2.3: Legal Foundations and National Guidelines for Safe Medication Administration

There are many federal and state laws, as well as national guidelines, that have been established to protect public health and safety. This section will explain how the FDA, DEA, Joint Commission, CMS, a State’s Nurse Practice Act, State Boards of Nursing, and state legislatures protect the consumer from medication harm.

2.3a – Food and Drug Administration

To protect the public, the U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation’s food supply, cosmetics, and products that emit radiation. Some of the ways that the FDA protects the public health regarding medications are by enforcing an official drug approval process based on evidence-based research; issuing Black Box Warnings for medications with serious adverse reactions; and regulating over-the-counter (OTC) medications. Each of these actions are further explained below.

Developing New Drugs

American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world. The main consumer watchdog in this system is the FDA’s Center for Drug Evaluation and Research (CDER).

The center’s best-known job is to evaluate new drugs before they can be sold. CDER’s evaluation not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely. The center ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks.

Development and Approval Process of Drugs by the FDA

https://med.libretexts.org/Bookshelves/Nursing/Nursing_Pharmacology_(OpenRN)/02%3A_Legal_and_Ethical/2.03%3A_Leg…

Updated: Sat, 24 Sep 2022 16:02:58 GMT
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Drug companies conduct extensive research and work to develop and test a drug. The company then sends CDER the evidence from these tests to prove the drug is safe and effective for its intended use. Before the drug is approved as safe for use in the United States, a team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company’s data and proposed labeling. If this independent and unbiased review establishes a drug’s health benefits outweigh its known risks, the drug is approved for sale. Before a drug can be tested in people, the drug company or sponsor performs laboratory and animal tests to discover how the drug works and whether it’s likely to be safe and work well in humans. Next, a series of clinical trials involving volunteers is conducted to determine whether the drug is safe when used to treat a disease and whether it provides a real health benefit.

**FDA Approval: What it Means**

FDA approval of a drug means that data on the drug’s effects have been reviewed by CDER, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population. The drug approval process takes place within a structured framework that includes:

- **Analysis of the target condition and available treatments**: FDA reviewers analyze the condition or illness for which the drug is intended and evaluate the current treatment landscape, which provide the context for weighing the drug’s risks and benefits. For example, a drug intended to treat patients with a life-threatening disease for which no other therapy exists may be considered to have benefits that outweigh the risks even if those risks would be considered unacceptable for a condition that is not life threatening.

- **Assessment of benefits and risks from clinical data**: FDA reviewers evaluate clinical benefit and risk information submitted by the drug maker, taking into account any uncertainties that may result from imperfect or incomplete data. Generally, the agency expects that the drug maker will submit results from two well-designed clinical trials to be sure the findings from the first trial are not the result of chance or bias. In certain cases, especially if the disease is rare and multiple trials may not be feasible, convincing evidence from one clinical trial may be enough. Evidence that the drug will benefit the target population should outweigh any risks and uncertainties.

- **Strategies for managing risks**: All drugs have risks. Risk management strategies include an FDA-approved drug label, which clearly describes the drug’s benefits and risks and information pertaining to the detection and management of any risks. Sometimes, more effort is needed to manage risks. In these cases, a drug maker may need to implement a Risk Management and Mitigation Strategy (REMS).

Although many of the FDA’s risk-benefit assessments and decisions are straightforward, sometimes the benefits and risks are uncertain and may be difficult to interpret or predict. The agency and the drug maker may reach different conclusions after analyzing the same data, or there may be differences of opinion among members of the FDA’s review team. As a science-led organization, the FDA uses scientific and technological information to make decisions through a deliberative process.

**Black Box Warnings**

The Food and Drug Administration (FDA) approves a drug for marketing after determining that the drug’s benefits of use outweigh the risks for the condition that the drug will treat. However, even with the rigorous FDA evaluation process, some safety problems surface only after a drug has been on the market and has been used in a broader population. If a safety problem surfaces, Black Box Warnings are issued by the FDA and appear on a prescription drug’s label. The purpose is to call attention to serious or life-threatening risks.
Critical Thinking Activity 2.3a

Levofloxacin is an antibiotic that received FDA approval. However, after the drug was on the market, it was discovered that some patients who took levofloxacin developed serious, irreversible adverse effects such as tendon rupture. The FDA issued a Black Box Warning with recommendations to reserve levofloxacin for use in patients who have no alternative treatment options for certain indications: uncomplicated UTI, acute exacerbation of chronic bronchitis, and acute bacterial sinusitis. [4]

A nurse is preparing to administer medications to a patient and notices that levofloxacin has been prescribed for the indication of pneumonia. There is no other documentation in the provider’s notes related to the use of this medication.

What is the nurse’s best response?

Note: Answers to the Critical Thinking activities can be found in the “Answer Key” sections at the end of the book.

2.3b – U.S. Drug Enforcement Agency (DEA)

The U.S. Drug Enforcement Agency (DEA) enforces the controlled substances laws and regulations of the United States. This includes enforcement of the Controlled Substances Act (CSA) that pertains to the manufacture, distribution, and dispensing of legally produced controlled substances that nurses administer to patients. [5]

Because controlled substances have a greater chance of being misused and abused, there are additional laws and procedures that must be followed when working with these medications. The federal government administers some laws regarding controlled substances. The DEA is responsible for enforcing these laws, and many federal laws are summarized in a document called the Pharmacist’s Manual. [6] Most controlled substance laws, however, come from the state governments. Health care professionals are responsible for following the most stringent of the two laws, whether it be state law or federal law.

Federal Laws

The following are excerpts of federal laws that are applicable to professional nursing.
**Prescriptions:** A prescription for a controlled substance may be written only by a provider (physician or mid-level provider like a nurse practitioner) that has a DEA registration number.

A prescription for a Schedule II (most controlled class of medications, like opioids) must be written or electronically sent to the pharmacy through DEA approved software. Prescriptions over the phone or fax are not accepted.

It is then up to state law to decide how long a written Schedule II prescription is valid and if there are any limits on the quantity of medication that can be dispensed.

Refilling a Schedule II medication is not allowed. Schedule III or IV medications may be refilled only 5 times.

**Records:** There is a “closed system” for record keeping of controlled substances to prevent diversion.

To maintain a “closed system” of record keeping for controlled substances, hospitals, clinics, and pharmacies must maintain records on the whereabouts of the medication from manufacturing the medication, receipt by the pharmacy, distribution to the patient, to disposal of waste. What does this look like in practice? Inventory counts of controlled medications occur frequently, controlled substance access by individual employees is audited often, detailed records are kept for all transactions, and waste is often disposed of differently than other pharmaceuticals.

**Wisconsin State Laws**

**Prescriptions:** A Schedule II prescription is only good for 60 days after it is written.

Pharmacies and practitioners are required to participate in a prescription drug monitoring program when dispensing or prescribing a monitored prescription drug (most often opioid pain medications).

![Wisconsin State Law Regarding Controlled Substance](https://med.libretexts.org/Bookshelves/Nursing/Nursing_Pharmacology_(OpenRN)/02%3A_Legal_and_Ethical/2.03%3A_Leg…)

**Scheduled Medications**

The Controlled Substances Act (CSA) places all substances that are regulated under existing federal law into one of five schedules. This placement is based on the substance’s medical use, potential for abuse, and safety or dependence liability. Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence, whereas Schedule V drugs represent the least potential for abuse. An alphabetic listing of drugs and their schedule are located on the DEA website at “CSA Scheduling by Alphabetical Order.” Sample medications for each schedule are included in Figure 2.2.

![Figure 2.2 Definitions and Sample Medications for Each Type of Scheduled Medication](https://med.libretexts.org/Bookshelves/Nursing/Nursing_Pharmacology_(OpenRN)/02%3A_Legal_and_Ethical/2.03%3A_Leg…)

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule I</td>
<td>No currently accepted medical use and a high potential for abuse.</td>
<td>Heroin, LSD, and marijuana</td>
</tr>
<tr>
<td>Schedule</td>
<td>Description</td>
<td>Examples</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Schedule II</td>
<td>High potential for abuse, with use potentially leading to severe psychological or physical dependence.</td>
<td>Vicodin, cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin</td>
</tr>
<tr>
<td>Schedule III</td>
<td>Moderate to low potential for physical and psychological dependence. Abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.</td>
<td>Tylenol with codeine, ketamine, anabolic steroids, testosterone</td>
</tr>
<tr>
<td>Schedule IV</td>
<td>Low potential for abuse and low risk of dependence.</td>
<td>Xanax, Soma, Valium, Ativan, Talwin, Ambien, Tramadol</td>
</tr>
<tr>
<td>Schedule V</td>
<td>Lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Generally used for antidiarrheal, antitussive, and analgesic purposes.</td>
<td>Robitussin AC with codeine, Lomotil, Lyrica</td>
</tr>
</tbody>
</table>

Drug overdoses are still a public health crisis in the United States, and the misuse of prescription opioids, which are scheduled medications, continue to contribute to a large percentage of overdose deaths. Many problems associated with drug abuse are the result of legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic. The mission of DEA’s Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. The DEA provides education regarding related topics that apply to nurses such as drug diversion, state prescription drug monitoring systems, current drug trends, telemedicine, and proper drug disposal.\[11\]

**Drug Diversion**

Drug diversion involves the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use. The most common drugs diverted from the health care facility setting are opioids. Diversion of controlled substances is not uncommon and can result in substantial risk not only to the individual who is diverting the drugs but also to patients, coworkers, and employers. Impaired providers can harm patients by providing substandard care, denying medications to patients, or exposing patients to tainted substances. Tampering is the riskiest and most harmful type of diversion. Commonly, the diverter removes medication from a syringe, vial, or other container and injects himself or herself with the medication. The diverter then replaces the stolen medication with saline or sterile water or another clear medication or liquid. The “replacement liquid” is later used on the patient by an unaware provider. When tampering, the diverter may rarely use sterile technique. Ultimately the patient doesn’t receive the required medication and may be exposed to the diverter’s blood.\[12\],[13],[14]

DEA at Rx Abuse Online Reporting\[15\]

The National Council of State Boards of Nursing (NCSBN) created a Substance Abuse Disorder in Nursing brochure.
The brochure states, "Many nurses with substance use disorder (SUD) are unidentified, unreported, untreated, and may continue to practice where their impairment may endanger the lives of their patients. SUD among health care providers also creates significant legal and ethical responsibilities for colleagues who work with these individuals. You have a professional and ethical responsibility to report a colleague’s suspected drug use to your nurse manager or supervisor and, in some states or jurisdictions, to the board of nursing. You have a vital role in helping to identify nurses with SUD, so it is necessary for you to be aware of the indicators that may signal that a nurse has a problem.

It can be hard to differentiate between the subtle signs of impairment and stress-related behaviors, but there are three areas to watch: behavior changes, physical signs, and drug diversion. Behavioral changes can include changes or shifts in job performance; absences from the unit for extended periods; frequent trips to the bathroom; arriving late or leaving early; and making an excessive number of mistakes, including medication errors. Behavioral changes can be physical, including subtle changes in appearance that may escalate over time; increasing isolation from colleagues; inappropriate verbal or emotional responses; and diminished alertness, confusion, or memory lapses. When nurses are using drugs and unable to obtain them from a treating health care provider, they may turn to the workplace for access or diversion, often causing narcotic discrepancies, such as incorrect narcotic counts, large amounts of narcotic wastage, numerous corrections of medication records, frequent reports of ineffective pain relief from patients, offers to medicate coworkers’ patients for pain, altered verbal or phone medication orders, and variations in controlled substance discrepancies among shifts or days of the week.

The earlier an SUD in a nurse is identified and treatment is started, the sooner patients are protected and the better the chances are of the nurse safely returning to work. You need to acknowledge that health care professionals are not immune to developing an SUD, and you should ignore stereotypes of what a “typical” person with a SUD looks like. It is important for nurses to not only be aware of the warning signs of SUD, but also be cognizant that SUD is a disease that can affect anyone regardless of age, occupation, economic circumstances, ethnic background, or gender. This will help you to identify issues in a coworker or colleague because you will be able to see behaviors and performance without the notion of “nurses wouldn’t do that” or “someone like this would never have an SUD.” In most states, a nurse may enter a nondisciplinary alternative-to-discipline program, which is designed to refer nurses for evaluation and treatment, monitor the nurse’s compliance with treatment and recovery recommendations, monitor abstinence from drug or alcohol use, and monitor the practice upon return to work. You need to acknowledge that health care professionals are not immune to developing an SUD. When a colleague treated for an SUD eventually returns to work, it is important that you help to create a supportive environment that encourages continued recovery.

Prescription Drug Monitoring Programs (PDMP)

In addition to drug diversion programs, prescription drug monitoring programs (PDMP) have been established in several states to address prescription drug abuse, addiction, and diversion. A PDMP is a statewide electronic database that collects designated data on substances dispensed in the state. By providing valuable information about controlled substance prescriptions that are dispensed in the state, it aids healthcare professionals in their prescribing and dispensing decisions. The PDMP also fosters the ability of pharmacies, healthcare professionals, law enforcement agencies, and public health officials to work together to reduce the misuse, abuse, and diversion of prescribed controlled substance medications.
Proper Drug Disposal

![Controlled Substances Collection Receptacle](image)

Figure 2.2 Controlled Substances Collection Receptacle to help prevent drug diversion

The Secure and Responsible Drug Disposal Act of 2010 allows users to dispose of controlled substances in a safe and effective manner. A Johns Hopkins study on sharing of medication found that 60% of people had leftover opioids they hung on to for future use; 20% shared their medications; 8% would likely share with a friend; 14% would likely share with a relative; and only 10% securely locked their medication. This act has resulted in "National Take Back Days" in all 50 states, as well as new collection receptacles. Nurses should teach patients who are prescribed controlled substances how to dispose of them properly so that they don’t end up being abused or overdosed by another person. Figure 2.3 shows an example of a controlled substances collection receptacle to prevent drug diversion.

Critical Thinking Activity 2.3b
A nurse is providing discharge education to a patient who recently had surgery and has been prescribed hydrocodone/acetaminophen tablets to take every four hours as needed at home. The nurse explains that when the medication is no longer needed when the post-op pain subsides, it should be dropped off at a local pharmacy for disposal in a collection receptacle. The patient states, “I don’t like to throw anything away. I usually keep unused medication in case another family member needs it.”

1. What is the nurse’s best response?

A nurse begins a new job on a medical surgical unit. One of the charge nurses on this unit is highly regarded by her colleagues and appears to provide excellent care to her patients. The new nurse cares for a patient that the charge nurse cared for on the previous shift. The new nurse asks the patient about the effectiveness of the pain medication documented as provided by the charge nurse during the previous shift. The patient states, “I didn’t receive any pain medication during the last shift.” The nurse mentions this incident to a preceptor who states, “I have noticed the same types of incidents have occurred with previous patients, but didn’t want to say anything.”

2. What is the new nurse’s best response?

Note: Answers to the Critical Thinking activities can be found in the “Answer Key” sections at the end of the book.

2.3c – Joint Commission

The Joint Commission is a national organization that accredits and certifies over 20,000 health care organizations in the United States. The mission of the Joint Commission is to continuously improve health care for the public by inspiring health care organizations to excel in providing safe and effective care of the highest quality and value. Some of the initiatives that the Joint Commission supports for promoting the safe use of medications include the development of a Safety Culture and associated root cause analyses, the Speak Up Campaign, National Patient Safety Goals, and a Do Not Use List of Abbreviations. Each of these initiatives is further explained below.

Joint Commission Do Not Use List of Abbreviations

Safety Culture

The Joint Commission Center for Transforming Healthcare develops effective solutions for health care’s most critical
safety and quality problems with a goal to ultimately achieve zero harm to patients. Some of the projects the Center have developed include improved hand hygiene, effective handoff communications, and safe and effective use of insulin.

The Center has also been instrumental in creating a focus on a “Safety Culture” in health care organizations. A safety culture empowers staff to speak up about risks to patients and to report errors and near misses, all of which drive improvement in patient care and reduce the incident of patient harm. It has been estimated that the average cost of a medical error is $11,366, resulting in approximately $17.1 billion in costs in 2008. According to the Institute of Medicine, "The biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm."[28]

Creating A Safety Culture

As a result of the focus on creating a safety culture, whenever a medication error or a “near miss” occurs, nurses should submit an incident report according to their institution’s guidelines. The incident report triggers a root cause analysis to help identify not only what and how an event occurred, but also why it happened. When investigators are able to determine why an event or failure occurred, they can create workable corrective measures that prevent future errors from occurring.[29]

An example of safety culture in action is from 2006, when three babies died after receiving incorrect heparin doses to flush their vascular access devices. A root cause analysis found that pharmacy technicians accidentally placed vials containing more concentrated heparin (10,000 units/mL) in storage locations in patient care areas designated for less concentrated heparin vials (10 units/mL). Additionally, the heparin vials were similar in appearance, so the nurses did not notice the incorrect dosage until after it was administered. In response to the root cause analysis, the hospital no longer stocks heparin 10 units/mL vials in pediatric units and uses saline to flush all peripheral lines. In the pharmacy, 10,000 units/mL heparin vials were separated from vials containing other strengths. Workable corrective measures were thus implemented to prevent future tragedies from occurring as a result of incorrect doses of heparin.[30]

Speak Up

The goal of the Joint Commission Speak Up™ initiative is to help patients become more informed and involved in their health care to help prevent medication errors. Speak Up™ materials are intended for the public and have been put into a simplified, easy-to-read format to reach a wider audience.[31]

Joint Commission Patient Speak Up Brochure

National Patient Safety Goals

The National Patient Safety Goals (NPSG) were established by the Joint Commission in 2002 to help accredited organizations address specific areas of concern related to patient safety. Annually, the Joint Commission determines the current highest priority patient safety issues with input from practitioners, provider organizations, purchasers, consumer
groups, and other stakeholders and develops National Patient Safety Goals.

Use the link below to read more information about the current NPSG for hospitals. Two of the current National Patient Safety Goals relate specifically to medication administration: Patient ID and Use Medicines Safely.

National Patient Safety Goals for Hospitals

**Patient ID**

Use at least two ways to identify patients. For example, use the patient’s name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment.

**Use Medicines Safely**

Before a procedure, label medicines that are not labeled. For example, medicines in syringes, cups, and basins should be labelled in the area where medicines and supplies are set up.

Take extra care with patients who take medicines to thin their blood (anticoagulants).

Record and pass along correct information about a patient’s medicines. Find out what medicines the patient is taking. Compare those medicines to new medicines given to the patient. Make sure the patient knows which medicines to take when they are at home. Tell the patient it is important to bring their up-to-date list of medicines every time they visit a doctor.

**Joint Commission Official Do Not Use List**

The Joint Commission maintains an Official Do Not Use List of abbreviations. These abbreviations have been found to commonly cause errors in patient care. Accredited agencies are expected to not use these abbreviations on any written or pre-printed materials.

This list does not currently apply to preprogrammed health information technology systems (i.e., electronic medical records or CPOE systems), but it remains under consideration for the future.

**Official Do Not Use List**

**CMS: Centers for Medicare and Medicaid Services**

The Centers for Medicare & Medicaid Services (CMS) is a federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid. The CMS establishes and enforces regulations to protect patient safety in hospitals that receive Medicare and Medicaid funding.

CMS regulations related to medication administration include identifying what should be included in a prescription for the administration of medication, using the “five rights” when administering medications, reporting concerns about a
Medication order, assessing and monitoring patients receiving medications, and documenting medication administration. Each of these regulations is further discussed below.

**Medication Orders**

Medications must be administered in response to an order from a practitioner or on the basis of a standing order that is appropriately authenticated subsequently by a practitioner. All practitioner orders for the administration of drugs and biologicals must include at least the following:

- Name of the patient
- Age and weight of the patient to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital’s policies. (Note that dose calculations are based on metric weight (kg, or g for newborns)
- Date and time of the order
- Drug name
- Dose, frequency, and route
- Dose calculation requirements, when applicable
- Exact strength or concentration, when applicable
- Quantity and/or duration, when applicable
- Specific instructions for use, when applicable
- Name of the prescriber

**Basic Safe Practices for Medication Administration: The Five Rights**

CMS states that hospitals’ policies and procedures must reflect accepted standards of practice that require the following information is confirmed prior to each administration of medication. This is often referred to as the “five rights” of medication administration practice.

The original version of this chapter contained H5P content. You may want to remove or replace this element. [37]

Note: Recent literature has identified up to nine “rights” of medication administration, including Right patient, Right drug, Right route, Right time, Right dose, Right documentation, Right action (appropriate reason), Right form, and Right response. However, there does not (yet) appear to be consensus about expanding beyond the 5 “rights.” [38]

Many agencies have implemented bar code medication scanning to improve safety during medication administration. Bar code scanning systems reduce medication errors by electronically verifying the “5 rights” of medication administration. For example, when a nurse scans a bar code on the patient’s wristband and on the medication to be administered, the data is delivered to a computer software system where algorithms check various databases and generate real-time warnings or approvals. Research studies have shown that bar code scanning reduces errors resulting from administration of a wrong dose or wrong medication, as well as errors involving medication being given by the wrong route. However, it is important to remember that bar code scanning should be used in addition to performing the...
The five rights of medication administration, not in place of this important safety process. Additionally, nurses should carefully consider their actions when errors occur during the bar code scanning process. Although it may be tempting to quickly dismiss the error and attribute it to a technology glitch, the error may have been triggered due to a patient safety concern that requires further follow-up before the medication is administered. It is important for nurses to investigate errors that occur during the bar code scanning process just as they would do if an error is discovered during the traditional five rights of medication process.

Concerns About Medication Orders

CMS encourages hospitals to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. [39]

Assessment/Monitoring of Patients Receiving Medications

CMS states that observing the effects medications have on the patient is part of the multifaceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels.
- Physical signs and clinical symptoms relevant to the patient’s medication therapy, such as confusion, agitation, unsteady gait, pruritus, etc.
- Factors contributing to high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors include, but are not limited to, age, altered liver and kidney function, drug-to-drug interactions, and first-time medication use may contribute to increased risk.

The nurse should consider patient risk factors, as well as the risks inherent in a medication, when determining the type and frequency of monitoring. It is also essential to communicate information regarding patients’ medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff. Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention per established protocols and should be reported immediately to the practitioner responsible for the care of the patient. An example of vigilant post-medication administration monitoring would be for post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. In addition, the patient and/or family members should be educated to notify nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication. [40]
Documentation

CMS regulations require that the documentation record of medication administration contain all practitioners’ orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, vital signs, and other information necessary to monitor the patient’s condition. Documentation is expected to occur after actual administration of the medication to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. \[^{[41],[42]}\]

Critical Thinking Activity 2.3c

A nurse is preparing to administer morphine, an opioid, to a patient who recently had surgery.

1. Explain the 5 rights that the nurse will check prior to administering this medication to the patient.
2. Outline 3 methods the nurse can confirm patient identification.
3. What should the nurse assess prior to administering this medication to the patient?
4. What should be monitored after administering this medication?
5. What should the nurse teach the patient (and/or family member) about this medication?
6. What information should be included in the shift handoff report about this medication?

Note: Answers to the Critical Thinking activities can be found in the “Answer Key” sections at the end of the book.

2.3d – Wisconsin State Statutes, Nurse Practice Act, and Board of Nursing

In addition to federal laws, national regulations, guidelines, and initiatives, there are state laws that govern nursing. For regulations specific to nursing, the Wisconsin state legislature enacts a Nurse Practice Act and delegates authority to the Wisconsin State Boards of Nursing to enforce the Nursing Practice Act. \[^{[43]}\]

The purpose of the Wisconsin Board of Nursing is to protect the public through licensure, education, legislation, and discipline. The Nurse Practice Act (NPA), as stated in Wisconsin Statutes Chapter 440 (Department of Safety and Professional Services) and 441 (Board of Nursing), grants the Board of Nursing the authority to regulate education as
well as the licensure and practice of registered nurses (RNs), licensed practical nurses (LPNs), and advanced practice nurse prescribers (APNPs). [44]

It is important for all nurses to understand their scope of practice as outlined in the Nurse Practice Act (NPA) and Wisconsin Board of Nursing Administrative Rules. Each nurse is accountable for the quality of care he or she provides and is expected to practice at the level of education, knowledge, and skill ordinarily expected of one who has completed an approved nursing program. Furthermore, all nurses are expected to recognize the limits of their knowledge and experience and to appropriately address situations that are beyond their competency. Nurses are responsible to be knowledgeable regarding all laws and rules that relate to their nursing practice. [45]

Wisconsin Board of Nursing [46]

Wisconsin Practice Act: Standards of Practice

The Wisconsin Nurse Practice Act outlines the standards of care provided by a registered nurse (RN), also known as the Nursing Process. An RN utilizes the nursing process in the execution of general nursing procedures in the maintenance of health, prevention of illness, or care of the ill. This standard is met through steps of the nursing process, including:

- **Assessment**: The systematic and continual collection and analysis of data about the health status of a patient culminating in the formulation of a nursing diagnosis.

- **Planning**: Development of a nursing plan of care for a patient, which includes goals and priorities derived from the nursing diagnosis.

- **Intervention**: The nursing action to implement the plan of care by directly administering care or by directing and supervising nursing acts delegated to LPNs or less skilled assistants.

- **Evaluation**: The determination of a patient’s progress or lack of progress toward goal achievement, which may lead to modification of the nursing diagnosis. [47]

Wisconsin Practice Act: Rules of Conduct

The Wisconsin Nurse Practice Act also outlines Rules of Conduct expected of nurses. Nurses can receive disciplinary action from the Board of Nursing ranging from a reprimand to revocation of their license if they do not follow the Rules of Conduct. It is important for nurses to protect their licenses to maintain current knowledge about expected rules of conduct in each state where they practice nursing. Details regarding rules and conduct and grounds for denying or taking disciplinary action by the Wisconsin Board of Nursing can be found in Chapter N7, “Rules of Conduct.” [48] [49]


Common reasons related to medication administration for the Board of Nursing to take disciplinary action against a nursing license include, but are not limited to:

- Noncompliance with federal, jurisdictional, or reporting requirements, including:
  - Practicing beyond the scope of practice.
• Confidentiality, patient privacy, consent, or disclosure violations.
• Fraud, deception or misrepresentation, including:
  ◦ Falsification of patient documentation.
• Unsafe practice or substandard care, including:
  ◦ Failing to perform nursing with reasonable skill and safety.
  ◦ Departing from or failing to conform to the minimal standards of acceptable nursing practice that may create unnecessary risk or danger to a patient’s life, health, or safety. Actual injury to a patient need not be established.
  ◦ Failing to report to or leaving a nursing assignment without properly notifying appropriate supervisory personnel and ensuring the safety and welfare of the patient or client.
  ◦ Practicing nursing while under the influence of alcohol, illicit drugs, or while impaired by the use of legitimately prescribed pharmacological agents or medications.
  ◦ Inability to practice safely due to alcohol or other substance use, psychological or physical illness or impairment.
  ◦ Executing an order which the licensee knew or should have known could harm a patient.
• Improper supervision or allowing unlicensed practice.
• Improper prescribing, dispensing, or administering medication or drug-related offenses.

**Wisconsin Statutes, Chapter 961: Uniform Controlled Substances Act**

The Wisconsin Statutes are a compilation of the general laws of the state of Wisconsin and include chapters related to the regulation of nursing, as well as the Uniform Controlled Substances Act.

**Wisconsin Statutes**

Chapter 441 defines the Board of Nursing and relates to the Regulation and Licensure of Nursing. Chapter 961 is the Uniform Controlled Substances Act. The Wisconsin legislature finds that the abuse of controlled substances constitutes a serious problem for society. As a partial solution, laws regulating controlled substances have been enacted with penalties. Chapter 961 does not apply to the nondrug use of peyote and mescaline in the bona fide religious ceremonies of the Native American Church. See the link below for more information about the regulations related to Schedule I through V drugs in the State of Wisconsin.

**Chapter 961: Uniform Controlled Substances Act**

**Wisconsin’s Enhanced Prescription Drug Monitoring Program (ePDMP)**

The ePDMP is a new tool to help combat the ongoing prescription drug abuse epidemic in Wisconsin. By providing valuable information about controlled substance prescriptions that are dispensed in the state, it aids healthcare professionals in their prescribing and dispensing decisions. The ePDMP also fosters the ability of pharmacies, healthcare professionals, law enforcement agencies, and public health officials to work together to reduce the misuse, abuse, and diversion of prescribed controlled substance medications. See the link below to read more information about Wisconsin’s ePDMP.
Wisconsin’s Enhanced Prescription Drug Monitoring Program (ePDMP)

Wisconsin Department of Safety and Professional Services: Professional Assistance Procedure (PAP)

The Professional Assistance Procedure (PAP) is a voluntary non-disciplinary program to provide support for credentialed professionals with substance abuse disorder who are committed to their own recovery. The goal is to protect the public by promoting early identification of chemically dependent professionals and encouraging rehabilitation. It provides an opportunity for qualified participants to continue practicing, without public discipline, while being monitored and supported in their recovery.

Wisconsin’s Professional Assistance Procedure

Critical Thinking Activity 2.3d

A nurse is disciplined by the Wisconsin Board of Nursing for an incident reported by her employer that she arrived at her shift intoxicated. The nurse shares with a nursing colleague, “I love taking care of patients. I worked so hard to obtain my nursing license – I don’t want to lose it. I know my drinking has gotten out of control, but I don’t know where to turn.”

What is the best advice by the nursing colleague for this nurse with a drinking problem?

Note: Answers to the Critical Thinking activities can be found in the “Answer Key” sections at the end of the book.

1. U.S. Food and Drug Administration. (2019) [Link]
4. This work is a derivative of Daily Med by U.S. National Library of Medicine in the public domain. [Link]
5. U.S. Department of Justice - Drug Enforcement Administration. (n.d.). Drug scheduling. [Link]


44. Wisconsin Department of Safety and Professional Services. (n.d.). Wisconsin nurse practice act (NPA)


51. Wisconsin State Legislature. (n.d.). *Chapter 961 uniform uncontrolled substances act*. [https://docs.legis.wisconsin.gov/statutes/statutes/961](https://docs.legis.wisconsin.gov/statutes/statutes/961)
