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(FORM UPDATED: 08/11/2010)

## WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

**2009-10**

(session year)

**Joint**

(Assembly, Senate or Joint)

**Committee for Review of Administrative Rules ...**

### **COMMITTEE NOTICES ...**

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(**ab** = Assembly Bill)                      (**ar** = Assembly Resolution)                      (**ajr** = Assembly Joint Resolution)  
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\* Contents organized for archiving by: Stefanie Rose (LRB) (June 2012)

**STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD**

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**IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 09-099)**

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TO: Senator Jim Holperin, Senate Co-Chairperson  
Joint Committee for the Review of Administrative Rules  
Room 409 South, State Capitol  
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form rules relating to remote dispensing sites.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

Thank you.

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**STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD**

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**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE  
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 09-099  
PHARMACY EXAMINING BOARD : (s. 227.19 (3), Stats.)**

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**I. THE PROPOSED RULE:**

The proposed rule, including the analysis and text, is attached.

**II. REFERENCE TO APPLICABLE FORMS:**

No new or revised forms are required by these rules.

**III. FISCAL ESTIMATES:**

The department estimates that this rule will require staff time in the Division of Board Services. The total on-going salary and fringe costs are estimated at \$7,100. The department finds that this rule has no significant fiscal effect on the private sector.

**IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:**

With the enactment of 2007 Wisconsin Act 202, the Pharmacy Examining Board created rules relating to remote dispensing sites. This proposed rule-making order sets forth the process and procedures for establishing and operating remote dispensing sites.

The Pharmacy Examining Board created a committee to draft remote dispensing guidelines after 2007 Wisconsin Act 202 became effective. The committee met once and devised several safeguards to protect the safety of the public. Since the remote dispensing model departs from the traditional dispensing model, the board sought to address drug security, and the supervision of remote site staff, privacy, labeling and quality assurance in the context of remote site dispensing. The final guidelines are the result of committee discussions and recommendations that were finalized by the full board.

**V. NOTICE OF PUBLIC HEARING:**

A public hearing was held on December 2, 2009.

Eric Knox, WI Department of Corrections, Waupun, WI, appeared for information only.

The following individuals appeared and provided testimony:

Matthew Mabie, Hometown Pharmacy, Cottage Grove, WI  
Ted Grabarczyk, Pharm.D. Candidate, Madison, WI (also submitted written comments)  
Jason Knox, Community Memorial Hospital, Oconto, WI  
Tom Engels, Pharmacy Society of Wisconsin, Madison, WI (also submitted written comments)  
Gary Plank, Marshfield Clinic, Stratford, WI

**Summary of Public Hearing Comments:**

Matthew Mabie. Mr. Mabie stated he was in support of the proposed rule, but advocated that a mileage requirement defining the geographical distance requirement should be included in the rule. He suggested a 10 mile distance requirement.

Jason Knox. Mr. Knox stated his support of the proposed rule, but did not support s. Phar 7.095 (7) (c), the 2000 hour work requirement. He argued that 2000 hours of work is not a good gauge of competency of a pharmacy technician and that evaluating a pharmacy technician's competence should be left within the supervising pharmacist's discretion. Mr. Knox suggested a training program in lieu of the 2000 hour work requirement due to the hours themselves being an inappropriate assessment tool. He suggested that the board provide more guidance on what should be included in a training program.

Tom Engels. Mr. Engels stated that he supported the proposed rules, but argued that the proposed rule should be amended to include a 10-15 mile geographical distance requirement that the board could waive by variance.

Gary Plank. Mr. Plank stated that he was in favor of the proposed rule, but did not support s. Phar 7.095 (7) (c), the 2000 hour work requirement. He stated that 2000 hours is not a good number to determine the competency of a pharmacy technician. He urged the board to strike this provision from the rule or amend the language. Secondly, Mr. Plank opposed the addition of any language defining the geographical distance requirement of remote dispensing sites with mileage requirements.

Ted Grabarczyk. Mr. Grabarczyk stated that he was opposed to the proposed rule as drafted, but that he was in support of the rule if it were amended to include a mileage requirement. He presented written comments along with a survey that he had conducted as part of his rotation with the Hometown Pharmacies (MD Group LLC).

**Board's Response to the Public Hearing Comments:**

After review and discussion of the comments provided at the public hearing, the board made the following changes to the proposed rules:

The board amended s. Phar 7.095 (7) (c) – the definition of “remote dispensing site.”  
The board deleted the language indicating that remote does not mean geographical

distance and added that remote means geographical distance greater than 10 miles from an existing licensed pharmacy in Wisconsin open to the public. A modification to the distance requirement may be submitted for further board determination.

Also, the board amended s. Phar 7.095 (7) (c), amending the 2000 hour work requirement to 1500 hours. The board also changed the language relating to the training program to relevant equivalent practice.

## **VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:**

**Comment 5.b.** Section Phar 7.095 (5) (a) provides that a remote dispensing site must comply with the requirements of s. Phar 7.01, including “visual access of prescription orders, labels, and dispensed product.” If the rule requires a site to comply with the requirements of s. Phar 7.01, why is special emphasis placed on prescription orders, labels, and dispensed products? It seems that a cross-reference to s. Phar 7.01 is sufficient.

**Response:** The board changed “Comply with the requirements under s. Phar 7.01, including visual access of prescription orders, labels and dispensed product.” To comply with the requirements under s. Phar 7.01, and visually inspect prescription orders, labels and dispensed product.”

## **VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:**

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1), Stats.

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULE-MAKING: : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 09-099)

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PROPOSED ORDER

An order of the Pharmacy Examining Board to create Phar 7.095, relating to remote dispensing sites.

Analysis prepared by the Department of Regulation and Licensing.

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ANALYSIS

**Statutes interpreted:**

Sections 450.06 (1) and 450.062, Stats.

**Statutory authority:**

Sections 15.08 (5) (b), 227.11 (2), 450.02 (3) (d) and 450.062, Stats.

**Explanation of agency authority:**

The board is authorized under s. 450.02 (3) (d), Stats., to promulgate rules necessary for the administration of ch. 450, Stats., and under s. 450.062, Stats., to promulgate rules relating to the establishment and operation of remote dispensing sites.

**Related statute or rule:**

Section Phar 7.09 relates to the use of automated dispensing systems.

**Plain language analysis:**

SECTION 1 creates s. Phar 7.095, which sets forth the process and procedures for establishing and operating remote dispensing sites.

As stated in s. 450.06 (1), Stats., except as provided in rules adopted by the board under s. 450.062, Stats., no pharmacist may dispense at any location that is not licensed as a pharmacy by the board. The board is proposing to adopt these rules to set forth the process and procedures for establishing and operating remote dispensing sites.

The proposed rules include definitions for “health care facility,” “managing pharmacist,” “practitioner,” “remote dispensing site,” and “supervising pharmacy.” The proposed rules also clarify that a remote dispensing site shall not be licensed as a pharmacy and that no person may use or display certain titles in connection with the operation of a remote dispensing site. In addition, the proposed rules identify where remote dispensing sites may be located; the requirements for operating remote dispensing sites; the requirements for dispensing; the responsibilities of managing pharmacists, and the requirements for pharmacy technicians and interns.

**Summary of, and comparison with, existing or proposed federal regulation:**

There is no existing or proposed federal regulation.

**Comparison with rules in adjacent states:**

**Illinois:**

Statutes: Section 225 ILCS 85

Rules: Section 1330.98

Illinois’ statutes provide a significant amount of detail as to tele-pharmacy, remote prescription processing, common electronic filing, automated dispensing and storage systems, and centralized prescription filling. Tele-pharmacy is included as part of the definition of the practice of pharmacy. Tele-pharmacy models must meet a set of conditions regarding pharmacist responsibility, technician training, supervision and patient counseling. Remote prescription processing, or “outsourcing” occurs when at least one of eight listed functions are identified. Conditions under which remote prescription processing may occur are also specified, including ownership, electronic filing and record maintenance provisions. The statutes are very detailed regarding automated pharmacy systems/remote dispensing. Subjects covered include: security; procedures; confidentiality; designated personnel; storage (temperature, proper containers, handling outdated drugs); dispensing and delivery; home pharmacy supervision and re-stocking of systems that use removable cartridges. The rules provide additional detail for automated dispensing and storage systems, including provisions relating to documentation, storage, security, record keeping, stocking, proper containers, and quality assurance.

**Iowa:**

Rules: Chapters 9 and 18.

Chapter 9 of Iowa’s rules relates to automated medication dispensing systems, including: pharmacist responsibilities; quality assurance; policies and procedures; system, site and process requirements; dispensing and distributing; security and confidentiality; records; error identification and logging; verification and accuracy; reporting; and outpatient automated medication dispensing. Chapter 18 addresses centralized filling and

processing, including: system qualifications; labeling; legal compliance; patient notification; originating pharmacy compliance; policies and procedures; and records.

**Michigan:**

Statutes: Section 333.17753, Michigan Public Health Code

Rules: Chapter 338

Michigan's statutes include a section on centralized prescription filling, which lists the record-keeping, security and quality improvement conditions that apply to outsourcing. The rules state that a license is required at each separate location where drugs are prepared or dispensed.

**Minnesota:**

Statutes: Section 150.01

Rules: Section 6800.0800, 2600, 4075, 6600

Minnesota's statutes define central service pharmacy as a pharmacy that may provide dispensing functions, drug utilization review, packaging, labeling, or delivery of a prescription product to another pharmacy for the purpose of filling a prescription. Minnesota's rules provide definitions for community and hospital satellite pharmacies. Plans for satellite pharmacies must be submitted to the board for approval. The rules also specify the requirements for vending machines (responsibility, policies and procedures), centralized processing and filling (ownership, filing, policy and procedures manual, records, tracking of drugs, security, quality improvement, counseling and notification), and freedom of choice.

**Summary of factual data and analytical methodologies:**

The board created a committee to draft remote dispensing guidelines after 2007 Wisconsin Act 202 (Senate Bill 409) became effective. The committee met once and devised several safeguards to protect the public. Since the remote dispensing model departs from the traditional dispensing model, the board sought to address drug security, training and supervision of remote site staff, privacy, labeling and quality assurance in the context of remote site dispensing. The final guidelines, which have been written into this rule draft, are the result of committee discussions and recommendations that were finalized by the full board.

**Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report:**

This rule will have an impact on small businesses, though it is not clear exactly what impact it will have. The board received correspondence expressing concerns and suggesting that the remote sites will adversely impact chain and independent pharmacies in the region, making it more difficult to compete. One pharmacy owner suggested



protective language in the remote dispensing rules that would disallow remote sites within a pre-determined radius of existing pharmacies. The board took up the concerns at its July 22, 2009 meeting and deliberated on the benefits and costs of the legislation, noting that its primary purpose is to increase access to prescription drugs. The board also noted that small business concerns were heard while the legislation was pending, resulting in Amendment 1 to Senate Bill 409, which limited remote dispensing to sites specifically identified in the legislation. It was noted in testimony that there is a likelihood that small businesses will benefit from new ventures with clinics and practitioners. The board also considered other possibilities, such as improved care coordination and the increased likelihood of patients to fill prescriptions at a remote site located at a health clinic.

Section 227.137, Stats., requires an “agency” to prepare an economic impact report before submitting the proposed rule-making order to the Wisconsin Legislative Council. The Department of Regulation and Licensing is not included as an “agency” in this section.

**Anticipated costs incurred by private sector:**

The department finds that this rule has no significant fiscal effect on the private sector.

**Fiscal estimate:**

The department estimates that this rule will require staff time in the Division of Board Services. The total on-going salary and fringe costs are estimated at \$7,100.

**Effect on small business:**

These proposed rules were reviewed and discussed by the department’s Small Business Review Advisory Committee which determined that these rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at [hector.colon@drl.state.wi.us](mailto:hector.colon@drl.state.wi.us), or by calling (608) 266-8608.

**Agency contact person:**

Pamela Haack, Paralegal, Department of Regulation and Licensing, Division of Board Services, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-266-0495; email at [pamela.haack@wisconsin.gov](mailto:pamela.haack@wisconsin.gov).

**Place where comments are to be submitted and deadline for submission:**

Comments may be submitted to Pamela Haack, Paralegal, Department of Regulation and Licensing, Division of Board Services, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, WI 53708-8935, or by email to [pamela.haack@wisconsin.gov](mailto:pamela.haack@wisconsin.gov).

Comments must be received on or before December 2, 2009, to be included in the record of rule-making proceedings.

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TEXT OF RULE

SECTION 1. Phar 7.095 is created to read:

**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 means a geographical distance greater than 10 miles from an existing licensed pharmacy in Wisconsin open to the public.

(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. The board may grant a variance to the distance requirement upon receipt of a written request for a variance.

(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 possesses documented equivalent experience acceptable to the board.

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(END OF TEXT OF RULE)  
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The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated \_\_\_\_\_ Agency \_\_\_\_\_  
Chairperson  
Pharmacy Examining Board

Phar 7.095 CR09-099 (Remote dispensing) Draft to Leg 12-3-09



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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Ronald Sklansky  
*Clearinghouse Director*

Terry C. Anderson  
*Legislative Council Director*

Richard Sweet  
*Clearinghouse Assistant Director*

Laura D. Rose  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE 09-099

AN ORDER to create Phar 7.095, relating to remote dispensing sites.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

10-29-2009 RECEIVED BY LEGISLATIVE COUNCIL.

11-19-2009 REPORT SENT TO AGENCY.

RS:DWS





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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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Ronald Sklansky  
*Clearinghouse Director*

Richard Sweet  
*Clearinghouse Assistant Director*

Terry C. Anderson  
*Legislative Council Director*

Laura D. Rose  
*Legislative Council Deputy Director*

### CLEARINGHOUSE RULE 09-099

#### Comments

**[NOTE:** All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated September 2008.]

#### 2. Form, Style and Placement in Administrative Code

a. In s. Phar 7.095 (1) (a), it appears that the word “mental” should be inserted before the phrase “help center” in order to duplicate the language of s. 150.84 (2), Stats.

b. In s. Phar 7.095 (3) (a), the phrase “under s. 150.84 (2), Stats.,” is unnecessary because of the definition of the term “health care facility” in sub. (1) (a). The phrase should be deleted.

c. In s. Phar 7.095 (4) (a) (intro.), “all of the following” should be inserted after the word “states.” See also subs. (4) (a) 2. (intro.), (5) (intro.), and (7) (intro.) for appropriate indications to the reader of whether all or any of the requirements in the following subunits must be met.

d. Section Phar 7.095 (5) (c) should be rewritten to read: “Comply with federal law if a remote dispensing site dispenses controlled substances.” Similarly, sub. (6) (a) 4. should be rewritten to read: “Retain documentation of the monthly inspection visits at the remote dispensing site for two years.”

#### 5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In the rule preface discussion of Illinois rules, the consistent use of semi-colons and commas should be observed. In the sentence beginning with the phrase “Subjects covered



include,” it appears that a semi-colon should be inserted before the word “dispensing” and should be inserted after the word “delivery.”

b. Section Phar 7.095 (5) (a) provides that a remote dispensing site must comply with the requirements of s. Phar 7.01, including “visual access of prescription orders, labels, and dispensed product.” If the rule requires a site to comply with the requirements of s. Phar 7.01, why is special emphasis placed on prescription orders, labels, and dispensed product? It seems that a cross-reference to s. Phar 7.01 is sufficient.

c. In s. Phar 7.095 (6) (a) 3., the phrase “inventory; ensure” should be replaced by the phrase “inventory, to ensure” and the phrase “to ensure” should be inserted before the phrase “that remote dispensing.”