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PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD

Room 121A, 1400 East Washington Avenue, Madison, WI 53703
Contact: Dan Williams (608) 266-2112
April 6, 2017

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

B. Legislation and Rule Matters – Discussion and Consideration

1) Phar 7 Relating to Practice of Pharmacy
2) Update on Legislation and Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

NOTE: This document captures the Committee's past work on Phar 7. It is not arranged in the specific order or numbering that it will be under the new Phar 7.

Prescription Requirements

(1) A prescription drug order shall include all of the following:

(a) Date of issue

(b) Name and address of the practitioner. Prescriptions written by a delegate of the practitioner shall include the name of the delegate and the practitioner.

(c) Name, strength, dosage, form and quantity of the drug.

(d) Directions for use of the drug.

(e) Refills, if any.

(f) Name of patient and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.

(g) If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.

(h) If prescription is issued under s. 255.07 (2), the name and address of the authorized entity.

(i) Practitioner's written signature, or electronic or digital signature.

(2) A prescription drug order must be communicated to a pharmacist, or when recorded in such a way that the pharmacist may review the prescription drug order as transmitted.

Answering machines or voice mail in pharmacies. Oral prescription orders may be received at a pharmacy via a telephone answering device or voice mail and dispensed by the pharmacist provided other requirements of reducing the prescription order to writing, labeling and filing are met.

[NOTE: Prescription orders transmitted electronically remains unchanged from current rule]

Prescription orders transmitted electronically.

(1) Except as provided in s. 453.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(2) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order does all of the following:

(a) Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

(b) Identifies the individual sender's name and telephone number for oral confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission.

(c) Is designated "electronically transmitted prescription", or with similar words or abbreviations to that effect.

(d) Contains all other information that is required in a prescription order.

(3) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.

(4) Any visual or electronic document received in connection with an electronically transmitted prescription order shall be accessible only within the professional service area of the pharmacy to protect patient confidentiality and assure security.
(5) A pharmacist who receives a prescription order electronically shall ensure the security, integrity and confidentiality of the prescription order and any information contained in the order. To maintain the confidentiality of patient records, the electronic system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the prescription has been dispensed, any alterations in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration.
(6) Access to the electronic mail system for the receipt of prescription orders electronically may only be acquired by use of a password or passwords, known only to individuals authorized to access the system.
(7) A pharmacist may not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent other pharmacy laws.

Prospective Drug Use Review
(1) A pharmacist shall review the patient record prior to dispensing each prescription drug order for all of the following:
- (a) Known allergies.
- (b) Rational therapy contraindications.
- (c) Reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors.
- (d) Reasonable directions for use.
- (e) Potential or actual adverse drug reactions.
- (f) Drug to drug interactions.
- (g) Drug to food interactions.
- (h) Drug to disease contraindications.
- (i) Therapeutic duplication;
- (j) Proper utilization and optimum therapeutic outcomes.
- (k) Potential abuse or misuse.

(2) Upon recognizing any of the items in sub. (1) (a) to (k), the pharmacist shall take appropriate steps to avoid or resolve the problem. The pharmacist may consult with the prescriber.

Label Requirements
(1) In this section, ambulatory patient does not include those in a correctional facility. All prescribed drugs or devices for outpatient, ambulatory patient or inpatient self-administration shall have a label attached to the container disclosing all of the following:
- (a) Critical information for patients which shall be displayed in a field size and text size which is in the best interest of patient care and includes all of the following:
  1. a. Except as provided in subd. 1. b to e., the legal name of the patient
     b. For an antimicrobial rug dispensed under s. 450.11 (1g), Stats., the full name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".

c. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the name of the person to whom the opioid antagonist is delivered.

d. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), the name of the school, authorized entity, or other person specified under s. 255.07 (3).

e. If the patient is an animal the last name of the owner, name of the animal and animal species.

2. Directions for use as indicated by the prescriber using numeric instead of alphabetic characters for numbers and simplified language without unfamiliar words or medical terminology.

3. Symptom or purpose if the patient indicates in writing to the prescriber that the patient wants the information on the label.

4. Drug name. If the prescription is written for a brand name and a generic drug is dispensed, include the phrase "generic for" and specify the brand name unless the prescriber requests the brand name be omitted.

5. Drug strength.

6. The use by date indicating the date after which the medication shall not be used.

(b) Important information for patients which shall not supersede the critical information for patients includes all of the following:

1. Pharmacy name.
2. Pharmacy telephone number.
3. Prescriber name.
4. Date the prescription was filled.
5. Prescription number.
6. Drug quantity.
7. Number of remaining refills.
8. Written or graphic product descriptions.
9. Any cautions or other provisions.

(2) All prescribed drugs and devices for prescriptions or devices for use by inpatients of a hospital, or health care facility shall have a label attached to the container disclosing all of the following:

(a) Patient's legal name.
(b) Drug name.
(c) Route of administration, if not oral.
(d) Drug Strength.
(e) Prescriber name.
(f) Date of dispensing.
(g) Dispensing pharmacy.
(h) If the drug was repackaged, the name of the person who repackaged it.
(i) Special storage conditions, if required.

(3) Subs. (1) and (2) do not apply to complimentary samples of drug products or devices dispensed by a practitioner to his or her patients.

Transfer of prescription order information.

(1) General requirements. A pharmacist or pharmacist intern 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 in one of the following ways:

1. Verbal communication between two pharmacists.
2. Electronically by shared database.
3. Electronically with the transfer pharmacist verifying the information being transferred and the receiving pharmacist initiating verbal communication only if there are questions.
4. By facsimile machine with the information being transferred verified verbally between two 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 or recorded in a similar manner in a computer system.

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 schedule III to V 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.

[NOTE: Still working on the concept for non-controlled substances of contacting to see what the prescription is without formally transferring (ie original not voided)]

Prescription renewal.

Repeal Phar 7.01 (1) (f) and amend the following:

Prescription renewal limitations. ~~A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription 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

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.

(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.

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

(3) 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) Identification number or institutional unique number.

(h) Manufacturer.

Medication profile record system. (1) An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans 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) Full patient name, or other identifying information including species if animal.
(b) Address of the patient.
(c) Birth date of the patient or if not human birthdate of the owner.
(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) Prescription identification number
(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.

[NOTE: Return to this issue as part of the delivery:
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.]
[NOTE: Leaning toward being silent but may come back to: System Backup (Auxiliary Records Maintenance)]

<u>Procurement, storage, and recall of drugs and devices.</u>

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

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

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

(4) All drugs and devices shall be stored at the proper temperature.

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

<u>Out-of-date drugs or devices.</u>

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.

Prepackage Drugs

(1) A Pharmacy prepackaging drugs shall do all of the following:

(a) Have written policies and procedures have been developed that address the processes of prepackaging within the pharmacy;

(b) The prepackaging processes are conducted under conditions that ensure the integrity of the drug and under the direct supervision of a pharmacist;

(c) The prepackaged drugs are labeled with all the following components:

1. Drug name.
2. Pharmacy control and manufacturer lot number.
3. Name of the manufacturer or distributor of the drug.
4. Beyond use date.
5. Records of all prepackaging operations are maintained and include all the following:

a. Name, strength, dosage form, quantity per container, and quantity of containers of the drug being prepackaged.

b. 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. Name, initials, or identification codes of the pharmacist or technician that prepackaged the drug and the name or initials of the pharmacist that verified the appropriateness of the prepackaged drug.

f. Date the drug is prepackaged.

(2) All drugs prepackaged are stored at appropriate temperatures and under appropriate conditions.

Technicians

(1) As used in this section, “pharmacy technician" means a non-pharmacist or non-pharmacist intern who, under the general supervision of a pharmacist who regularly coordinates, directs and inspects the activities of the pharmacy technician, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management. “Pharmacy technician" does not include ancillary persons which include, clerks, secretaries, cashiers or delivery persons, who may be present in the pharmacy.

(2) Each technician shall have a designated supervising pharmacist while on duty. The supervising pharmacist shall provide general supervision to the technician at the site where the delegated functions are performed. A supervising pharmacist shall be available to the technician at all times for consultation either in person or within 15 minutes of contact by telecommunication or other means.

(2) A pharmacist may delegate technical dispensing functions to a pharmacy technician. Technical dispensing functions include any of the following:

(a) Accepting written or electronic prescription orders of the prescribing practitioner or from the prescribing practitioner's agent.

(b) Accepting original oral prescription orders from the prescribing practitioner or prescribing practitioner's agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

(c) Requesting authorization for a refill from the prescribing practitioner.

(d) Accepting oral authorization for a refill from the prescribing practitioner or prescribing practitioner's agent, provided there are no changes to the original prescription order.

(e) Accepting a request from a patient to refill a prescription.

(f) Obtaining and entering patient or prescription data into the patient information system.

(g) Preparing a prescription label.

(h) Retrieving medication from stock, counting or measuring medication, and placing the medication in its final container.

(i) Reconstituting prefabricated dosage forms.

(j) Compounding pharmaceuticals pursuant to written policies and procedures.

(k) Affixing a prescription label to its final container.

(L) Placing ancillary information on the prescription label.

(m) Prepackaging and labeling drugs for dispensing by a pharmacist.

(n) Preparing unit dose carts for final review by a pharmacist.

(o) Retrieving and transporting stock medication to and from pharmacist approved areas.

(p) Other technical functions that do not require the professional judgment of a pharmacist.

(q) Transferring the prescription to the patient or agent of the patient, provided that the pharmacist has first provided a patient consultation.

(3) A pharmacy technician may not do any of the following:

(a) Provide the final verification for the accuracy, validity, completeness of a filled prescription or medication order unless the person is validated for technician-check-technician.

(b) Perform any of the following tasks:

1. Complete the final drug regimen screening, including screening for therapeutic duplication, drug-to-drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.
2. Administer any prescribed drug products, devices or vaccines.

(c) Provide patient counseling or consultation.

[NOTE: Discussion of remote dispensing technicians will take place when discussing remote dispensing sites.]

<u>Patient Counseling</u>

(1) "Patient counseling" means a discussion of matters which will enhance or optimize drug therapy and may include:

(a) Name and description of the drug.

(b) Dosage form, dose, route of administration and duration for drug therapy.

(c) Intended use of the drug and expected action.
(d) Special directions and precautions for preparation, administration and use by the patient.
(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
(f) Techniques for self-monitoring drug therapy.
(g) Proper storage and appropriate disposal method of unwanted or unused medication.
(h) Prescription refill information.
(i) Action to be taken in the event of a missed dose.
(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) A pharmacist shall give the patient or patient's agent appropriate consultation relative to the prescription for all new medication to the patient or change in the patient's therapy. The consultation shall occur before the transfer of medication to the patient. This requirement is not satisfied by only offering to provide consultation.

(3) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.

(4) Notwithstanding sub. (1), a consultation is not required when a health care provider is administering the medication.

(5) Notwithstanding sub. (1), prescriptions delivered by an agent of the pharmacist to a location of the patient's choice are required to be accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist.