



# Wisconsin Phar 7 Updates

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January 2021



**Pharmacy Society  
of Wisconsin**



The Wisconsin Pharmacy Examining Board updated and wrote Phar 7 – Pharmacy Practice over the course of many years in an attempt to comprehensively update the chapter for modern pharmacy practice. The updated version of this rule is effective January 1, 2021.

The Pharmacy Society of Wisconsin has created this 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.

A copy of Phar 7 can be found online [here](#).

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## SECTION D

# A. Pharmacists

## 1. Drug Utilization Review

A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

- Known allergies
- Rational therapy
- Contraindications
- Reasonable dose, duration of use, and route of administration, considering the age, and other patient factors
- Reasonable directions for use
- Potential or actual adverse drug reactions
- Drug interactions with food, beverages, other drugs or medical conditions
- Therapeutic duplication
- Reasonable utilization and optimum therapeutic outcomes
- Potential abuse or misuse

Upon recognizing a concern with any of the items above, the pharmacist shall take steps to mitigate or resolve the problem

## 2. Final Check

A final check of accuracy and correctness is required for any prescription drug product or device dispensed and shall include all of the following:

- Verifying label is correct and meets labeling requirements
- Verifying the drug product or device is correct
- Completion of the drug utilization review

A section specifying the components of the final check was added in addition to the already required check of accuracy and correctness of the prescription

For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If the above is completed by a delegate-check-delegate or automated technology, the prescription record shall identify the delegate performing the check

The drug utilization now has its own section in Phar 7 with an expanded definition, including the required elements of completing a DUR prior to dispensing

### 3. Patient Consultation

<i>Counseling Required</i>	<i>Counseling Not Required</i>
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	

**Counseling is no longer required on renewal/refill prescriptions if no other conditions of this column are met**

Consultation shall contain any of the following information that, in the pharmacist's professional judgement, serves the best interest of the patient:

- Name and description of the drug
- Form, dose, route of administration and duration for drug therapy
- Intended use of the drug and expected action
- Directions and precautions for preparation, administration, and use
- Common severe side or adverse effects or interactions and

therapeutic contraindications that may be encountered, including their avoidance, and the action required if they do occur

- Techniques for self-monitoring drug therapy
- Action to be taken in the event of a missed dose
- Proper storage and appropriate disposal method of unwanted or unused medication

**The consultation required in this section shall be communicated verbally when, in the pharmacist's professional judgment, it is in the best interest of the patient**

**A prescription drug or device delivered by common carrier, mail, or delivery service or picked up at a drive through window shall include a copy of information which is board approved stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board**

**A pharmacist shall provide the patient or patient's agent, for all consultations required, a written patient drug education monograph**

**Every licensed pharmacy dispensing directly to a patient or patient's agent inside the pharmacy shall conspicuously post a board approved sign stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board**

**The consultation required in this section may occur before or after delivery of the prescription to the patient or patient's agent**

#### 4. 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.

#### 5. Administration of Drug Products and Devices Other than Vaccines

- A pharmacist or person engaged in the practice of pharmacy (i.e. pharmacy intern or graduate intern) may administer a drug product or device if certain conditions are met
- After the pharmacist administers a prescribed drug product or device, the pharmacist, a person engaged in the practice of pharmacy, or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.
- A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.
- A pharmacy intern nor graduate intern may not administer a prescribed drug product or device unless the person satisfies all of the following:
  - » Successfully completes a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board
  - » Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council of Pharmacy Education or the board.
  - » After administering the prescribed drug product or device, notifies the prescribing practitioner or enters the information in a patient record system shared by the prescribing practitioner.
- The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.
- A course of study and training in administration technique shall include all of the following topics:
  - » Safe injection practices to prevent infections.
  - » Anatomy.
  - » Proper injection techniques.
  - » The five rights of administration including right patient, right drug, right dose, right route, and right time.
  - » Patient reassessment after administration including signs and symptoms of adverse drug reactions.
  - » Best practices in documentation of the medication administration.
- This section does not apply to the administration of vaccines (see s. 450.035 for vaccine administration requirements)

# B. Prescriptions

Prescriptions no longer have a one-year expiration date from when they are written, regardless on number of refills remaining or PRN status

## 1. Prescription Orders

“Standing order” means an order transmitted electronically or in writing by a practitioner for a drug or device that does not identify a particular patient at the time it is issued for the purpose of drug or device dispensing or administration to individuals that meet criteria of the order. A copy of the standing order must be retained subject to pharmacy records requirements (see Section D-5).

<i>Required Component</i>	<i>Prescription Order</i>	<i>Prescription Pursuant to a Standing Order</i>
Date of issuance	X	X
First and last name and address of the practitioner	X	X
First and last name of the delegate, if ordered by a delegate of the practitioner, and the first and last name and address of the practitioner	X	X
Name, strength, quantity of drug product or device	X	X
Directions for use of the drug product or device	X	X
Refills, if any	X	X
Symptom or purpose for which the drug is being prescribed if the patient indicates in writing to the practitioner that the patient wants the symptom or purpose for the prescription to be disclosed on the label	X	
Name and address of the patient except if the prescription is an epinephrine auto-injector for a school or authorized entity, is a prescription for an opioid antagonist, or is a prescription for expedited partner therapy	X	X
If prescription is issued for an epinephrine auto-injector for a school, the name and address of the school	X	X
If the prescription is issued for an epinephrine auto-injector for an authorized entity, the name and address of the authorized entity or individual	X	X
Practitioner’s written, electronic, or digital signature	X	
Indicate the prescription is pursuant to a standing order		X

## Electronic Prescription

- A practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient
- Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders
- The prescribing practitioner’s electronic signature, or other secure method of validation shall be provided electronically with a prescription order

## Verbal Prescription

- Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail
- The verbal prescription shall be reduced to writing or entered into a computer system (See Section D-5) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information

## Alterations

- Any alterations that modify the original intent of a prescription shall be documented including the identification of the pharmacist responsible for the alteration and the practitioner or practitioner's delegate who authorized the alteration

## 2. Prescription Labels

- This section does not apply to institutional pharmacies as defined in Section D-9
- Labeling requirements do not apply to complimentary samples of drug products or devices dispensed in original packaging by a practitioner to his or her patients

New  
required  
label  
elements

Label Component	Required	May Include
Identification of the patient by first and last name, unless one of the following applies: <ul style="list-style-type: none"> <li>expedited partner therapy → EPT or full phrase</li> <li>opioid antagonist → last name only</li> <li>epinephrine auto-injector → school name, authorized entity, or other person specified</li> <li>animal → last name of owner, name of animal, and species of animal</li> </ul>	X	
Symptom or purpose if order specifies	X	
Name and strength, unless omission requested by prescriber	X	
Date for which medication shall not be used after	X	
Pharmacy name, address, and telephone number	X	
Prescriber name	X	
Quantity	X	
Number of refills or quantity remaining	X	
Directions for use	X	
Symptom or purpose if requested by patient		X
Both generic name and brand name, if prescription order lists both names and the generic name is dispensed, unless practitioner requests brand name be omitted		X
Written or graphic product descriptions		X
Any cautions or other provisions		X

## 3. Transferring Prescriptions

- A transfer of prescription order information between pharmacies licensed in this state or another state, for the purpose of **original or refill dispensing of non-controlled substances, and refills of controlled substances**, may occur if all of the following conditions are satisfied:
  - The transfer or prescription order information is communicated either verbally by two pharmacists or electronically or by facsimile machine between the two pharmacies
  - A transfer of prescription information verbally shall be reduced to writing or entered into a computer system and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information
  - A pharmacist shall transfer a prescription upon patient request pursuant to this section
- A shared computer system used for transferring prescription order information shall, in addition to meeting the requirements of Section D-5, contain a shared real time electronic file database with a complete record of all prescriptions filled and dispensed.

When transferring a prescription, Phar 7 updates **REQUIRE** pharmacists to document first **AND** last names of the pharmacist communication – previously, a first name was sufficient



<i>Item</i>	<i>Non-Controlled</i>	<i>Controlled</i>
VOID on face of invalidated prescription, either written or recorded in a similar manner on a prescription order in a computer system meeting the requirements	X	X
Name, address of pharmacy prescription transferred to, and date of transfer on invalidated prescription	X	X
DEA of pharmacy transferred to		X
First and last name of pharmacist transferring information, either in writing or recorded in a computer system meeting the requirements	X	X
TRANSFER on face of transferred prescription, either in writing or recorded in a computer system meeting the requirements of Section D-5	X	X
First and last name and address of patient for transferred prescription	X	X
First and last name and address of prescriber for transferred prescription	X	X
DEA of prescribing practitioner		X
Name, strength, form, quantity, directions for use of transferred prescription	X	X
Original date of issuance, original date of dispensing if previously filled	X	X
Original number of refills	X	X
Original order number	X	X
Number of valid refills remaining or total quantity remaining	X	X
Date of last refill	X	X
Pharmacy's name and address from which the prescription was transferred	X	X
Pharmacy's name, address, and order number from which the prescription originated from, if different from transferring pharmacy	X	X
DEA of pharmacy transferred from		X
DEA of pharmacy from which the prescription originated from, if different from transferring pharmacy		X
First and last name of the pharmacist transferring and receiving the order information	X	X

### **Special Conditions for Controlled Substance Transfers:**

- The transfer of prescription order information is permissible only on a one-time basis. Pharmacies electronically sharing a computer system may transfer up to the maximum refills permitted by law and the prescriber's authorization.
- Refill transfers for Schedule III-V controlled substances shall be communicated verbally between two pharmacists.

# C. Unlicensed Persons

## 1. Persons who have completed their second year of pharmacy school or pharmacists from another state applying for licensure

A person engaged in the practice of pharmacy is defined as one of the following:

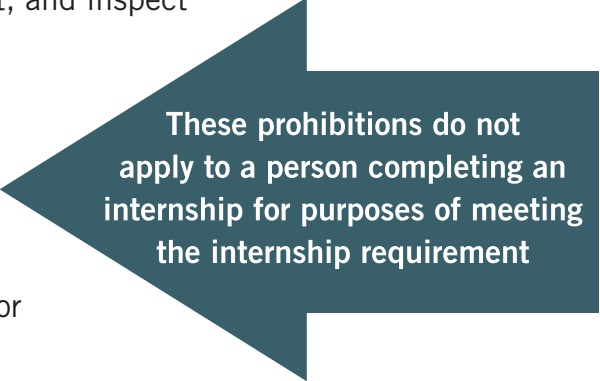
- A person who has successfully completed his or her second year in, and is enrolled at, an accredited school of pharmacy and whose practice of pharmacy is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.
- A person who has applied for a license whose practice of pharmacy is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and during the period before which the board takes final action on the person's application

Limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

- Direct supervision = immediate availability to continually coordinate, direct, and inspect in real time the practice of another

## 2. Unlicensed Persons

- This section does not apply to a person engaged in the practice of pharmacy (see Section C-1)
- A pharmacist shall provide general supervision of unlicensed personnel. A pharmacist shall be available to the unlicensed person for consultation either in person or contact by telecommunication means
  - » General supervision = continually coordinate, direct, and inspect the practice of another
- An unlicensed person may not do any of the following:
  - » Provide the final check on the accuracy and correctness of drug product or device dispensing unless the person is validated for delegate-check-delegate
  - » Complete the DUR
  - » Administer any prescribed drug products, devices, or vaccines
  - » Provide patient specific counseling or consultation
- A managing pharmacist shall provide training to or verify competency of unlicensed person prior to the unlicensed person performing a delegated act
- The managing pharmacists shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific unlicensed persons. This record shall be provided to the board upon request.
- A pharmacist may delegate to an unlicensed person any delegated act approved by the managing pharmacist.



**These prohibitions do not apply to a person completing an internship for purposes of meeting the internship requirement**

### **3. Delegate-Check-Delegate**

#### **Definitions**

- “Delegate” means a person to whom the pharmacist has delegated the task of product verification.
- “Delegate-check-delegate” means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.
- “Product verification” means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.
- “Supervising pharmacist” means the pharmacist licensed in this state who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

#### **Delegate qualifications: A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:**

- Is at least 18 years old.
- Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.
- Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:
  - » Elements of correct product including all of the following:
    - Drug name.
    - Strength.
    - Formulation.
    - Expiration date.
    - Beyond use date.
  - » Common dispensing medication errors and concepts including all of the following:
    - Wrong medication.
    - Wrong strength.
    - Wrong formulation.
    - Extra or insufficient quantity.
    - Omitted medications if utilizing unit dose or compliance packaging.
    - Expired medication.
    - Look-alike or sound-alike errors.
    - High-alert medications.
  - » Eligible medications for delegate-check-delegate.
  - » Organizational policies and procedures on reporting of medication errors.
  - » Overview of the medication use process including all of the following:
    - Procurement
    - Ordering
    - Dispensing
    - Administration
    - Monitoring

- » A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
  - Wrong drug.
  - Wrong strength.
  - Wrong formulation.
  - Omitted medication, if utilizing unit dose or compliance packaging.
- Completed the following validation process:
  - » The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
  - » A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.
- A delegate who completed the pilot program validation process between October 1, 2016, and September 30, 2019, meets the delegation qualifications unless the delegate fails to meet the quality assurance standards

### Eligible Product

- ***Institutional pharmacies.*** The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:
  - » Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
  - » Has a drug utilization review performed by a pharmacist prior to dispensing.
  - » Will be administered by an individual authorized to administer medications at the institution where the medication is administered.
- ***Community pharmacies.*** The delegate may do the product verification in a community pharmacy if the medication meets all of the following:
  - » Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
  - » Has a drug utilization review performed by a pharmacist prior to dispensing.
  - » Includes a description of the medication on the prescription label that allows for a non-pharmacist to check the accuracy of the medication after it is delivered.

### Quality Assurance

- A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.
- A record of each delegate-check-delegate audit shall include all of the following:
  - » Name of the product verification delegate.
  - » Total number of product verifications performed.
  - » Number of product verifications audited by the pharmacist.
  - » Percentage of product verifications audited by pharmacist.
  - » Percentage of accuracy.
  - » Number of product verification errors identified.
  - » Type of error under

- On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.
- A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

### **Policies and Procedures**

- Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

### **Records**

- Each pharmacy shall maintain for 5 years the following records:
  - » All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
  - » Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.
  - » Quality assurance audits and quarterly assessments.
- Records shall be made available to the board upon request.

# D. Pharmacies

“Managing pharmacist” means a pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel..

## **1. 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.

“Control number” means a unique number used to identify a repackaged drug or drug product in reference to a record that contains NDC, expiration date, and lot number.

A pharmacy repackaging for stock any non-sterile drugs shall do all of the following:

- The repackaging for stock process is conducted under conditions that ensure the integrity of the drug
- Products repackaged for stock shall include a beyond use date that ensures the integrity of the drug
- The repackaged container shall be selected to mitigate adulteration from light, temperature, and humidity
- The repackaged for stock drugs are labeled physically or electronically with all of the following components:
  - » Drug name, strength, form and beyond use date
  - » One of the following identifiers:
    - Pharmacy control number
    - NDC number and manufacturer lot number
    - Name of manufacturer or distributor of the drug product, and the manufacturer lot number
- Records of all repackaging for stock operations are maintained and include all the following:
  - » Name, strength, form, quantity per container, and quantity of containers
  - » NDC numbers or the name of the manufacturer or distributor of the drug product
  - » Manufacturer lot number
  - » Original container’s expiration date and the beyond use date for the new containers
  - » First and last name of the pharmacist or delegate that repackaged the drug and the first and last name of the pharmacist that verified the accuracy of the repackaging
  - » Date of repackaging
  - » Any pharmacy control numbers



## **2. Delivery by common carrier or delivery services**

Utilization of common carrier or delivery services to deliver a prescription to a location of the patient's choice from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

- 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, including all of the following
  - » Timeliness of delivery
  - » Condition of the prescription drug upon delivery
  - » Failure to receive the proper 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

**NEW  
TOPIC**

## **3. 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

**NEW  
TOPIC**

## **4. Return or exchange of health items**

- Definitions
  - » "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene
  - » "Original container" means the container in which a health item was sold, distributed, or dispensed
  - » "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.
- No health item after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:
  - » Where the health item was dispensed in error, was defective, adulterated, or misbranded
  - » When in professional judgment of the pharmacist substantial harm could result to the public or patient if it were to remain in the possession of the patient, patient's family or agent, or other person
  - » A health item that is prepackaged for consumer use without a prescription when returned in compliance with all applicable state and federal laws
    - Note: the DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances

**See Section  
D-9-E for more  
information regarding  
returning and exchanging  
health items in  
institutional  
pharmacies**

- A health item returned to a pharmacy may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. A returned health item shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.
- It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of repackaging or relabeling of that previously dispensed drug or device, and subsequent return of the drug or device is for the same patient's use
- It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity
- This section does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

## **5. Pharmacy Records**

Pharmacy records shall be maintained for a minimum period of 5 years unless otherwise specified in state or federal law.

### **Prescription Records**

- A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purpose of original or refill dispensing if the system is:
  - » Capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining
  - » Equipped with an auxiliary procedure which, during periods of down-time, shall be used for documentation of prescription dispensing
    - The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded, and that all of the appropriate data are retained for online entry as soon as the computer system is again available for use
- A record of all prescriptions dispensed shall be maintained for a minimum period of 5 years after the date of the last refill
- All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system
- A paper prescription for non-controlled substances may be scanned and stored electronically in the computer system
  - » The prescription becomes an electronic prescription

### **Medication Profile Record System**

- An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or refill, are dispensed
- The system shall be capable of permitting the retrieval of information
- The following minimum information shall be retrievable:
  - » Patient's first and last name, or if not human, name of pet, species and last name of owner
  - » Address of the patient
  - » Birth date of the patient or if not human birthdate of the owner
  - » Name of the drug product or device dispensed



- » Strength of the drug product or device dispensed
- » Form of the drug product or device dispensed
- » Quantity of the drug product or device prescribed, dispensed, and remaining
- » Number of refills prescribed
- » Directions for use
- » Prescription order number
- » Original date of issue
- » Dates of dispensing
- » Prescriber's first and last name
- The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by patient or agent of the patient
  - » If none, this should be indicated
- Medication profile records shall be maintained for a minimum period of 5 years following the date of the last dispensing

## **6. Central Shared Services**

### **Definitions**

- Central shared services pharmacy means a pharmacy licensed in this state acting as an agent of an originating pharmacy
- Labeling pharmacy means the central shared services pharmacy or originating pharmacy which is responsible for product verification
- Originating pharmacy means a pharmacy licensed in this state that uses a central shared services pharmacy

### **Requirements: an originating pharmacy may use a central shared services pharmacy only pursuant to the following requirements**

- The central shared services pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract.
- The central shared services pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number that it provides services to.
- The central shared services pharmacy and originating pharmacy maintain a written protocol delineating each pharmacy's assumption of responsibility for compliance with state and federal law.
- Unless the central shared services pharmacy shares a computer system with the originating pharmacy and contains the medication profile record, it may not perform drug utilization review to satisfy the final check requirement
- The prescription label attached to the container shall contain the name and address of the labeling or originating pharmacy. The date on which the prescription was dispensed shall be the date on which the labeling pharmacy filled the prescription order.
- The originating pharmacy or central shared services pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.
- In addition to meeting the other recordkeeping requirements required by state and federal law, the central shared services pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for the final check

## **7. Delivery Systems**

### **Definitions**

- “Delivery system” means a structure, controlled by a pharmacy licensed in this state, that a prescription is placed in for patient pick-up
- “Supervising pharmacy” means a licensed pharmacy that oversees the operations and administration of remote dispensing.

### **Delivery System**

- Prescription shall be stored in a secure delivery system immediately upon delivery to the location of the delivery system. Only the patient or patient’s agent shall be able to open the door or locker containing only the patient’s prescription.
- The delivery system shall be designed in a manner which does not disclose protected health information.
- The delivery system shall maintain appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.
- The use of a delivery system does not create an exemption to the requirement of an identification card for certain controlled substances
- A log shall be maintained by the dispensing pharmacy of all prescriptions delivered to the delivery system.
- 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 and procedures for all of the following:
  - » Stocking of the delivery system.
  - » Determining access to the delivery system
  - » Detection and mitigation of diversion and theft.

### **Automated Direct-to-patient Dispensing System**

- In this section “supervising practitioner” means the practitioner who is responsible for the operation of the automated direct- to-patient dispensing system and requirements of this section.
- An automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations may operate for purposes of 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, juvenile detention facility, care center for children and youth, secured residential care center for children and youth, type 1 juvenile correctional facility, type 2 residential care center for children and youth, or type 2 juvenile correctional facility
- The supervising practitioner will ensure all of the following requirements are met:
  - » Individuals with 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.
  - » The automated direct-to-patient dispensing system shall label the prescription in compliance with labeling requirements
  - » The automated direct-to-patient dispensing system shall maintain records of all prescription fills and dispenses
  - » The reporting of all monitored prescription drugs dispensed from the automated direct-to-patient dispensing system to the prescription drug monitoring program.

**NEW  
TOPIC**

The supervising practitioner or delegate shall establish written policies and procedures for automated direct-to-patient dispensing system for all of the following:

- Stocking
- Determining access
- Detection and mitigation of diversion and theft

## **8. Remote Dispensing**

In this section, “supervising pharmacist” means a Wisconsin licensed pharmacist, appointed by the managing pharmacist, who is responsible for the remote dispensing and compliance with this section.

### **Location**


- A pharmacist or a person engaged in the practice of pharmacy may dispense at any of the locations below
  - » Individuals with 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.
  - » The automated direct-to-patient dispensing system shall label the prescription in compliance with labeling requirements
  - » The automated direct-to-patient dispensing system shall maintain records of all prescription fills and dispenses
  - » The reporting of all monitored prescription drugs dispensed from the automated direct-to-patient dispensing system to the prescription drug monitoring program.

### **Title**

- No person may use or display the title “pharmacy”, “drugstore,” “apothecary,” or any other title, symbol or insignia having the same or similar meanings in connection with remote dispensing.

### **Requirements**

- A remote dispensing location shall display a sign, easily viewable by customers, that states all of the following
  - » Prescriptions may be filled at this location
  - » This remote dispensing location is being supervised by a pharmacist located at all of the following:
    - Name of pharmacy
    - Address of pharmacy
    - Telephone of pharmacy
  - » Patient has a right to pharmacist consultation and information and information on how to file a complaint to the board
- Remote dispensing may not occur if the supervising pharmacy is closed
- A prescribed drug or device may not be dispensed in the absence of the ability of a patient and pharmacist’s delegate to communicate with a pharmacist.
- Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for a minimum of **5 years**.



**Extended from  
2-year requirement**

## **Dispensing Requirements**

- Remote dispensing shall comply with all of the following
  - » Visually inspecting all prescription orders, labels and dispensed product
  - » Labeling requirements (see Prescription labels) + name and address of supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed
  - » Final check (see final check)
  - » Federal law if dispensing controlled substances

## **Responsibilities of Managing Pharmacist or Supervising Pharmacist**

- The managing pharmacist of the supervising pharmacy or the supervising pharmacist shall do all of the following
  - » Have written policies and procedures for system operation, safety, security, accuracy and access
  - » Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors
  - » Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy
  - » Retain documentation of the visits at the remote dispensing location for a minimum of 5 years
  - » Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end
- The managing pharmacist at the supervising pharmacy or supervising pharmacist is responsible for all remote dispensing connected to the supervising pharmacy

## **Delegate Requirements**

- A person engaged in the practice of pharmacy shall meet the following requirements to remote dispense
  - » Be 18 years of age or older
  - » Be a high school graduate or have equivalent education
  - » Have completed 1500 hours of work as a pharmacist delegate within the 3 years prior to engaging in remote dispensing or completed an accredited pharmacy technician training program

## **9. Institutional Pharmacies**

### **Definitions**

- “Chart order” means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or practitioner’s delegate for a drug product or device
- “Institutional facility” means a facility, 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 operated under the authority of the department of corrections.

- “Institutional pharmacy” means a pharmacy that provides pharmacy services to an institutional facility

### **Chart Orders**

- A chart order shall contain all of the following
  - » First and last name of the patient
  - » Patient’s medical record number or date of birth
  - » Date of issuance
  - » Name, strength, and form of the drug product or device prescribed
  - » Directions for use
  - » The signature by one of the following methods:
    - If handwritten, the practitioner’s or delegate’s signature
    - Electronic signature of the practitioner or delegate
  - » Chart orders prepared by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name of the practitioner.

### **Labels**

- All prescribed drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label attached to the container disclosing the following
  - » Drug name, strength, and form
  - » Beyond use date or expiration date
  - » Special storage conditions, if required

### **Security and Access**

- Arrangements shall be made in advance by the managing pharmacist for access of drugs by the health care staff of the institutional facility when dispensing by a pharmacist is not available
- In the absence of a pharmacist, drugs shall be stored in a manner in which only authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons
- The managing pharmacist shall develop policies and procedures in place to mitigate and prevent theft and diversion.

### **Return or Exchange of Health Items**

- Definitions
  - » “Health item” means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene
  - » “Original container” means the container in which a health item was sold, distributed, or dispensed
  - » “Tamper-evident package” means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.
- A health item which has been sold, distributed or dispensed, may be returned to the institutional pharmacy under the following conditions:
  - » The health item was dispensed in error, was defective, adulterated, or misbranded
  - » When in the professional judgment of the pharmacist substantial harm could result to the public or patient if it were to remain in the possession of the patient, patient’s family or agent, or other person
  - » A health item that is prepackaged for consumer use without a prescription when returned in compliance with all applicable state and federal laws

- » if the health item has not left the control of the health care facility staff authorized to have access to prescription drug products.
- A health item returned to an institutional pharmacy, may be sold, distributed, or dispensed to the institutional facility if all of the following apply:
  - » The health item was never in the possession and control of the patient
  - » The health item was sold, distributed or dispensed in a tamper-evident package and, for a drug product, includes the beyond use date or expiration date and manufacturer's lot number.
  - » The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

## **Automated Technology Product Verification**

- Definitions
  - » "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check
  - » "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.
- Automated technology product verification qualifications
  - » Product verification may be done only by an automated technology which meets all of the following
    - Located within a licensed pharmacy
    - Utilizing barcodes or another machine-readable technology to complete the product verification
    - Validated by the following process
      - ◊ The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%
      - ◊ A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process
    - Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations
- Eligible products
  - » The automated technology may do the product verification if the product meets all of the following:
    - Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date
    - Has a drug utilization review performed by a pharmacist prior to delivery
    - Will be administered by an individual authorized to administer medications at the institution where the medication is administered.
- Policies and procedures
  - » Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request

- Records
  - » Each pharmacy shall maintain for 5 years the following records:
    - All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate
    - Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
    - Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures
    - Documentation of the dates of all software upgrades
    - Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.
  - » Records shall be made available to the board upon request