



**PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD**

Room 121A, 1400 East Washington Avenue, Madison, WI 53703
Contact: Dan Williams (608) 266-2112
November 3, 2016

*Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. A **quorum of the Board may be present during any committee meetings.***

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Legislation and Rule Matters – Discussion and Consideration (2-16)

- 1) Phar 7 Relating to Practice of Pharmacy
 - a) Transfer of Prescriptions
 - b) Prescription Renewal Limitations
 - c) Records
 - d) Procurement, Storage and Recall
 - e) Out of Date Drugs or Devices
 - f) Prepackaging Drugs
- 2) Update on Legislation and Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 26 October 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Rules Committee			
4) Meeting Date: 3 November 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? A. Approval of Agenda B. Phar 7 Relating to Practice of Pharmacy 1. Transfer of Prescriptions 2. Prescription Renewal Limitations 3. Records 4. Procurement, Storage and Recall 5. Out of Date Drugs or Devices 6. Prepackaging Drugs C. Update on Pending or Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: 			
11) Authorization			
<i>Sharon Henes</i>		<i>26 October 2016</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

TRANSFER OF PRESCRIPTIONS

Phar 7.055 Transfer of prescription order information. (1) General requirements. A pharmacist may transfer prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:

- (a) The transfer is communicated directly between 2 pharmacists either by verbal transfer or by a computer system transfer meeting the requirements of sub. (4). Communication by facsimile machine is not allowed unless the prescription order information being transferred is verified verbally between 2 pharmacists.
- (b) A computer system used to record a verbal transfer of prescription order information for a non-controlled substance meets the requirements of s. Phar 7.05 (1) (a) and (b).
- (c) The pharmacist receiving the verbal transfer of prescription order information for either a controlled or a non-controlled substance records the transferred information in writing unless a computer system transfer meeting the requirements of sub. (4) is used.
- (d) All original and transferred prescription orders are maintained for a period of 5 years from the date of the last refill.
- (e) A written copy of any prescription order for a prescribed drug provided by a pharmacist is identified in writing as "COPY – FOR INFORMATION ONLY." No prescribed drug may be dispensed based on an information copy.
- (f) A pharmacist making or receiving a transfer of prescription order information is licensed in the state in which he or she performs an act required by this section.

(2) Non-controlled substances. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

- (a) The pharmacist making the transfer records the following information:
 1. The word "VOID" is written on the face of the invalidated prescription order or recorded in a similar manner to "VOID" on a prescription order in a computer system meeting the requirements of s. Phar 7.05 (1) (a) and (b).
 2. The name and address of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order or in a computer system meeting the requirements of s. Phar 7.05 (1) (a) and (b).
 3. A transfer of prescription order information for a non-controlled substance for the purposes of refill dispensing is limited to the number of authorized refills.
- (b) The pharmacist receiving the transferred prescription order information shall record in writing the following:
 1. The word "TRANSFER" on the face of the transferred prescription order.
 2. The name and address of the patient, the name and address of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.
 3. The date of issuance of the original prescription order.
 4. The original number of refills authorized on the original prescription order.
 5. The date of original dispensing if the prescription order has previously been dispensed.

6. The number of valid refills remaining and the date of the last refill.
7. The pharmacy's name, address, and the prescription order number from which the prescription order information was transferred.
8. The name of the pharmacist making the transfer.
9. The name, address and telephone number of the pharmacy from which the original prescription order was transferred if different than subd. 7.

(3) Controlled substances. The transfer of prescription order information for controlled substances for the purposes of refill dispensing is permissible pursuant to the following requirements:

(a) The transfer of prescription order information is permissible only on a one time basis unless a computer system meeting the requirements of sub. (4) is used.

(b) If a computer system meeting the requirements of sub. (4) is used, a transfer of prescription order information for the purposes of refill dispensing is limited to the number of authorized refills.

(c) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist making the transfer shall record in writing the following information:

1. The word "VOID" is written on the face of the invalidated prescription order.
2. The name, address and DEA registration number of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order and the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(d) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist receiving the transferred prescription order information shall record in writing the following information:

1. The word "TRANSFER" on the face of the transferred prescription order.
2. The name and address of the patient, the name, address and DEA number of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.
3. The date of issuance of the original prescription order.
4. The original number of refills authorized on the original prescription order.
5. The date of original dispensing.
6. The number of valid refills remaining and the dates and locations of previous refills, if applicable.
7. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order information was transferred if different from the pharmacy from which the prescription order was originally dispensed.
8. The name of the pharmacist making the transfer.
9. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order was originally dispensed.

(4) Use of computer system. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.05 (1) (a) and (b), contain a common central processing unit electronically sharing a real-time, on-line database to which both the transferring and receiving pharmacy have access.

NABP Model Rules

Transfer of a Prescription Drug Order

Pharmacies utilizing automated data-processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted in subsection (4) below. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

- (1) The information is communicated directly between Pharmacists or Certified Pharmacy Technicians and the transferring Pharmacist or Certified Pharmacy Technician records the following information:
 - i. write the word "VOID" on the face of the invalidated Prescription Drug Order;
 - ii. record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;
 - iii. record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and
 - iv. the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.
- (2) The Pharmacist or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:
 - i. Write the word "TRANSFER" on the face of the transferred Prescription Drug Order.
 - ii. Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:
 - A. date of issuance of original Prescription Drug Order;
 - B. original number of refills authorized on original Prescription Drug Order;
 - C. date of original Dispensing;
 - D. number of valid refills remaining and date of last refill;
 - E. Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
 - F. name of transferring Pharmacist or Certified Pharmacy Technician.
 - iii. Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmacist Care.
- (3) Both the original and transferred Prescription Drug Order shall be maintained for a period of five years from the date of last refill.
- (4) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed, and, further, that a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order or to which the Prescription Drug Order is transferred and shall protect against the illegal use or disclosure of Protected Health Information.

- (5) In an emergency, a Pharmacy may transfer original Prescription Drug Order information for a non-controlled substance to a second Pharmacy for the purpose of Dispensing up to a 72-hour supply without voiding the original Prescription Drug Order.

PRESCRIPTION RENEWAL LIMITATIONS

Phar 7.01 (1)(f) The pharmacist or pharmacist-intern as directed and supervised by a pharmacist shall Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the prescription order, medication profile record or uniformly maintained and readily retrievable document the following information:

1. Date renewed.
2. Name of practitioner authorizing renewal, if different from the original prescriber.
3. Quantity of drug dispensed.
4. Identification of the pharmacist renewing the prescription.

Phar 7.03 Prescription renewal limitations. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed (PRN) by the patient, shall not be renewed beyond one year from the date originally prescribed. No prescription order containing either specific or PRN renewal authorization is valid after the patient-physician relationship has ceased.

RECORDS

Phar 7.05 **Prescription records.** (1) 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 purposes of original or refill dispensing if the system:

- (a) Is capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining. The system shall be designed so that the pharmacy can receive the printout within 48 hours after requesting the printout.
- (b) Is 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 on-line entry as soon as the computer system is again available for use.

(1m) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last refill.

(2) All systems used for maintaining a record of any prescription dispensing shall include:

- (a) Patient's identification.
- (b) Name, strength and dosage form of the drug product dispensed.
- (c) Quantity dispensed.
- (d) Date of all instances of dispensing.
- (e) Practitioner's identification.
- (f) Pharmacist's identification.
- (g) Retrieval designation.

Phar 7.07 **Medication profile record system.** (1) An individual medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions, original or renewal, are dispensed for outpatient use. The system shall be capable of permitting the retrieval of information. The system need not be limited to individual medication profile records.

(2) The following minimum information shall be retrievable:

- (a) Patient name, or other identifying information.
- (b) Address of the patient.
- (c) Birth date of the patient if obtainable.
- (d) Name of the drug product dispensed.
- (e) Strength of the drug product dispensed.
- (f) Dosage form of the drug product dispensed.
- (g) Quantity of the drug product dispensed.
- (h) Directions for use.
- (i) Retrieval designation assigned to the prescription order.
- (j) Date of all instances of dispensing, for original and renewal prescriptions.
- (k) Practitioner identification.

(3) 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 the patient or agent of the patient. If none, this should be indicated.

(4) At the time a prescription order is reviewed by the pharmacist for dispensing, the pharmacist shall review the medication profile record of the patient for the previously dispensed medication history and shall determine whether the prescription order presented should be dispensed.

(5) Medication profile records, if used as the only documentation of renewal dispensing, shall be maintained for a period of not less than 5 years following the date of the last entry. If the profile records are not used as the only documentation of renewal dispensing they shall be maintained for a period of not less than 1 year from the date of the last entry.

NABP Model Rules

(a) Patient Records¹

- (1) A patient record system shall be maintained by all Pharmacies and dispensing Practitioners for patients for whom Prescription Drug Orders are Dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously Dispensed Drugs at the time a Prescription Drug Order is presented for Dispensing, and be created and stored in a manner to protect against illegal use or disclosure of Protected Health Information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
 - (i) full name of the patient for whom the Drug is intended;
 - (ii) street address and telephone number of the patient;
 - (iii) patient's age or date of birth;
 - (iv) patient's gender;
 - (v) a list of the patient's medications taken during the preceding 24 months; and
 - (vi) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.
 - (2) The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, Drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs or Devices currently being used by the patient which may relate to Prospective Drug Review.
 - (3) A patient record shall be maintained for a period of not less than ten years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.
- (4) Protected Health Information may be used or disclosed as allowed under state and federal privacy rules.
- (5) Significant Adverse Drug Reactions shall be reported to the Practitioner and an appropriate entry shall be made in the patient's record.

¹ The Pharmacist should have access to clinical and laboratory data concerning each patient, and should monitor each patient's response to his or her Drug therapy. Any unexpected or untoward response should be reported to the prescribing physician. If the Pharmacist is not doing this monitoring, the identity of the health care provider that has assumed this responsibility should be documented in the patient's profile.

It is acceptable for new Prescription Drug Order data to be added to the patient profile, but original entries may not be altered.

- (b) Records of Dispensing/Delivery
- (1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years² and shall include, but not be limited to:
 - (i) quantity Dispensed for original and refills, if different from original;
 - (ii) date of receipt, Dispensing, Delivery, Distribution, or other disposition;
 - (iii) serial number (or equivalent if an institution);
 - (iv) the identification of the Pharmacist responsible for Dispensing;
 - (v) name and Manufacturer of Drug Dispensed if Drug Product selection occurs; and
 - (vi) records of refills to date.
 - (2) Pharmacies that ship medications by mail, common carrier, or other type of Delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the Delivered medication.³
- (c) Electronic Recordkeeping
- (1) Systems Policies and Procedures

An up-to-date policy and procedure manual shall be developed by the Pharmacist-in-Charge that explains the operational aspects of the computerized recordkeeping system and shall:

 - (i) include examples of all required output documentation provided by the computerized recordkeeping system;
 - (ii) outline steps to be followed when the computerized recordkeeping system is not operational due to scheduled or unscheduled system interruption;
 - (iii) outline regular and routine backup file procedure and file maintenance;
 - (iv) outline audit procedures, personnel code assignments, and personnel responsibilities; and
 - (v) provide a quality assurance mechanism for data entry validation.
 - (2) Data Storage and Retrieval.
 - (i) the system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term “sight-readable” means that an authorized individual shall be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy; and
 - (ii) the system shall provide online retrieval (via CRT display or hard copy printout) of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription Drug Order requirements and records of Dispensing as indicated in Section 3 of this Rule; and
 - (iii) the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV are subject to the following conditions:

² States should check federal laws and ensure that the number of years the state requires Dispensing records to be maintained are at least as many as federal requirements.

³ States that require pharmacies that ship medication by mail, common carrier, or other type of Delivery service to implement a mechanism to verify that the patient or caregiver has actually received the Delivered medication may want to consider allowing the mechanism to include a waiver provision that allows the patient or caregiver to request Delivery without Verification and advises the patient or caregiver of the possible consequences of receiving Delivery without Verification.

- (A) the system must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the Practitioner; full name and address of the patient; name, address, and DEA registration number of the Practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing Practitioner;
- (B) the system must also provide online retrieval (via computer monitor or hard copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity Dispensed, the identification code, or name or initials of the Dispensing Pharmacist for each refill and the total number of refills Dispensed to date for that prescription order;
- (C) Documentation of the fact that the refill information entered into the computer each time a Pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual Pharmacist who refilled such a prescription order. The individual Pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (eg, J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that Pharmacy for a period of two years from the Dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each Pharmacy using such a computerized application within 72 hours of the date on which the refill was Dispensed. It must be verified and signed by each Pharmacist who is involved with such dispensing. In lieu of such a printout, the Pharmacy shall maintain a bound logbook, or separate file, in which each individual Pharmacist involved in such Dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of _____ years after the date of Dispensing the appropriately authorized refill;
- (D) the electronic recordkeeping system shall have the capability of producing a printout of any Prescription Drug Order data. The system shall provide a refill-by-refill audit trail for any specified strength and

dosage form of any Drug. Such an audit trail shall be by printout, and include the name of the prescribing Practitioner, name and location of the patient, quantity Dispensed on each refill, date of Dispensing of each refill, name or identification code of the Dispensing Pharmacist, and unique identifier of the Prescription Drug Order; and

- (E) any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within 48 hours.
- (iv) if a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically and are subject to the following:
 - (A) records must be maintained electronically for _____ years from the date of their creation or receipt;
 - (B) records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read;
 - (C) records required by this section part must be made available to the state and federal agencies upon request;
 - (D) if the Pharmacy discontinues or changes the electronic prescription service provider or transfers the electronic Prescription Drug Order records to another Pharmacy, the Pharmacy must ensure that the records are stored in a format that can be retrieved, displayed, and printed in a readable format; and
 - (E) digitally signed prescription records must be transferred or migrated with the digital signature.
- (3) Security
To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the Drug has been Dispensed, any alterations in Prescription Drug Order data shall be documented, including the identification of the Pharmacist responsible for the alteration.
- (4) System Backup (Auxiliary Records Maintenance)
 - (i) In the event of an unscheduled system interruption, sufficient patient data and Prescription Drug Order data should be available to permit reconstruction of such data within a two-hour time period for the Pharmacist to Dispense Drugs with sound professional judgment.
 - (ii) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original Prescription Drug Order and that the maximum number of refills is not exceeded.
 - (iii) The auxiliary system shall be in place to provide for the maintenance of all necessary patient Drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this section shall preclude the Pharmacist from using professional judgment for the benefit of a patient's health and safety.
 - (iv) When the automated system is restored to operation, the information regarding Prescription Drug Orders Dispensed and refilled during the

inoperative period shall be entered into the automated system within 96 hours.

- (v) Routine backup systems and procedures (hard copy, copy, disk, etc) shall be in place and operational to ensure against loss of patient data.
- (vi) In the event that permanent Dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 24 hours.

PROCUREMENT, STORAGE AND RECALL

657—8.7(155A) Procurement, storage, and recall of drugs and devices.

8.7(1) Source. Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board to distribute to Iowa pharmacies or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) Sufficient stock. A pharmacy shall maintain sufficient stock of drugs and devices to fulfill the foreseeable needs of the patients served by the pharmacy.

8.7(3) Manner of storage. Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(4) Storage temperatures. All drugs and devices shall be stored at the proper temperature, as defined by the following terms:

a. "Controlled room temperature" means temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);

b. "Cool" means temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit). Drugs and devices may be stored in a refrigerator unless otherwise specified on the labeling;

c. "Refrigerate" means temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

d. "Freeze" means temperature maintained thermostatically between -20 degrees and -10 degrees Celsius (-4 degrees and 14 degrees Fahrenheit).

8.7(5) Product recall. There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

OUT OF DATE DRUGS OR DEVICES

657—8.8(124,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

PREPACKAGING DRUGS

NABP Model Rules

- (a) A Pharmacy may Prepackage Drugs under the following circumstances:
- (1) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;
 - (2) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;
 - (3) the Prepackaged Drugs are labeled with the following components:
 - (i) Drug Name;
 - (ii) Drug Strength;
 - (iii) Pharmacy Control and Manufacturer lot number;
 - (iv) Name of the Manufacturer or Distributor of the Drug; and
 - (v) Beyond-Use Date.
 - (vi) Records of all Prepackaging operations are maintained and include the following:
 - (A) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;
 - (B) the name of the Manufacturer or Distributor of the Drug;
 - (C) Pharmacy Control and Manufacturer lot number;
 - (D) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;
 - (E) the name, initials, or identification codes of the Certified Pharmacy Technician or Certified Pharmacy Technician Candidate that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and
 - (F) the date the Drug is Prepackaged.
- (v) All Drugs Prepackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs, or with requirements in the current edition of an official compendium.