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 (1-2)

B. Legislation and Rule Matters – Discussion and Consideration
   1) Phar 7 Relating to Practice of Pharmacy
      a) Previous Topics (3-7)
         Records (3-4)
         Procurement, storage, and recall of drugs and devices (4)
         Out-of-date drugs or devices (4)
         Prepackaged drugs (4-5)
         Technicians (5-6)
         Patient counseling (6-7)
      b) New Topics (8-17)
         Return or exchange of health items (8-10)
         Valid Prescriber/Patient Relationship (10)
         Remote dispensing (10-12)
         Center Fill (12-17)
   2) Update on Legislation and Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.
Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board’s agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.
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) ]

Procurement, storage, and recall of drugs and devices.
(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.

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.

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.]

Patient Counseling
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.
Return or exchange of health items

Phar 7.04 Return or exchange of health items. (1) In this section:
(a) “Health item” means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.
(b) “Inpatient health care facility” means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.
(c) “Original container” means the container in which a health item was sold, distributed or dispensed.
(d) “Resident health care patient” means a patient residing in a community-based residential facility that controls a resident’s prescribed and over-the-counter medications as specified by s. DHS 83.37
(e) “Secured institutional health care patient” means any of the following:
   1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.
   2. A juvenile patient who resides in a juvenile correctional facility, as defined in s. 938.02 (10p), Stats.; a secured residential care center for children and youth, as defined in s. 938.02 (15g), Stats.; a juvenile detention facility, as defined in s. 938.02 (10r), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.
(f) “Tamper-resistant package” means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.
(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:
(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.
(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their beyond use date.
(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient’s family or agent, or other person.
(d) For a secured institutional health care patient or resident health care patient where all of the following apply:
   1. The health item was never in the possession and control of the patient.
   2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer’s lot number.
   3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient.
   4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.
(e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered.
2. The pharmacist determines the contents are not adulterated.

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(3m) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or redispensed other than to a secured institutional health care patient.

(4) It is not a “return” for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient’s use. 

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(5) It is not a “return” for a patient or agent of a patient to deliver 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. 

Note: Cancer and chronic disease drug returns and redispensing pursuant to ch. DHS 148 are allowed provided the pharmacy follows the requirements in ch. DHS 148.

Note: A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison is not addressed in this rule. Such a drug may be redispensed to a patient in a state prison provided the requirements of s. 450.09 (7m), Stats., are satisfied.

NABP Model Rules

Return and reuse of Prescription Drugs

(1) Prescription Drugs may only be returned and reused providing that the Prescription Drugs:

1. were removed from the Pharmacy for delivery by Pharmacy staff, or a Pharmacy contracted delivery service and returned because the Prescription Drugs were not deliverable or the patient refused delivery, and such Prescription Drugs did not leave the control of the Pharmacy; and
2. Prescription Drugs were packaged in:
   A. the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
   B. the dispensing pharmacy's original packaging; and
   C. returned to the pharmacy immediately after the unsuccessful delivery attempt.
3. If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:
   A. the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
   B. the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the product quality as per United States Pharmacopeia (USP)
standards.
(2) All returned packaging must indicate that the Prescription Drug's integrity and stability has been maintained.
(3) All returned Prescription Drugs must have been returned on the same day as the attempted delivery and must be evaluated by appropriate Pharmacy staff to ensure such Prescription Drugs are not adulterated or misbranded.
(4) A state-licensed Pharmacist must verify compliance with all of the above elements.

Valid Prescriber/Patient Relationship

IOWA 657—8.20(155A) Valid prescriber/patient relationship. Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient’s use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining refills. The pharmacist shall, however, exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new order can be issued.

Remote Dispensing

450.01 (7) “Dispense” means to deliver a prescribed drug or device to an ultimate user or research subject by or pursuant to the prescription order of a practitioner, including the compounding, packaging or labeling necessary to prepare the prescribed drug or device for delivery.

450.062 Remote dispensing. Pursuant to rules promulgated by the board, a pharmacist may dispense at the following locations:
(1) A health care facility under s. 150.84 (2) or a facility identified under s. 980.065.
(2) The office or clinic of a practitioner.
(3) A county jail, rehabilitation facility under s. 59.53 (8), state prison under s. 302.01, or county house of correction under s. 303.16 (1).
(4) A juvenile correctional facility under s. 938.02 (10p), juvenile detention facility under s. 938.02 (10r), residential care center for children and youth under s. 938.02 (15d), secured residential care center for children and youth under s. 938.02 (15g), type 1 juvenile correctional facility under s. 938.02 (19), type 2 residential care center for children and youth under s. 938.02 (19r), or type 2 juvenile correctional facility under s. 938.02 (20).

Phar 7.095 Operation of remote dispensing sites. (1) DEFINITIONS. In this section:
(a) “Health care facility” means a facility, as defined in s. 647.01 (4), Stats., or any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health center or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.02, 50.03, 50.35, 51.08 or 51.09, Stats., or a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42 or 252.10, Stats.

(b) “Managing pharmacist” means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(c) “Practitioner” means a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs.

(d) “Remote dispensing site” means a dispensing site that is not licensed as a pharmacy. Remote does not mean geographical distance or location.

(e) “Supervising pharmacy” means a licensed pharmacy that oversees the operations and administration of all aspects of the remote dispensing site.

**2 Licensing Requirements and Use of Titles Relating to the Operation of Remote Dispensing Sites.**

(a) A remote dispensing site shall not be licensed as a pharmacy.

(b) 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 a remote dispensing site.

**3 Location of Remote Dispensing Sites.** A pharmacist may dispense at the following locations:

(a) A health care facility or a facility identified under s. 980.065, Stats.

(b) The office or clinic of a practitioner.

(c) A county jail, rehabilitation facility under s. 59.53 (8), Stats., state prison under s. 302.01, Stats., or county house of correction under s. 303.16 (1), Stats.

(d) A juvenile correctional facility under s. 938.02 (10p), Stats., juvenile detention facility under s. 938.02 (10r), Stats., residential care center for children and youth under s. 938.02 (15d), Stats., secured residential care center for children and youth under s. 938.02 (15g), Stats., type 1 juvenile correctional facility under s. 938.02 (19), Stats., type 2 residential care center for children and youth under s. 938.02 (19r), Stats., or type 2 juvenile correctional facility under s. 938.02 (20), Stats.

**4 Requirements for the Operation of Remote Dispensing Sites.**

(a) A remote dispensing site shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.

2. This store is a remote dispensing site being supervised by a pharmacist located at all of the following:

   a. Name of store.

   b. Address of store.

   c. Telephone number of store.

3. The pharmacist is required to talk to you each time you pick up a prescription.

(b) A remote dispensing site shall not open for operation if the supervising pharmacy is closed.

(c) A remote dispensing site shall not dispense a prescribed drug or device in the absence of the ability of a patient to communicate with the pharmacist.
(d) When closed, a remote dispensing site shall have a centrally monitored alarm. For all after hour entries, the personnel entering the site shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for 2 years.

(e) A remote dispensing site shall submit written notification to the board 30 days prior to operating the remote dispensing site.

(5) DISPENSING REQUIREMENTS. A remote dispensing site shall meet all of the following:

(a) Comply with the requirements under s. Phar 7.01 and visually inspect prescription orders, labels and dispensed product.

(b) Comply with the labeling requirements under s. Phar 7.12 (2) (g). The prescription label shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.

(c) Comply with federal law if a remote dispensing site dispenses controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACISTS. (a) The managing pharmacist of a remote dispensing site shall, in accordance with s. Phar 7.09, do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. 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 of inventory, and documentation of remedial training to prevent future errors.

3. Visit the remote dispensing site at least monthly to conduct controlled substance inventory, to ensure written policies and procedures are being followed, and to ensure that remote dispensing site personnel comply with all federal and state laws regulating the practice of pharmacy.

4. Retain documentation of the monthly inspection visits at the remote dispensing site for 2 years.

(b) The managing pharmacist at the supervising pharmacy is responsible for all remote dispensing sites connected to the supervising pharmacy.

(7) REQUIREMENTS FOR PHARMACY TECHNICIANS AND INTERNS. Pharmacy technicians and interns employed at a remote dispensing site shall satisfy all of the following requirements:

(a) Be 18 years of age or older.

(b) Be a high school graduate or have equivalent education.

(c) Have completed 1500 hours of work as a technician within the 3 years prior to the date of employment at the remote dispensing site or completed a training program approved by the

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**Center Fill**

**Phar 7.12 Central fill pharmacy.** (1) In this section:

(a) “Central fill pharmacy” means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) “Originating pharmacy” means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

(2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:
(a) The central fill 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 in compliance with
federal and state law.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including
name, address and DEA number, for which it processes a request for the filling or refilling of a
prescription order received by the originating pharmacy. The record shall be made available
upon request for inspection by the board or its agent.

(c) The central fill pharmacy and originating pharmacy maintain a written filling protocol
delineating each pharmacy’s assumption of responsibility for compliance with the prescription
drug compounding and dispensing requirements of this chapter and ch. Phar 8.

(d) The originating pharmacy shall remain responsible for compliance with the prescription
drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not
assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(e) The originating pharmacy shall at all times remain solely responsible to perform and
comply with the requirements of s. Phar 7.01 (1) (e) and (em).

(f) Unless the central fill pharmacy shares a common central processing unit with the
originating pharmacy, it may not perform processing functions such as the medication profile
record review of the patient, drug utilization review, refill authorizations, interventions and drug
interactions.

(g) The prescription label attached to the container shall contain the name and address of the
originating pharmacy as the licensed facility from which the prescribed drug or device was
dispensed for purposes of s. 450.11 (4) (a) 1., Stats. The date on which the prescription was
dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the central fill
pharmacy filled the prescription order.

(h) The originating pharmacy shall maintain the original of all prescription orders received for
purposes of filing and recordkeeping as required by state and federal law.

(i) The central fill pharmacy shall maintain all original fill and refill requests received from
the originating pharmacy and shall treat them as original and refill prescription orders for
purposes of filing and recordkeeping as required by state and federal law.

(j) In addition to meeting the other recordkeeping requirements required by state and federal
law, the central fill pharmacy and originating pharmacy shall each maintain records to identify
each of its pharmacists responsible for receiving and reviewing prescription orders and
compounding and dispensing pursuant to a prescription order and track the prescription order
during each step in the dispensing process.

(k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance
program for pharmacy services designed to objectively and systematically monitor and evaluate
the quality and appropriateness of patient care. Pursue opportunities to improve patient care,
resolve identified problems and ensure compliance with this section.

(L) The originating pharmacy shall provide the patient with the name and address of the
central fill pharmacy and obtain consent as required by applicable state and federal law.
CHAPTER 18
CENTRALIZED PRESCRIPTION FILLING AND PROCESSING

657—18.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for centralized prescription drug order filling or centralized prescription processing by a pharmacy. Any facility established for the purpose of filling or processing prescription drug orders on behalf of other pharmacies shall be licensed as a pharmacy and shall hold all necessary registrations. A hospital pharmacy may participate in centralized prescription filling only of prescription drug orders for noncontrolled substances pursuant to these rules. A hospital pharmacy may engage in centralized prescription processing pursuant to the requirements of rule 657—7.7(155A). Except as specifically identified in the rules, the requirements of these rules for centralized prescription filling or centralized prescription processing are in addition to the requirements of 657—Chapters 6, 7, and 8, and other rules of the board relating to services provided by pharmacies.

657—18.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“Central fill pharmacy” means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order filling on behalf of the originating pharmacy pursuant to these rules.

“Centralized prescription drug order filling” or “centralized filling” means the filling of a prescription drug order by a pharmacy on behalf of another pharmacy. “Centralized filling” does not include the processing or dispensing of a prescription drug order but may include any of the following filling functions:
1. Receiving prescription drug orders from the originating pharmacy;
2. Interpreting or clarifying prescription drug orders;
3. Entering prescription drug order information into a pharmacy’s prescription record system;
4. Selecting, counting, and placing the prescribed drug into an appropriate prescription container;
5. Affixing the prescription label, including any auxiliary labels, to the prescription container;
6. Obtaining refill and substitution authorizations;
7. Verifying all filling processes performed by the central fill pharmacy.

“Centralized prescription drug order processing” or “centralized processing” means the processing of a prescription drug order by a pharmacy on behalf of another pharmacy. “Centralized processing” does not include the filling or dispensing of a prescription drug order but may include any of the following processing functions:
1. Interpreting or clarifying prescription drug orders;
2. Entering prescription drug order information into a pharmacy’s prescription record system;
3. Interpreting clinical data for prior authorization for dispensing;
4. Performing formulary-directed therapeutic interchange.

“Central processing pharmacy” means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order processing on behalf of the originating pharmacy pursuant to these rules.

“DEA” means the U.S. Department of Justice, Drug Enforcement Administration.

“Dispense” means the delivery of a prescription drug or device to an ultimate user or the ultimate user’s agent by or pursuant to the lawful order of a practitioner. “Dispense” includes:
1. Receiving the prescription drug order from the patient, the patient’s agent, or the prescriber;
2. Delivering the filled prescription to the patient or the patient’s agent;
3. Providing drug information concerning a patient’s drug therapy;
4. Providing patient counseling;
5. Providing medication therapy management.

“Hospital” means a facility licensed pursuant to Iowa Code chapter 135B.

“Hospital pharmacy” means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities.
for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility.

“Mail order pharmacy” means a pharmacy located within a United States jurisdiction whose primary business is to dispense a prescription drug or device pursuant to a valid prescription drug order and to deliver the drug or device to a patient, including a patient in this state, via the United States Postal Service, a common carrier, or a delivery service. “Mail order pharmacy” includes a pharmacy that does business via the Internet or other electronic media.

“Medication therapy management” means the review of drug therapy regimens of a patient by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or for the purpose of evaluating and modifying the drug regimen in accordance with a collaborative drug therapy management protocol pursuant to rule 657—8.34(155A).

“Originating pharmacy” means a pharmacy that receives a prescription drug order from a patient, the patient’s agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient’s agent.

657—18.3(155A) General requirements.

18.3(1) Essential qualifications. An originating pharmacy may outsource prescription drug filling to a central fill pharmacy or prescription drug order processing to a central processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform the contracted functions.

18.3(2) Legal compliance. An originating pharmacy, a central fill pharmacy, and a central processing pharmacy shall comply with all provisions applicable to the pharmacy contained in federal and state laws, rules, and regulations to the extent applicable for the specific filling or processing activity and these rules, including but not limited to the following:

a. Each pharmacy located within Iowa shall maintain Iowa pharmacy licensure and, if the pharmacy dispenses controlled substances, the pharmacy shall maintain DEA and Iowa controlled substances registrations.

b. Each pharmacy located outside Iowa shall maintain Iowa nonresident pharmacy licensure in addition to the licensure requirements of the pharmacy’s home state.

c. Each pharmacist providing centralized prescription drug order processing or filling functions as an employee or agent of a central processing or central fill pharmacy located within Iowa shall maintain active licensure to practice pharmacy in Iowa.

d. Pharmacies shall comply with Iowa board rules relating to the duties that must be performed by a pharmacist.

e. Pharmacies shall comply with Iowa requirements for supervision of pharmacy technicians and pharmacy support persons.

18.3(3) Originating pharmacy responsibility. Except as specifically provided by this subrule, the originating pharmacy shall be responsible for all dispensing functions as the term “dispense” is defined in rule 18.2(155A). An originating pharmacy contracting only for centralized filling shall retain responsibility for all processing functions, and an originating pharmacy contracting only for centralized processing shall retain responsibility for all filling functions.

a. A mail order pharmacy engaged in the centralized filling of prescription drug orders may deliver a filled prescription directly to the patient and shall not be required to return the filled prescription to the originating pharmacy.

b. A central fill or a central processing pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review (DUR) pursuant to rule 657—8.21(155A). Only a pharmacist shall perform the DUR; the review shall not be delegated to a pharmacy technician, registered nurse, or other pharmacy support person. The pharmacist performing
the DUR shall document in the shared patient record all concerns, recommendations, observations, and comments resulting from that review. The pharmacist at the originating pharmacy shall utilize the DUR notes in counseling the patient pursuant to rule 657—6.14(155A).

18.3(4) Central fill label requirements. The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. A unique identifier indicating that the prescription was filled at the central fill pharmacy;

b. Serial number (a unique identification number of the prescription) as assigned by the originating pharmacy;

c. The name, address, and telephone number of the originating pharmacy;

d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. The name of the prescribing practitioner;

f. The date the prescription is filled by the central fill pharmacy;

g. The directions or instructions for use, including precautions to be observed;

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as “(generic name) Generic for (brand name product)”.

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as “(brand name product) for (generic name)”;

i. The initials or other unique identification of the pharmacist in the originating pharmacy who performed drug use review and transmitted the prescription drug order to the central fill pharmacy.

[ARC 8673B, IAB 4/7/10, effective 6/1/10]

657—18.4 Reserved.

657—18.5(155A) Patient notification and authorization.

18.5(1) Prior notification and authorization. A pharmacy that outsources prescription drug order filling or prescription drug order processing to another pharmacy shall, prior to outsourcing a patient’s prescription:

a. Notify the patient or the patient’s agent that prescription filling or processing may be outsourced to another pharmacy.

b. Provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact. Notification shall be provided through a notice to the patient or the patient’s agent by means of a sign prominently displayed in the originating pharmacy and through written notice provided to the patient or the patient’s agent prior to implementation of the program or upon commencement of services to a new patient, as applicable.

c. If a patient provides the originating pharmacy with notification that the patient no longer authorizes the originating pharmacy to outsource the patient’s prescription drug orders, the originating pharmacy shall discontinue outsourcing the filling or processing of the patient’s prescription drug orders.

18.5(2) Exception. The provisions of this rule do not apply to a patient in a facility, such as a hospital or long-term care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

657—18.6 to 18.9 Reserved.
657—18.10(155A) Policy and procedures.

18.10(1) Manual maintained. Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) Manual contents. The manual shall:
   a. Outline the responsibilities of each of the pharmacies;
   b. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing;
   c. Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and
   d. Include, but not necessarily be limited to, policies and procedures for:
      (1) Protecting the confidentiality and integrity of patient information;
      (2) Protecting each patient’s freedom of choice of pharmacy services;
      (3) Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function;
      (4) Complying with federal and state laws, rules, and regulations;
      (5) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and
      (6) Reviewing, at least annually, the written policies and procedures and documenting that review.

[ARC 1961C, IAB 4/15/15, effective 5/20/15]

657—18.11 to 18.14 Reserved.

657—18.15(155A) Records. Central fill or central processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or centralized processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of the pharmacist who performed drug use review and the pharmacist who transmitted the prescription drug order to the central fill or central processing pharmacy. These records may be maintained separately by each pharmacy or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.13, and 155A.28.

[Filed 6/2/05, Notice 1/19/05—published 6/22/05, effective 7/27/05]
[Filed 3/6/08, Notice 12/19/07—published 3/26/08, effective 4/30/08 ]
[Filed emergency 6/9/08—published 7/2/08, effective 7/9/08]
[Filed 11/24/08, Notice 10/8/08—published 12/17/08, effective 1/21/09]
[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09), IAB 4/7/10, effective 6/1/10]
[Filed ARC 1961C (Notice ARC 1793C, IAB 12/10/14), IAB 4/15/15, effective 5/20/15]

1 April 30, 2008, effective date of ARC 6671B delayed 70 days by the Administrative Rules Review Committee at its meeting held April 4, 2008.