Pharmacy Society of Wisconsin

MONTH OF ADVOCACY

One Voice. Together While Apart.

HOW A PILL BECOMES A LAW / 2021 LAW UPDATE

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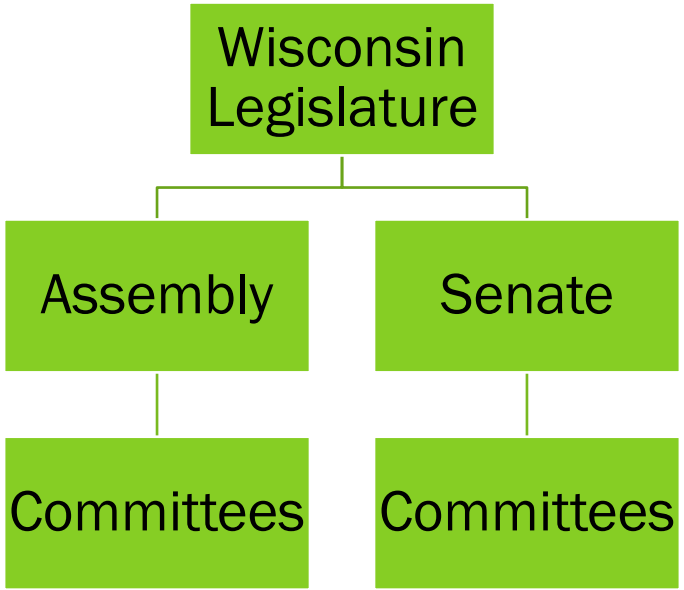
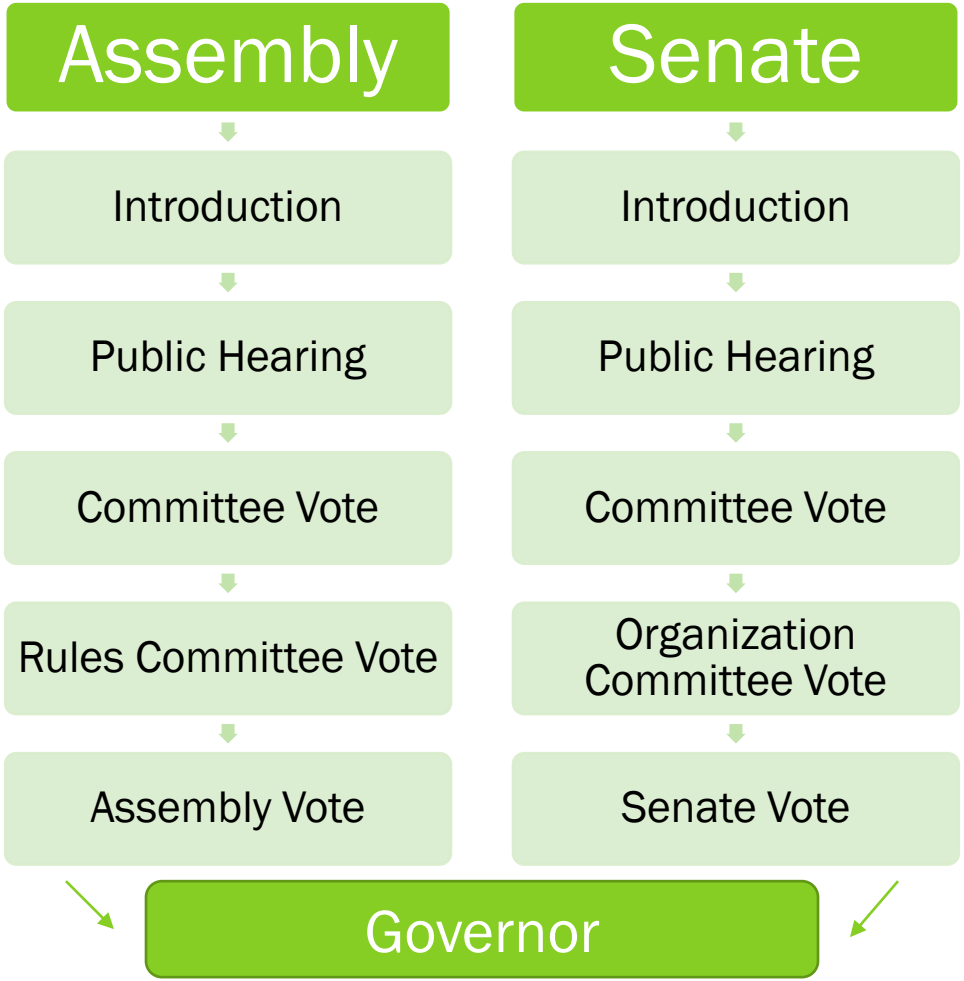
Pharmacy Society of Wisconsin

LEGISLATIVE, REGULATORY & PRACTICE

WISCONSIN STATE LEGISLATURE

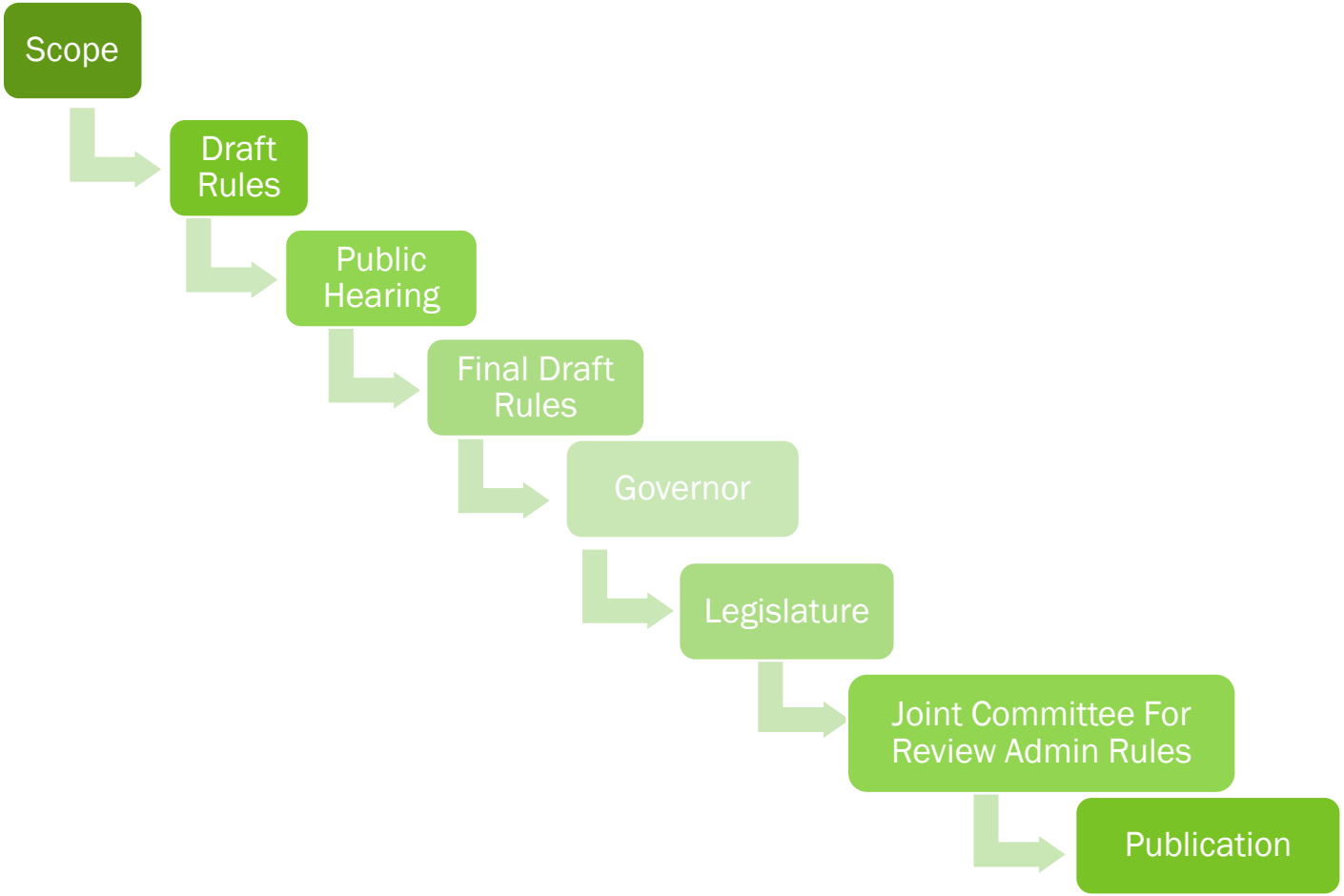


Senate: 33 members
Assembly: 99 members


Assembly
Introduction
Public Hearing
Committee Vote
Rules Committee Vote
Assembly Vote
Senate
Introduction
Public Hearing
Committee Vote
Organization Committee Vote
Senate Vote
Governor

ADMINISTRATIVE RULE-MAKING

- Statutes can define authority and power of an administrative agency
- Agencies make and enforce rules within areas of delegated authority
- Rulemaking is the power to promulgate regulations/rules that have the effect of law


Scope
Draft Rules
Public Hearing
Final Draft Rules
Governor
Legislature
Joint Committee For Review Admin Rules
Publication

ADVOCACY TOOLS

ADVOCACY TOOLS

- Contact a policymaker
- Visit a policymaker
- Contribute
- Testify at a hearing
- Educate

PSW VEHICLES

- Pharmacy Legislative Action Network (PLAN)
- Legislative Day
- Legislative Defense Fund
- Friends of Pharmacy Fund (Conduit)
- PSW Advocacy Council

LEGISLATIVE DEFENSE FUND

- Supports PSW advocacy efforts
- Funds do not go to any political candidate
- Contributed funds allocated by PSW

www.pswi.org/LDF

Friends of Pharmacy Fund

- Support pro-pharmacy political candidates
- Political contribution
- You must approve all donation allocations

www.pswi.org/FPF

DISCLAIMER

The Pharmacy Society of Wisconsin has created this presentation and accompanying toolkit as a resource for pharmacies and pharmacists practicing in Wisconsin. While every effort has been made to ensure the accuracy of this information, pharmacies and pharmacists should always ensure compliance with all state and federal laws, administrative rules, and regulations.

All pharmacies and pharmacists practicing in Wisconsin are responsible for complying with the laws and regulations as they are written.

PHARMACY PRACTICE CHANGES

Act	Law	Statute
2017 Act 18	Regulatory Clean-Up	450.09, 450.11, Phar 1.02, Phar 6.06
2017 Act 19	Emergency Refills	450.11(5)
2017 Act 42	Pharmacy Intern Immunizations	450.035
2017 Act 133	Epinephrine Auto-Injectors	255.07, 450.11(4)
2017 Act 149	Biologic Interchangeability	450.13
2017 Act 293	Technician Delegation	450.03, 450.062
2017 Act 305	Eye Drop Refills	632.895(16t)
2019 Act 24	Immunization Authority	450.035
2021 Act 3	Delegate Immunization	450.035

ACT 18: REGULATORY CLEAN-UP

1. Removes requirement for pharmacists and pharmacy to display a physical license.
2. Adapts the DEA definition of “long term care facility” to include assisted living facilities. This allows LTCF that provide extended health care to patients to accept faxed CII prescriptions.
3. Removes the requirement for inpatient chart orders to include the address of the prescriber.
4. Repeals mandatory minimum equipment requirements (e.g. mortar and pestle, torsion balances, spatulas, etc.)

ACT 19: EMERGENCY REFILLS

- Allows a pharmacist to dispense an emergency refill if certain conditions are met:
  - The pharmacist attempts to get authorization for a refill, but cannot reach the prescriber.
  - The patient is on a consistent drug therapy.
  - The patient has previously filled the prescription at the same pharmacy or within the same chain.
  - The drug is not a controlled substance.
  - The patient may receive one emergency refill per drug per year.
  - If the prescriber has indicated “no extensions” on the prescription order or has told the pharmacy it cannot extend the prescription, the pharmacy may not dispense an emergency refill
  - The emergency refill is for a maximum 7-day supply (exception: insulin/other drugs not packaged for 7-day supply).

ACT 42: INTERN IMMUNIZATION

- Allows pharmacy interns who have completed at least two years of pharmacy school may administer immunizations to patients aged 6 and older.
  - Under prior law, interns could only immunize 18+

ACT 133: EPINEPHRINE AUTO-INJECTORS

- Any person who completes an approved training course may be prescribed an epinephrine auto-injector and administer it to a patient believed to be experiencing anaphylaxis.

ACT 149: BIOLOGIC INTERCHANGEABILITY

- Pharmacists may substitute a biologic drug declared "interchangeable" by the FDA in place of the prescribed drug.
- If an "interchangeable" drug is available, the pharmacist must inform the prescriber which drug product was dispensed.
  - Adjudication through a PBM or submission to EHR fulfills this requirement.
- *There are currently no FDA-approved interchangeable biologics*

ACT 293: TECHNICIAN DELEGATION

- Clarifies state law by specifically stating that pharmacists can delegate to unlicensed personnel, e.g. technicians.
- Allows pharmacy technicians to dispense medications at a remote dispensing site, pursuant to RDS regulations.

ACT 305: EYE DROP REFILLS

- Requires insurers that would cover eye drops to cover refills after 75% of the days since the last fill have passed.

ACT 24: IMMUNIZATION AUTHORITY

- Allows pharmacists to immunize without a protocol if following CDC/ACIP schedule for patients age 6+
- Allows pharmacists to immunize patients under 6 if the following conditions are met:
  - Patient-specific prescription order
  - Prescription must be written less than 30 days prior to immunization
  - Pharmacist must complete pediatric immunization training
- Requires all pharmacists to update WIR within 7 days of immunizing

ACT 3: DELEGATE VACCINES

- Any vaccine-trained student pharmacist may administer vaccines (no longer required to have completed two years of pharmacy school)
- Student immunizers can be supervised by any licensed healthcare professional who is trained in vaccination
- Certified and vaccine-trained technicians may administer vaccines under the supervision of a pharmacist
- Pharmacists, pharmacy students, and pharmacy technicians may administer injectable epinephrine or diphenhydramine in the case of an adverse vaccine reaction

CONTROLLED SUBSTANCE CHANGES

Act	Law	Statute
2017 Act 25	Schedule V Prescriptions	961.38(4)
2017 Act 60	Fentanyl Analogs	961.14(2)
2017 Act 98	Pseudoephedrine Tracking	961.23
2017 Act 99	Hospice Drug Disposal	450.115
2017 Act 160	Dextromethorphan	134.91
2017 Act 226	Tribal Identification Cards	450.11(1b)
2019 Act 68	Hemp/CBD Oil	961.34
2019 Act 121	PDMP	961.385

ACT 25: SCHEDULE V PRESCRIPTIONS

- Requires a prescription order for combination narcotic/non-narcotic drugs in Schedule V.
  - Acetaminophen/Codeine
  - Also ethyl-morphine, opium, dihydrocodeine, difenoxin, and diphenoxylate
- The dispensing of these drugs must be submitted to the PDMP.

ACT 60: FENTANYL ANALOGS

- All fentanyl analogs not otherwise scheduled are Schedule I controlled substances.

ACT 98: PSEUDOEPHEDRINE TRACKING

- Beginning June 1, 2018, all PSE sales must be electronically tracked through the National Precursor Log Exchange (NPLEx) System BEFORE the sale is complete.
- If a purchaser would exceed the maximum amount with the purchase, NPLEx will push a “stop sale.” Pharmacists cannot override the stop sale unless there is an imminent threat of harm (e.g. purchaser is threatening pharmacist).
- Paper logs no longer meet requirements unless there is a technological failure.

ACT 99: HOSPICE DRUG DISPOSAL

- Hospice staff may dispose of a deceased patient's controlled substances with permission of the patient's agent/trustee through a lawful drug disposal program.
  - Under prior law, only non-controlled substances could be disposed of by staff – controlled substances needed to be returned to the agent/trustee.

ACT 160: DEXTROMETHORPHAN

- Requires a prescription for dextromethorphan-containing products for patients under age 18.
- A patient over 18 MAY purchase a dextromethorphan-containing product for use by a patient under 18 without a prescription (e.g. parent may purchase for their child).

ACT 226: TRIBAL IDENTIFICATION CARDS

- Identification cards issued by a federally recognized tribe may be used when picking up a controlled substance.

ACT 68: HEMP/CBD OIL

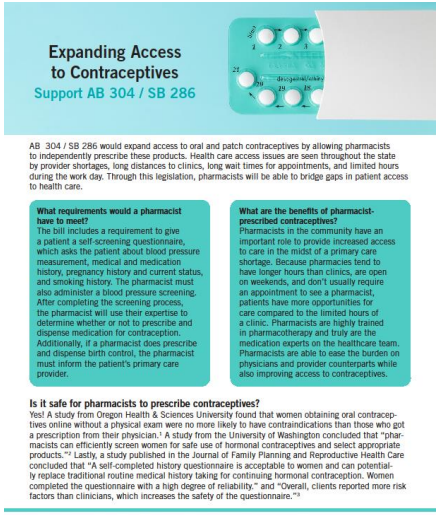
- Hemp-derived CBD with a THC content greater than 0.3% requires a physician certification to be sold/dispensed
- Hemp-derived CBD with a THC content of 0.3% or less is NOT a controlled substance; any vendor can sell these products
- A certification is not required for products with 0.3% or less THC
- Clarifies that pharmacies may sell CBD products.

ACT 121: PDMP

- Extends the sunset period for prescribers to check the PDMP before prescribing a controlled substance to October 30, 2025

2021 LEGISLATIVE PRIORITIES

- PBM Reform
- Provider Status
- COVID Response
- Remote Dispensing
- Technician Registration
- Contraception Prescribing
- Immunization Expansion – students & technicians



REGULATORY UPDATES

REGULATORY CHANGES

Rule	Topic	Administrative Code
CR 19-165	Storage	Phar 6
CR 19-164	Internships	Phar 17
CR 19-145	Pharmacy Practice	Phar 7

STORAGE

- Repeals requirements for a refrigerator in each pharmacy
- Requires drugs be stored at appropriate conditions to prevent adulteration
- Requires pharmacies to monitor temperature and humidity of the refrigerator, freezer and pharmacy; also requires record of the pharmacy's minimum and maximum temperature and humidity on each day the pharmacy is open

INTERNSHIPS

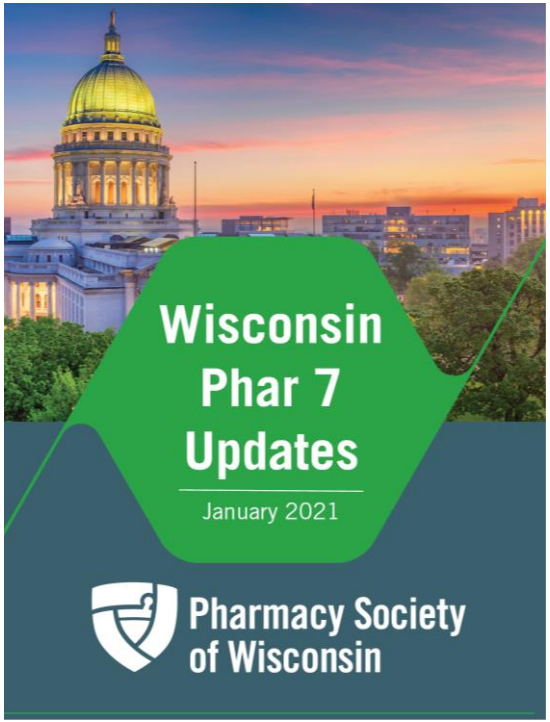
- Eliminated the different types of internships
- States that an “intern” is anyone completing the internship hours required for licensure
- Supervising pharmacist or school must track intern hours; can be tracked in the manner of their choosing

PHAR 7: BACKGROUND

- Various sections of Phar 7 have been updated over the years, but the last compete rewrite was in January, 1983
- PEB Goals: update chapter to remove outdated requirements, account for modern technologies/processes, clarify sections that cause confusion, align chapter with statutes and federal requirements
- Process began in June, 2013; rule approved by legislature in April, 2020
- New rule completely replaces old rule

RESOURCES

- Phar 7 (old version, expires 12/31/2020)
- Phar 7 (new version, effective 1/1/2021)
- Wisconsin Phar 7 Updates Guide from PSW



RULE COMPONENTS

A. Pharmacists
   1. Drug Utilization Review
   2. Final Check
   3. Patient Consultation
   4. Delegation
   5. Administration of Drug Products and Devices other than Vaccines

B. Prescriptions
   1. Prescription Orders
   2. Prescription Labels
   3. Transferring Prescriptions

RULE COMPONENTS

C. Unlicensed Persons

1.Persons who have completed their second year of pharmacy school or who are apply for license out of state

2. Unlicensed persons

3. Delegate-check-delegate

D. Pharmacies

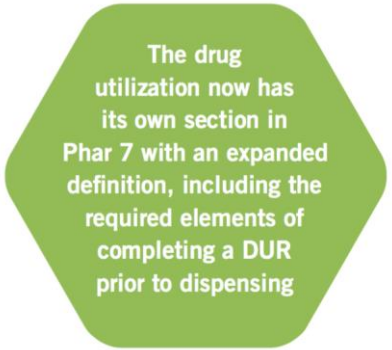
1. Repackaging for stock
2. Delivery by common carrier or delivery services
3. Procurement, recall, and out-of-date drugs and devices
4. Return or exchange of health items
5. Pharmacy records
6. Central shared services
7. Delivery systems
8. Remote dispensing
9. Institutional pharmacies

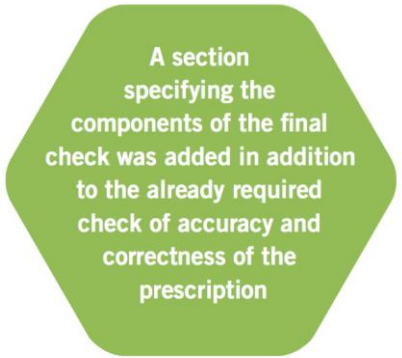
CHANGES: OVERVIEW

- Drug utilization review
- Final check
- Consultation
- Prescription expiration
- Prescription label requirements
- Transfer requirements

CHANGES: DURS AND FINAL CHECKS

- Drug Utilization Review
  - Completed prior to dispensing
  - Check for known allergies, rational therapy, contraindications, reasonable dose, etc.
  - Mitigate issues
- Final Check
  - Verifying label is correct and meets labeling requirements
  - Verifying the drug product or device is correct
  - Completion of the drug utilization review





CONSULTATION

- Previously, consults were required for all prescriptions dispensed regardless of patient's history
- Now, all patients have a right to consultation, but they are not required unless requested or a criteria below is met

Counseling Required	Counseling Not Required
Drug or device has not been dispensed previously to the patient	Drug or device is administered by any route by or in the presence of an individual with a scope of practice that includes drug or device administration or their delegate
Change in therapy	Patient or patient's agent refuses consultation
Patient or patient's agent requests counseling	
Whenever deemed necessary based upon the professional judgment of the pharmacist	

CONSULTATION

- When consults are given, a written patient drug education monograph must be provided as well
- Pharmacies must display a board-approved sign explaining a patient's rights to consult, and how to submit a complaint to the board
  - This information must be provided to patients who received prescriptions via delivery, mail order, drive-thru

PRESCRIPTIONS

- 1 year expiration date, regardless of number of refills
  - Starting in January, this will no longer be the case
- New requirements for label
  - Quantity
  - Number of refills or quantity remaining
  - Prescriber name
  - Most pharmacies already have this in practice
- Transfers
  - Must document first AND last name of pharmacist when completing transfers
  - Currently, first name is sufficient

DELEGATION

- A pharmacist may perform any patient care service delegated to the pharmacist by a physician
- The pharmacist shall document the delegation by a physician.
- The delegated act may not be started prior to the documentation.
- The documentation shall be maintained for a minimum of 5 years after the last delegated act under that delegation.

ADDITIONS

- Delegation
- Unlicensed persons
- Repackaging for stock
- Delivery by common carrier or delivery services
- Procurement, recall, and out-of-date drugs and devices
- Delivery systems
- Institutional pharmacies

UNLICENSED PERSONS

- Unlicensed persons:
  - Completed 2nd year of pharmacy school or pharmacists from another state applying for licensure – requires direct supervision, can perform any pharmacist task
  - "Unlicensed persons," e.g. technicians – requires general supervision, cannot do:
    - Final check
    - DUR
    - Counsel
- Delegate-check-delegate

REPACKAGING FOR STOCK

- “Repackaging for stock” means transferring a non-sterile drug product from the stock container in which it was distributed by the original manufacturer and placing it into a different stock container as a source for subsequent prescription dispensing without further manipulation of the drug.
- Ensure integrity of the drug and mitigate adulteration from elements
- Label with BUD, lot number, drug name, strength and form
- Maintain records of repackaging for stock including lot, NDC, expiration/BUD dates, name of person who repackaged and name of pharmacist who verified repackage

DELIVERY BY COMMON CARRIER OR DELIVERY SERVICE

- Can deliver to any location of a patient's choice to patient or patient's agent
- The delivery method is appropriate to prevent drug adulteration
- The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device
- Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient.
- If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm

PROCUREMENT, RECALL AND OUT-OF-DATE DRUGS AND DEVICES

- A pharmacy shall have a system for identifying a drug or device subjected to a product recall and for taking appropriate actions as required by the recall notice
- A drug or device may not be dispensed after the drug's or device's expiration date or beyond use date.
- Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed

DELIVERY SYSTEMS

- Delivery System
  - “Locker”-style pick-up
  - Only the patient or patient’s agent shall be able to open the door or locker containing only the patient’s prescription.
  - Protect health information
  - Maintain appropriate environmental controls
  - The use of a delivery system does not create an exemption to the requirement of an identification card for certain controlled substances
  - A log of all prescriptions delivered to the delivery system must be kept
  - The delivery system shall be inventoried at least weekly and a list of unclaimed prescriptions shall be reviewed by a pharmacist.
  - The managing pharmacist shall establish written policies for stocking, determining access, and detection and mitigation of diversion/theft

AUTOMATED DIRECT-TO-PATIENT DISPENSING SYSTEM

- Practitioner dispensing
  - A health care facility
  - The office or clinic of a practitioner
  - A county jail, rehabilitation facility, state prison, or county house of correction
  - A juvenile correctional facility
- Access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to the supervising practitioner or a delegate.
- Follow labeling requirements
- Maintain records of all dispenses
- The managing pharmacist shall establish written policies for stocking, determining access, and detection and mitigation of diversion/theft

INSTITUTIONAL PHARMACIES

- *A pharmacy that provides pharmacy services to any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services; a county jail; and a correctional facility.*
- Chart orders
- Labels
- Security and access
- Return or exchange of health items
- Automated technology product verification

WHERE TO FIND SPECIFICS

- Statutes:

  https://docs.legis.wisconsin.gov/statutes/prefaces/toc

  - Pay most attention to § 450 & § 961
- Administrative Code:

  https://docs.legis.wisconsin.gov/code/admin_code

  - Pay most attention to Phar and CSB
- Still have questions?

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