The purpose of this course is to explain the V schedules of controlled substances and their storage, administration, documentation, and disposal.

Goals

Upon completion of this course, the healthcare provider should be able to:

- Describe the five schedules of controlled substances and provide examples for each schedule.
- Discuss 3 storage methods for controlled substances.
- Describe narcotic counts associated with different storage methods.
- Describe 7 types of administration.
- List at least 8 common side effects for both opiate agonists and opiate agonist-antagonists.
- Describe the use of opiate antagonists.
- Describe important elements to documentation.
- Describe at least 3 ways in which drug diversion may occur.
- Describe 3 methods of disposal.

Introduction

In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control act, which included the Controlled Substances Act (CSA). The CSA established the current classification system used for
narcotics (Schedule I through IV). Both the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) control the classification of drugs, determining which drugs to add or remove. The DEA regulates controlled substances.

Criteria for classification include an estimation of the potential for abuse, risk to public health, potential for psychic or physiological dependence, as well as the current medical use, and limitations resulting from international treaties. It’s important to note that some drug classification systems are not consistent internationally and some drugs (such as heroin) classified as Schedule I in the United States are used medically in other countries.

Narcotic (opiate) analgesics may be natural, semisynthetic, or synthetic alkaloid derivatives of opium and are classified as opiate agonists and opiate agonist-antagonists.

- **Opiate agonists:** These include natural opiate agonists (morphine, codeine), semi-synthetic analogs (hydromorphone, oxycodone), and synthetic opioids (meperidine, fentanyl, methadone). They act by binding to opiate receptors in the central nervous system, both interfering with the pain pathway and with the perception of pain.

- **Opiate agonist-antagonists:** These include pentazocine (Talwin®), nalbuphine HCL (Nubain®), Dezocine (Dalgan®), butorphanol (Stadol®), and buprenorphine (Buprenex®). They act by stimulating some receptor sites and antagonizing (blocking) others, resulting in depression of the CNS and alterations in perception of pain.

Controlled substances include those on schedules I through V. The DEA does not regulate substances in Schedule VI although states may regulate these drugs to some degree.

<table>
<thead>
<tr>
<th>Schedules (include some non-narcotic drugs)</th>
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</table>
| **I** | **Criteria:** High potential for abuses, no accepted medical use in treatment, and lack of accepted safety for use under medical supervision.  
**Drugs** (Opiates, opiate derivatives, psychedelic substances, depressants, and stimulants): Include heroin, marijuana (currently approved for medical use in some states), peyote, GBH, MDMA AKA as “Ecstasy,” LSD, mescaline, and MMDA.  
**Prescription:** None allowed in the US. |
| **II** | **Criteria:** High potential for abuse, currently accepted medical use in treatment.  
**Drugs** (Cocaine, amphetamines, barbiturates, etc.): Include cocaine, heroin, marijuana, and other drugs as defined by the DEA.  
**Prescription:** Medical. |
use in treatment, and abuse may lead to severe psychological or physical dependence.

**Drugs:** Include cocaine, opium, morphine, methadone, Ritalin®, Concerta®, Focalin®, oxycodone, oxymorphone, fentanyl, hydromorphone, hydrocodone (regardless of preparation), codeine (≥ 90 mg per unit dose), secobarbital, meperidine, pentobarbital, and amphetamines.

**Prescription:** May be directly dispensed by practitioner to user or with a written prescription. (Some limited emergency situations allow for oral prescription). No refills are allowed and prescriptions must be retained but practitioners may provide a patient with multiple prescriptions for the same controlled substance to allow the patient to receive a 90-day supply for legitimate medical purpose, but each prescription must indicate the earliest date by which it can be filled.

<table>
<thead>
<tr>
<th>III Criteria:</th>
<th>Potential for abuse less than for schedule I or II drugs, currently accepted medical use in treatment, and abuse may lead to moderate or low physical dependence or high psychological dependence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs:</td>
<td>Anabolic steroids, intermediate-acting barbiturates (talbutal), buprenorphine (Buprenex®), dihydrocodeine, ketamine, codeine when compounded with an NSAID, marinol, and paregoric.</td>
</tr>
<tr>
<td>Prescription:</td>
<td>May be directly dispensed by practitioner to user or with written or oral prescription, with a 6-month or 5-refill limitation without renewal by practitioner.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV Criteria:</th>
<th>Low potential for abuse compared to Schedule III drugs, currently accepted medical use in treatment, and abuse may lead to limited physical or psychological dependence compared to Schedule III drugs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs:</td>
<td>Include benzodiazepines (Xanax®, Librium®, Klonopin®, Valium®), benzodiazepine-like drugs (Ambien®, zopiclone, zaleplon AKA Sonata®), long-acting barbiturates (phenobarbital), partial agonist opioid analgesics (Talwin®), butorphanol (Stadol®, stimulant-like drugs (modafinil), pentazocine, and antidiarrheal drugs (difenoaxin).</td>
</tr>
<tr>
<td>Prescription:</td>
<td>May be directly dispensed by practitioner to user or with written or oral prescription, with a 6-month or 5-refill limitation without renewal by practitioner.</td>
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</table>

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<tr>
<th>V Criteria:</th>
<th>Low potential for abuse compared to Schedule IV drugs, currently accepted medical use in treatment, and abuse may lead to limited physical or psychological dependence compared to Schedule IV drugs.</th>
</tr>
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<tbody>
<tr>
<td>Drugs:</td>
<td>Include cough suppressants with low-dose codeine,</td>
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</table>
antidiarrheals with low does opium or diphenoxylate, pregabalin (Lyrica®), dezocine, pyrovalerone, and centrally-acting antidiarrheals when mixed with atropine (Lomotil®).

**Prescription:** For medical purposes only.

**Storage**

Schedule II through V drugs must be handled as controlled substances and securely locked (usually with double locks or special locks) in a substantially constructed cabinet. Twenty or thirty years ago, most facilities simply kept stock narcotics in a locked cabinet in a locked medicine room, but storage and delivery of medications have changed—and the number of controlled substances has increased. Now, there are many options, and these vary widely from one facility to another.

**Note:** Personal belongings, such as a purse or billfold, should NEVER be kept in secure areas used for controlled substances, such as a medicine room or inside a medicine cart.

**Locked cabinets**

Double-locking cabinets (requiring two keys on one door or two keys for double doors) are still used, especially in smaller facilities, such as long-term care facilities.

Only authorized personnel are allowed access to the keys, and this type of cabinet is usually contained in a locked room to further limit access. Note that this type of cabinet is not refrigerated, so some controlled substances will need to be stored in a securely locked refrigerator or refrigerated cabinet or container.

Controlled substances are now usually provided in individual dose containers rather than bulk (such as 30 mL vials or 100 tablet bottles).

With this system, some form of record (written, computerized) is kept each time a drug is removed from the storage cabinet because this system requires a manual narcotics count. The usual information recorded includes the date, time, drug, patient for whom the drug is intended (name, ID, room number), the name of the prescriber, and the name of the healthcare provider procuring the drug.
**Narcotics count:** With this type of storage, the traditional end-of-shift narcotics count with the oncoming nurse counting and the outgoing nurse verifying is usually conducted.

**Medicine carts**

There are many types of medicine carts, but most have individual drawers to hold medications for each patient rather than each drug. Some medicine carts have special more secure drawers to hold controlled substances with a double-locking system. Depending on the system, controlled substances may be co-mingled or in separate drawers.

Refrigerated controlled substances are usually kept in a central area under double-lock in some type of refrigerator or refrigerated container. Controlled substances should not be placed in regular medicine drawers, as these drawers are not adequately secure.

With this system, as with a medicine cabinet, some form of record should be kept each time a drug is dispensed, as a manual narcotics count must be completed.

**Narcotics count:** Then end-of-shift count is also conducted with this type of storage, but because the narcotics may be stored in a number of different carts, different pairs of nurses may be conducting counts at the different carts.

**Automated drug dispensing systems**

About 80% of hospitals now utilize some type of automated drug dispensing system with computerized access. These systems also vary widely although they all have automated record keeping and require user names and passwords (and sometimes barcodes) for access.

Some automated systems have individual drawers for patients and others individual
drawers for medications, like a mini-pharmacy.

These systems are more secure and allow restricted access. For example, a nurse may only be able to access medications for his or her patients. These systems were originally developed primarily for narcotics, dispensing individual doses and maintaining accurate records, but the use has expanded rapidly to include most other drugs.

The drugs kept in an automated drug dispensing system may vary from one unit to another. For example, the drugs maintained in obstetrics may be different from those on the oncology units. These systems are filled and maintained by pharmacy personnel, so errors can still occur during stocking of drugs. The drawers where controlled substances are placed are usually more secure than drawers for other drugs.

Studies show that most hospital units use about 60 controlled substances and many of the larger automated systems can accommodate this many different drugs, but controlled substances should not be placed in less secure drawers if there are more drugs needed than available drawers. In some cases, rarely used drugs may be placed in only one or two automated dispensing systems rather than in all of them.

A major advantage to this type of system is that there is less wastage and more accurate record keeping. Narcotics counts are automated. Some of these systems include a secure container for disposal of wasted narcotics. Additionally, computerized systems send the patient’s medication profile directly to the pharmacy where it can be accessed by the pharmacist.

Also, these systems help to monitor for diversion as they can pinpoint records for individual patients and individual caregivers. If for example, one nurse gives many more narcotics than other nurses, this information is easily tracked.

These systems should be in a well-lit area with sufficient surrounding workspace in close proximity to information and documentation systems. The override function, which allows medications to be dispensed to a patient prior to order review and pharmacist approval should allow limited access and only for approved drugs, such as those used in emergency situations in which need outweighs the risk of medicine error.
Narcotic counts: Because the automated computerized systems automatically maintain an accurate narcotics count, some facilities have eliminated the narcotics count altogether or left it to pharmacy staff. In some facilities, however, periodic manual counts may be done on some routine schedule, such as once a week or once a month. The counts may be blind or verifying:
- **Blind**: Those counting do not see the actual number of doses remaining but do the count and enter the number into the system.
- **Verifying**: Those counting see the actual number of doses remaining and count to verify that the number is correct. This system is more prone to counting errors than the blind method.

Narcotic administration and documentation

**Routes**  
Narcotics can be administered by a number of different routes:
- **Oral medications**: Observe for level of consciousness, gag reflex, and presence of nausea or vomiting. Use calibrated medicine cups for liquids but doses smaller than 5 mL should be measured in a syringe to ensure accuracy. Solid oral medications (pills, tablets, capsules) should be delivered in a paper medicine cup, but individually-wrapped medications should be opened in the presence of the patient.
- **Sublingual/buccal medications**: Assess integrity and condition of mucous membranes under the tongue and in the buccal cavity. Medications should be withheld if tissues are red and irritated or mucosa is severely dry from dehydration. Document placement of the sublingual wafer and alternate sides with subsequent administrations.
- **Enteral instillations (per NG tube)**: Assess patency of tube to ensure it is positioned correctly and not obstructed. Pills and tablets are usually crushed and dissolved in 15 to 30 mL of warm water before instillation. Capsules are opened and poured into the warm water to dissolve.
- **Parenteral administration**: Verify the proper route (SubQ, IV, IM) and best site for administration as well as any need for dilution. IV administration may be used for severe pain. IM
administration is usually avoided or contraindicated for opioids while subQ administration is common.

- **Rectal administration**: Can be used as an alternative to oral administration, but rates of absorption may vary widely and doses may need to be titrated for the individual. While tablets and capsules can be given rectally, suppositories are preferred. Because there is minimal fluid in the rectal vault, medications may dissolve at varying rates. Stool in the rectum may also interfere with absorption or result in expulsion of the medication. The usual initial dosage rectally is the same as an oral dosage.

- **Transdermal**: Examine skin to ensure it is dry, non-irritated and intact and circulation is adequate prior to application according to manufacturer’s directions. After application, the site and surrounding tissue should not be exposed to external heat sources, such as heating pads, as increased heat may increase release of the drug, resulting in overdose.

- **PCA**: Verify physician’s orders when setting PCA unit and ensure that the patient is cognizant and able to comprehend directions for use. The subQ route is usually used for PCA although the IV route can also be used but requires an indwelling IV catheter.

**Documentation** When administering a controlled substance, such as a narcotic, to a patient, the purpose of the drug should be clearly documented. For example, if for dyspnea, the patient’s condition should be described and the respiratory rate as well as description of skin color and ventilation (rales, wheezing, decreased ventilation).

When administering controlled substances for pain management, the most common reason, documentation should include:

- **Reason for the administration** (such as pain in left knee) and the degree of pain, utilizing the appropriate pain scale, such as the 1-10 scale, FACES, CRIES, and Pain Assessment in Advanced Dementia (PAINAD), depending on the patient’s age and condition.

- **Patient, medication, dosage, route, time**. This information should be recorded immediately after administration and not at a later time or at the end of the shift. In automated systems, this information is recorded when the drugs are removed, so they
should be administered promptly so that the recorded time is accurate. If there is a delay between the time the medication is dispensed and given, then the next dose may be given too soon.

- **Response to medication**, including description and degree of pain, utilizing the same pain scale. Evaluating the response to the drug should correspond to the onset of action for the individual drug and its peak performance. For example, relief of pain may occur within 5 to 10 minutes for an IV medication but may be delayed for 20 to 30 minutes or longer for oral medications. Some drugs may peak within 1.5 hours, but others may peak in 4 hours.

An equianalgesic chart that lists medications with morphine as the referent, indicating dosages of different drugs equivalent to morphine and onset, peak, and duration of action should be readily available at dispensing stations and on medicine carts or in medicine rooms.

Patients should be carefully observed for adverse effects, specific to the drugs taken. While many adverse effects are similar, opiate agonists tend to have more adverse symptoms than opiate agonist-antagonists. Any adverse effect must be documented.

<table>
<thead>
<tr>
<th>Opiate agonists</th>
<th>Opiate agonist-antagonists</th>
</tr>
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<tbody>
<tr>
<td><strong>CNS</strong>: dizziness, confusion, insomnia, disorientation, and seizures (infants and children).</td>
<td><strong>CNS</strong>: Euphoria, dizziness, drowsiness, change in mood, confusion, and light-headedness.</td>
</tr>
<tr>
<td><strong>CV</strong>: Orthostatic hypotension, bradycardia, palpitations, and cardiac arrest.</td>
<td><strong>CV</strong>: Tachycardia, palpitations, and hypertension.</td>
</tr>
<tr>
<td><strong>Skin</strong>: Pruritis, rash, urticaria, flushing, and cold, clammy skin.</td>
<td><strong>Skin</strong>: Rash pruritis, local irritation at inject site, and flushing.</td>
</tr>
<tr>
<td><strong>EENT</strong>: Visual disturbances and pupil constriction.</td>
<td><strong>EENT</strong>: Visual disturbances.</td>
</tr>
<tr>
<td><strong>GI</strong>: Nausea, vomiting, constipation, anorexia, dry mouth, and biliary colic.</td>
<td><strong>GI</strong>: Dry mouth, nausea, vomiting, constipation, and altered sense of taste.</td>
</tr>
<tr>
<td><strong>GU</strong>: Urinary retention, urinary urgency, dysuria, and oliguria.</td>
<td><strong>GU</strong>: Urinary retention.</td>
</tr>
<tr>
<td><strong>Respiratory</strong>: Depression, arrest.</td>
<td><strong>Resp</strong>: Depression.</td>
</tr>
<tr>
<td>Other: Hypothermia and muscle flaccidity.</td>
<td>Other: Allergic reactions and shock.</td>
</tr>
<tr>
<td><strong>Note</strong>: Many common drugs are pregnancy category B while others are category C.</td>
<td><strong>Note</strong>: Drugs are pregnancy category C.</td>
</tr>
</tbody>
</table>
If severe adverse effects occur, an opiate antagonist may need to be administered to reverse effects. Opiate antagonists are another class of drugs that block the effects of opiates:

- **Opiate antagonists:** These include naloxone (Narcan®) and nalmefene HCL (Revex®). They act by competing with narcotics for receptor sites and blocking the action of opiates. Used to treat overdose, they may induce withdrawal symptoms in those who are dependent.

**Drug diversion**

About 15% of healthcare providers have drug dependence at some point during their professional careers. Healthcare providers who are dependent on drugs put patients at risk because of impaired judgment and diversion of patients’ drugs. Diversion occurs in a number of ways:

- Stealing drugs and falsifying records. For example, a nurse may procure the drug, take it, and chart it given to the patient.

- Stealing injection drugs and administering saline or sterile water to the patient. In some cases, nurses have filled the syringes with narcotics, given themselves injections, refilled the syringes with NS, and injected the NS back into the vials, using the same syringes and contaminating the vials.

- Stealing drugs that are to be wasted because they weren’t used or because they are expired and to be destroyed.

Hospitals must have procedures in place to prevent, detect, and report any diversion of controlled substances. There are a number of warning signs that diversion may be occurring:

- Patients receive maximum pain dose but do not appear to have relief of pain (especially if this is a recurring pattern).
- Patient’s dose is less than a full vial, so some must be wasted.
- Healthcare provider frequently visits the facility during off times.
- Change in healthcare provider behavior, work habits, and productivity.
- Sloppy or inaccurate charting.
- Healthcare providers asking others to sign for disposal after the fact.

**Disposal**

Hospitals and other facilities utilize a range of different methods to dispose of unused or excess narcotics. For example, a single-use vial
may contain two mL of a drug while the prescribed dose is one mL. In that case, one mL must be disposed of. Or an oral medication may be procured for a patient who then is unable to take the medication or refuses it. This medication cannot be placed back into the secure storage container or saved for later but must be disposed of.

When controlled substances must be disposed of, the disposal should be witnessed by two healthcare providers who are licensed to dispense drugs, such as two RNs, and the disposal documented with both healthcare providers signing. This should be done immediately after procuring the drug. The nurse should not carry the excess narcotic on a tray or in a pocket or place it in an unsecured medication drawer for later disposal because this increases the risk of diversion or errors in documentation but should immediately ask for a witness and dispose of the drug according to established protocol.

**Under no circumstances** should a healthcare provider agree to sign for unwitnessed disposal of narcotics after the fact. Doing so could make the healthcare provider complicit in diversion or arouse suspicion of unprofessional conduct.

For injectables, the nurse should draw up into the syringe only the amount to be given to the patient and not draw a greater amount, intending to only inject, for example, half of the drug in the syringe because this poses a risk of overdose.

Drawing the full amount and wasting part of it prior to administering the drug may result in contamination of the needle (although if syringes are prefilled and a partial dose is given, this may be necessary). A better practice, when possible, is to use a second syringe to withdraw the remaining drug from a vial to be disposed of or to dispose of the vial with the medication inside—depending on the disposal method available.

Each facility should have protocols in place for the disposal of medications. In many cases, medications (such as unused but securely stored drugs) are returned to the pharmacy for disposal.

### Disposal methods

<table>
<thead>
<tr>
<th><strong>Pick-Up and Mail Back</strong></th>
<th>These are services that uses an on-site collection device. Provider fees are determined by the pickup or mail back frequency. All on-site collection devices are destined for incineration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical</strong></td>
<td>This is a viable method of destruction in the new DEA</td>
</tr>
</tbody>
</table>
### Destruction

Regulations. Drug disposal in a bottle technology comes ready-to-use, no additives to activate and contains a non-toxic liquid solution. Medication are placed into the bottle. The medications dissolve in the liquid solution. Next, the bottle contains activated carbon. The carbon will adsorb and inactivate the liquid slurry. The carbon adoption is permanent and prevents leaching/tainting of drinking water and other harmful environmental effects. Always ask the supplier for an MSDS and independent studies to support product claims. Note, some chemical destruction contains hazardous ingredients. Do NOT use these products.

### Incinerating

Incinerating involves placing materials in hazardous waste containers for incineration and is the preferred method of disposal but is more expensive than flushing and not always available. Additionally, not all hazardous waste containers are adequately secured or tamper proof. In some facilities, liquid waste is injected or poured into small plastic bags containing kitty litter, coffee grounds, or other absorbant material so it is absorbed prior to disposal in a hazardous waste container.

Some automatic dispensing carts have secure hazardous waste containers lined with absorbant material into which both liquid and solid narcotic wastes may be disposed of for later incineration.

### Transferring to reverse distributors

Some pharmacies contract to dispose of out-of-date, damaged, or otherwise unusable controlled substances with reverse distributors. These are companies that are licensed to recycle and/or destroy controlled substances.

### Conclusion

Because protocols for handling and disposing of controlled substances vary widely from one facility to another, the healthcare provider should have a clear understanding of the policies and protocols in place. In some cases, protocols may need updating as technology is introduced, and nurses may take a proactive role. Narcotics counts average about 20 minutes in most cases because of the increasing numbers of drugs, so decreasing the frequency of narcotics counts or eliminating them as a nursing responsibility can save considerable time.
As with all medications, controlled substances should be given as prescribed to the correct patient and documented carefully, noting any adverse effects. While the use of generic medications makes identifying pills, tablets, and capsules by appearance more difficult, the nurse should always check the labels on unit doses to ensure that the correct medication has been stocked.

References

- Blackmere, J. et al. (2010). Determining the most efficient controlled substance inventory practice that minimizes discrepancies and maximizes security.