department of Justice, tasked with enforcing the U.S. government's laws and regulations relating to controlled substances within the United States.

Q. Who must register with the DEA?

A. Anyone requesting authority to dispense and administer controlled substances must register with the DEA through the Office of Diversion Control. For our purposes, registrants apply as either individual practitioners or hospital/clinic.

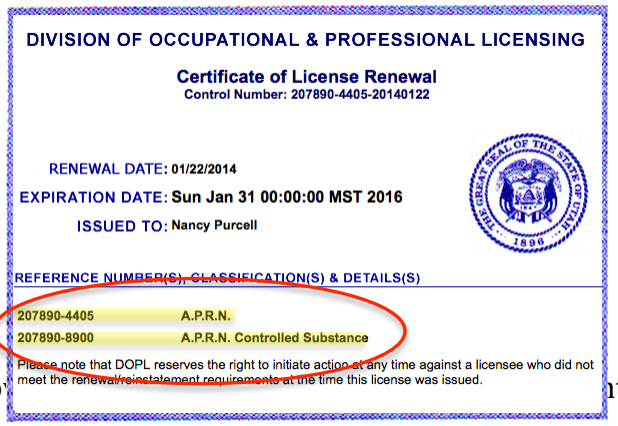
- **Individual practitioners** would be the medical director for the program. An Individual Practitioner can be an MD, DO, dentist, veterinarian, PA, NP,
  - He/she must have a separate DEA certificate for each base within the program.
  - If the base is a *non-hospital* based program, the medical director will hold the DEA certificate and be listed by the doctor's name as well as the name, address of the base. (ie, "John Doe, MD – Ajax Medical Service, 123 Main St., Anywhere, State, 12345)***. A DEA certificate must be held for <u>each</u> base within the program.***
- **Hospitals** would register as an Institutional Practitioner.
- Certificates are valid for 3 years. They are given a certificate with their DEA number on it.
- An agent or employee of a registered dispenser is *not* required to register with the DEA.
- The registrant keeps the certificates. DEA numbers need to be kept secure and *not* for public display.
- ***<u>All programs must comply with federal AND state Controlled Substance Guidelines and Registration.</u>***

Q. Is the DEA number and state professional license the same thing?

A. No. They are two different numbers. A practitioner can hold a state professional license with or without privileges to prescribe controlled substances. If a practitioner requests controlled "prescriptive privileges", they must apply to the state department of professional license for that additional privilege.

Each state varies as to whether the practitioner holds 1 license or 2 licenses. The DEA Office of Diversion Control maintains a list of what professional licensing is required for each state. (Utah is one of the states that require a separate professional license to prescribe controlled substances. See Nancy's Utah nursing license and DEA certificate for examples:)

(***State professional nursing license***)


DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

Certificate of License Renewal
Control Number: 207890-4405-20140122

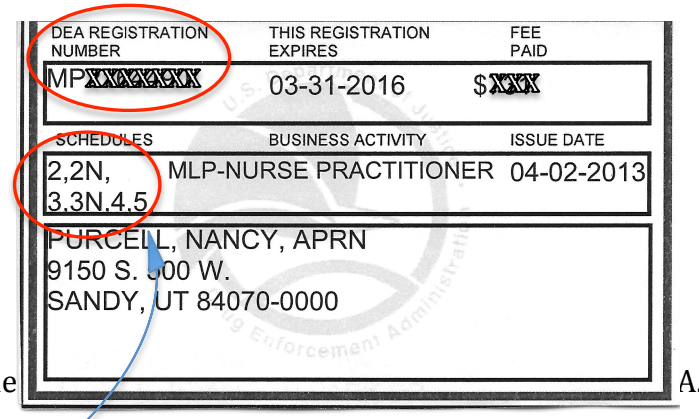
RENEWAL DATE: 01/22/2014
EXPIRATION DATE: Sun Jan 31 00:00:00 MST 2016
ISSUED TO: Nancy Purcell

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAILS(S)

207890-4405 A.P.R.N.
207890-8900 A.P.R.N. Controlled Substance

Please note that DOPL reserves the right to initiate action at any time against a licensee who did not meet the renewal/reinstatement requirements at the time this license was issued.

(***DEA Certificate w/ number***)


DEA REGISTRATION NUMBER: MPXXXXXXX
THIS REGISTRATION EXPIRES: 03-31-2016
FEE PAID: $XXX
SCHEDULES: 2,2N, 3,3N,4,5
BUSINESS ACTIVITY: MLP-NURSE PRACTITIONER
ISSUE DATE: 04-02-2013
PURCELL, NANCY, APRN
9150 S. 500 W.
SANDY, UT 84070-0000

Ho[illegible]t the [illegible]A.

Q. How do I know what controlled substances privileges are being authorized?

A. It will be listed on the DEA certificate.

Q. Can someone besides the registrant/practitioner use the DEA number?

A. A registrant may authorize one or more individuals, whether or not located at his/her registered location, to place an order for Schedule II controlled substances on the registrant's behalf ***by executing a power of attorney (PO)*** for each such individual.

- The power of attorney is to be retained in the files with the DEA Forms 222.
- The power of attorney may be revoked by the registrant in writing.

Q. Are all drugs considered controlled substances?

A. No. Drugs fall into several different categories:

- Over-the-counter (OTC) for which no prescription is required;
- Legend prescription drugs that require a prescription;
- Specific prescription drugs that are deemed to be controlled substances and a prescription is required from a person with a DEA registration. *(narcotics, steroids, amphetamines, benzodiazepines)*

Q. What are controlled substances?

A. A controlled substance is a drug or other substance that come under the jurisdiction of the DEA and are listed in one of five schedules or categories. Controlled substances are designated as Schedule I - V (C-I, C-II, C-III, C-IV and C-V) according to their medical use, potential for abuse, and safety or dependence liability.

Schedule I (or C-I) have a high potential for abuse and are not accepted for medical use in the U.S., except under certain research criteria. Schedule II-IV are approved by the FDA for therapeutic use. *Not all controlled substances are narcotics but all narcotics **are** controlled substances.* Those medications that are not classified as controlled substances have a "Schedule-N" classification. Appendix B is a list of the most common drugs that will be found in transport program's drug bags, along with their schedule classification, common indication for use and alternate brand names.

Q. What is the process by which medications are ordered?

A. Ordering controlled substances requires a DEA license. Ordering drugs can be processed by hardcopy or electronically.

- Paper-form: Schedule II (C-II) drugs must be ordered using the Controlled Substance Ordering Form **(DEA Form 222)**. It is requisitioned directly from the DEA and is required to be filled out in triplicate. *Only Schedule I/II registrants (or their attorney-in-fact) can order DEA Form 222.* The DEA Form 222 also allows the exchange of controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).
- Electronic ordering: Any registrant permitted to order Schedule II-IV controlled substances may do so electronically via the DEA Controlled Substance Ordering System (CSOS) and maintain the

records of these orders electronically for two (2) years. To utilize the CSOS, a registrant must first enroll in the DEA's CSOS.

Schedule III, IV, and V drugs, as well as other non-controlled substance medication orders, *do not* require a DEA Form 222. These drugs can be ordered directly from the manufacturer. However, they may asked to provided a copy of your DEA Registration before your order will be prepared and shipped.

Q. What are all the different DEA forms for?

A. There are several different forms used for handling controlled substances. Here are a list of the more common forms and what they are used for:

Form 41: Used to return or destroy drugs to the DEA or other acceptable recipient. (AKA Reverse Distributor)

Form 82: Notice of inspection to be conducted by DEA inspectors of controlled premises

Form 106: Report theft, loss or shortage of controlled substances

Form 222: Order form for Schedule I/II drugs. These may ***never*** be destroyed or discarded. If not used, write "VOID" across them maintained on file. If a Form 222 is lost, it should be immediately reported to the DEA.

Form 222a: Used to obtain DEA Form 222

Form 224: New application for registration for retail pharmacies, hospitals, clinics, practitioners and teaching institutions

Form 224a: Renewal application for registration

Q. How are medications to be stored?

A. Storage of medications are handled differently depending on whether they are controlled substances, non-controlled substances, refrigerated, or non-refrigerated.

- **Controlled Substance Storage:** All controlled substances must be locked. DEA specifies that they be stored:
  - In a safe or steel cabinet
  - If < 750 pounds be bolted or cemented down to prevent theft of container
  - Be equipped with an alarm or other monitoring system
  - Locked with limited access only to those authorized personnel as indicated (medical only)
    - State regulations generally require double locks.
    - Combination lock should have combo changed periodically.
  - Door hinges on the inside of room
  - Building or steel cage perimeter around premises are locked and monitored
  - Schedule II-V drugs *may be stored together* (logs just have to be separated out)
- **Non-Controlled Medications:** May be stored with Schedule III-V medications if written permission by DEA Special Agent in Charge for area.
- **Refrigerated versus Room Temperature:** Most medications are stored at room temperature ideally 68-77° F (20-28° C) or according to state and local regulations (will need to check EMS regulations for this info). Some medications must be refrigerated (ie, Ativan, surfactant preparations). Refrigerator temps should be maintained 36-46° F (2-8° C). *No refrigerated medication can be stored in room temperatures but room temperature medications can be stored in the frig without disrupting their stability.* All medications should be warmed to room temperature prior to administration to patient. Some medications (specifically Mannitol) will freeze if temperatures are too low. In climates with extreme temperatures, controls must be in place to maintain medications within proper storage range.

- **Expired Medications:** Medications should be checked monthly for expiration. If medications are found to be expired, they must be labeled "EXPIRED" and placed somewhere that will avoid them becoming accidently administered to the patient. They *can* be stored with other medications but must be labeled. However, it is not recommended to store expired drugs along side other stock drugs to avoid confusion. ***However, Schedule II, III-V must be maintained under required locked security until they are disposed of.***

Q. What are the regulations concerning the transfer of drugs?

A. Drugs can be transferred between any DEA-licensed registrant or LPOA-designated individual(s).[i] Controlled substances may be transferred within the following restrictions:

Schedule II drugs	DEA Form 222
Schedule III-IV drugs	Transfer Form
Non-controlled medications	NAAMTA requires a Transfer Form
Reverse Distribution	DEA Form 41

- **Can Transfer**
  - ✓ From base to company-owned airport storage room (and visa versa) without any extra documentation.
  - ✓ Only DEA registrants, or individuals authorized by POA to act on behalf of the registrant, can pick up/return orders of controlled substance inventory stock to/from a supplier (i.e., pharmacy, corporate office) provided:
    - Individual presents authorized copy of registrant-signed POA
    - Presents legal photo ID
    - Copy of applicable controlled substance form (see table above)
    - Original sealed shipping container with appropriate labeling

- **Cannot Transfer**
  - ✓ Drugs ordered for stock at a doctor's office to be dispensed to individual patients cannot be used as inventory drugs by the transport base.

Q. How are controlled substances to be disposed?

A. Every milliliter and milligram of *controlled substances* must be accounted for. There are two (2) ways in which drugs are disposed of—wasting (or destruction) and secondly, return distribution or transfer to another DEA registrant.

- **Wasting:** In the event that an entire syringe or open ampule of a controlled substance is not administered, the unused portion must be wasted or destroyed beyond reclamation. "Wastage" may be documented on a medication administration log or on a separate document. When controlled substances are wasted, the following documentation must occur:
  1. DEA registrant's name and address
  2. Date of wastage
  3. Time of destruction/wastage
  4. Patient's name
  5. Drug name, strength, and quantity destroyed
  6. Reason for the wastage
  7. Signatures (2) medical crewmembers performing the destruction/wastage

When drugs are wasted or destroyed, they must be destroyed beyond reclamation. ***Non-controlled medication does not need to be witnessed or accounted for.*** However, it is recommended that non-controlled medications be disposed of in an environmentally responsible manner.

- **Transfer or Return Distribution:** Controlled substances in vials that are not needed or have expired are to be suitably stored until disposed of.
  - **Expired:**
    - May ***not*** be destroyed on site without prior approval from the DEA.
    - Must be labeled "Expired" and returned back through a Return Distributor with DEA Form 41.
    - Return distributed controlled substances must be maintained under the same required security locks until returned or picked up. Contact your local DEA field office for a list of authorized Reverse Distributors in your area. They will provide you with a receipt to show that you transferred the controlled drugs to them.
  - **Non-expired:**
    - May either be transferred to another DEA-registered agent (another base) or returned through a Reverse Distributor with DEA Form 41.
    - Transferred Schedule II drugs require DEA Form 222, while Schedule III-V requires a Transfer Form.

Q. What recordkeeping is required for controlled substances?

A. Recordkeeping for medications differs for controlled substances and non-controlled substances/drugs. *Each and every time controlled substances change hands (change of shift, is used/restocked or drug bag found with a broken lock and relocked) an accurate drug count must be confirmed and proper documentation witness with two (2) medical crew signatures.*

There must be a paper trail of every controlled substance dosage unit from the day it was manufactured, through the distributor, to the hospital, pharmacy, EMS, practitioner or other and then ultimately to the end user or reverse distributor.

- ***DEA regulations require that all controlled substance records be maintained for two (2) years.***
- State professional licensing boards may require records to be maintained for a longer period of time.
- If a registrant chooses to use a supplier's invoice, billing record, or packing document as a record of receipt, it is that registrant's responsibility to assure that all the required information is documented on the receipt record.†
- There are five (5) different logs that must be maintained:
  1. Inventory (initial & annual) logs
  2. Change-of-shift drug count logs
  3. Medication Administration logs
  4. Wastage/Disposal/Transfer logs
  5. Temperature logs

  } DEA-required

† Shipping packages should ***NOT*** have any markings on outside indicating the contents are controlled substances.

- **Inventories:** All controlled substances must be inventoried regularly. *The inventory of Schedule II drugs must be maintained on a separate form and document than that of Schedule III—V drugs and non-controlled medications.* The following information must be documented on an inventory:
    1. Date
    2. Documentation of time of day inventory taken
    3. Drug name
    4. Drug strength
    5. Dosage form
    6. Quantity of dosage units on hand

  Inventories are conducted initially and annually. These are separate from change-of-shift inventories. All inventories should be conducted at the same time of day. There is no standardized inventory form as long as the above noted information is on the form. There must be a separate inventory form for each base. There are sample inventory forms on the internet that you may use or you may create your own.
    - **Count all controlled substances** regardless of whether they are in drug bags, set aside for destruction, transfer or expired.
    - **While the regulations do not require inventory of non-controlled drugs, it is good practice to account for ALL drugs, controlled and non-controlled.

- **Change-of –Shift Drug Counts** All base drugs are to be accounted for at the beginning and end of each shift. Count accuracy is to be witnessed by two (2) medical crew signatures—one from the departing shift and one from the oncoming shift.

- **Medication Administration** All medications administered must be documented in the patient's chart or Medication Administration Form. Companies may devise their own Medication Administration Form as long as all of the required information is documented:
    1) Date of administration
    2) Patient name or Transport #
    3) Transport #
    4) Drug name
    5) Drug strength
    6) Dosage form
    7) Quantity administered and wasted
    8) Name or initials of employee performing the administering/wastage
    9) Name or initials of employee witnessing any wastage

- **Wastage/Disposal/Transfer Forms** (See *Disposal of Medications* Section)
    - **Transferring of controlled substances among registrants** Controlled substances are routinely transferred among registrants, such as when you purchase drugs from a distributor or a pharmacy. If you transfer controlled substances to a reverse distributor or sell controlled substances to another registrant, records of transfer must be maintained. The Bureau's website provides a pre-printed Transfer of Controlled Substances Form as an example. If you use that form and complete it completely and accurately, your records of transfer should comply with the law.

      All transfers of Schedule II drugs must be documented on a DEA Form 222 Official Order Form.

Schedule III—V drugs may be transferred on the form provided by the Bureau or another form designed by the practitioner, as long as all required documentation is present. The document must include:

1) Name, address and DEA number of the supplier
2) Name, address and DEA number of the receiver
3) Date of the transfer
4) Name, strength, dosage form and quantity of the drug(s) transferred.

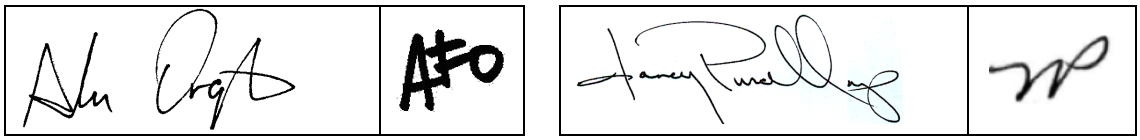
- **Temperature Logs** Drugs must be stored at required temperatures as prescribed by the DEA. Temperatures (frig and room) must be logged daily. State Controlled Substances Guidelines will dictate predetermined refrigerator and storage room temperatures.

Q. Can medical crewmembers use their initials to sign logs?

A. There are limited instances when medical crewmembers can use their initials in place of a full signature:

- Temperature logs
- Change-of-shift drug count logs

However, *each* log sheet must have a place at the bottom to identify the signature of the crewmember with the initials used. For example,



Q. Can controlled substances be exported to another country?

A. Yes. As long as the controlled substances are exported to a DEA-approved registrant with the appropriate import/export permits. The DEA must also be notified within 30 days of the export date.

Glossary

Agent

Individual authorized by a DEA registrant through power-of-attorney (POA) to act on behalf of the registrant.

Individual Practitioner

Physicians, nurse practitioners, physician's assistants, dentists, etc. An individual practitioner is *not* a pharmacist, pharmacy, or institutional practitioner.

Institutional Practitioner

A hospital or other entity (other than an individual) permitted to dispense a controlled substance, *not* including a pharmacy.

United States of America Jurisdiction

Customs territory of the USA, Puerto Rico, Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa.

BNDD

Bureau of Narcotics and Dangerous Drugs (BNDD). Former name of the Drug Enforcement Administration (DEA).

INCB

International Narcotics Control Board. Provides monitoring and support of governments' compliance with international drug control treaties. INCB also provides helpful information for

travellers, narcotic control regulations by country and international guidelines for national regulations concerning travellers under treatment with internationally controlled drugs. (http://www.incb.org/incb/en/publications/Guidelines.html)

APPENDIX A – COMMON MEDICATIONS IN TRANSPORT DRUG BAGS

MEDICATION	Controlled Schedule	Indications
Acetaminophen	N	pain
Adenosine	N	arrhythmias
Albuterol	N	asthma
Alprazolam (Xanax)	C-IV	sedation
Aspirin	N	blood thinner
Ativan (lorazepam)	C-IV	seizures, sedation
Atropine	N	cardiac arrest
Atrovent	N	asthma
Benadryl	N	antihistamine
Brethine (Terbutaline)	N	asthma, preterm labor
Calcium Gluconate	N	cardiac arrest
Cardizem (Diltiazem)	N	angina
Chloral Hydrate	C-IV	sedation
Cordarone (Amiodarone)	N	arrhythmias
Dexamethasone (Decadron)	N	anti-inflammatory
Dextrose 50% 25g	N	low blood sugar
Diazepam (Valium)	C-IV	sedation, seizures
Digitalis (Digoxin, Lanoxin)	N	cardiac
Dilantin (Phenytoin)	N	seizures
Diprivan (Propofol)	N	Anesthesia, seizures
Dobutamine	N	low blood pressure
Dopamine	N	low blood pressure
Epinepherine	N	low blood pressure, cardiac arrest, anaphylactic shock
Etomidate (Amidate)	N	sedation
Fentanyl	C-II	pain
Glucagon Kit	N	low blood sugar, high potassium
Haldol	N	psychosis sedation
Hydralazine	N	high blood pressure
Hydromorphone (Dilaudid)	C-II	pain
Ketamine	C-III	sedation
Labetalol	N	low blood pressure
Labetolol	N	high blood pressure
Lasix (Furosemide)	N	diuretic
Levophed	N	low blood pressure
Lidocaine	N	arrhythmias
Lopressor	N	high blood pressure
Magnesium Sulfate	N	high blood pressure

Mannitol	N	intracranial pressure
Meperidine (Demerol)	C-II	pain
Morphine	C-II	pain
Narcan	N	overdose
Nifedipine	N	high blood pressure
Nitroglycerin	N	angina
Pancuronium (Pavulon)	N	paralytic
Pentobarbital (Nembutal)	C-II	sedation
Phenobarbital	C-IV	sedation, seizures
Pitocin	N	preterm labor/bleeding
Procainamide (Pronestyl)	N	arrhythmias
Promethazine (Phenergan)	N	nausea
Rocuronium	N	paralytic
Romazicon (Flumazenil)	N	overdose
Sodium Bicarbonate	N	acidosis
Solumedrol	N	steroid, low blood pressure, anti-inflammatory
Succinycholine (Anectine)	N	paralytic
Thiamine	N	low blood sugar, alcoholic encephalopathy
Vecuronium Bromide	N	paralytic
Verapamil	N	cardiac
Versed (midazolam)	C-IV	sedation, seizures
Zofran	N	nausea

[i] U.S. Department of Justice, Drug Enforcement Agency. (2005). *Definition and registration of reverse distributors* (21 CFR Parts 1300, 1301, 1304, 1305, and 1307). Retrieved from website: http://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0502.htm