Certification Page
Regular and Emergency Rules

Revised June 2020

☐ **Emergency Rules** *(Complete Sections 1-3 and 5-6)* ■ **Regular Rules**

1. General Information

a. Agency/Board Name* Administration and Information, Dept of/WY State Board of Pharmacy

b. Agency/Board Address	c. City	d. Zip Code
1712 Carey Ave, Suite 200	Cheyenne	82002

e. Name of Agency Liaison	f. Agency Liaison Telephone Number
Matthew R. Martineau	(307)634-9636

g. Agency Liaison Email Address	h. Adoption Date
matt.martineau@wyo.gov	3/15/2023

i. Program Pharmacy, Board of

Amended Program Name (*if applicable*):

* ☐ *By checking this box, the agency is indicating it is exempt from certain sections of the Administrative Procedure Act including public comment period requirements. Please contact the agency for details regarding these rules.*

2. Legislative Enactment

For purposes of this Section 2, "new" only applies to regular (non-emergency) rules promulgated in response to a Wyoming legislative enactment not previously addressed in whole or in part by prior rulemaking and does not include rules adopted in response to a federal mandate.

a. Are these non-emergency or regular rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

■ **No.** ☐ **Yes.** If the rules are new, please provide the Legislative Chapter Numbers and Years Enacted (e.g. 2015 Session Laws Chapter 154):

3. Rule Type and Information

For purposes of this Section 3, "New" means an emergency or regular rule that has never been previously created.

a. Provide the Chapter Number, Title* and Proposed Action for Each Chapter. *Please use the "Additional Rule Information" form to identify additional rule chapters.*

Chapter Number:	Chapter Name:			
2	General Practice of Pharmacy Regulations	☐ New	■ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:			
20	Collaborative Practice Regulations	☐ New	☐ Amended	■ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:			
21	Fees	■ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			

4. Public Notice of Intended Rulemaking

a. Notice was mailed 45 days in advance to all persons who made a timely request for advance notice. ☐ No. ☑ Yes. ☐ N/A

b. A public hearing was held on the proposed rules. ■ No. ☐ Yes. Please complete the boxes below.

Date:	Time:	City:	Location:

5. Checklist

a. ☑ For regular rules, the Statement of Principal Reasons is attached to this Certification and, in compliance with Tri-State Generation and Transmission Association, Inc. v. Environmental Quality Council, 590 P.2d 1324 (Wyo. 1979), includes a brief statement of the substance or terms of the rule and the basis and purpose of the rule

b. ☐ For emergency rules, the Memorandum to the Governor documenting the emergency, which requires promulgation of these rules without providing notice or an opportunity for a public hearing, is attached to this Certification.

6. Agency/Board Certification

The undersigned certifies that the foregoing information is correct. By electronically submitting the emergency or regular rules into the Wyoming Administrative Rules System, the undersigned acknowledges that the Registrar of Rules will review the rules as to form and, if approved, the electronic filing system will electronically notify the Governor's Office, Attorney General's Office, and Legislative Service Office of the approval and electronically provide them with a copy of the complete rule packet on the date approved by the Registrar of Rules. The complete rules packet includes this signed certification page; the Statement of Principal Reasons or, if emergency rules, the Memorandum to the Governor documenting the emergency; and a strike and underscore copy and clean copy of each chapter of rules.

Signature of Authorized Individual	
Printed Name of Signatory	Matthew R. Martineau
Signatory Title	Executive Director
Date of Signature	3/23/2023

7. Governor's Certification

I have reviewed these rules and determined that they:

1. Are within the scope of the statutory authority delegated to the adopting agency;
2. Appear to be within the scope of the legislative purpose of the statutory authority; and, if emergency rules,
3. Are necessary and that I concur in the finding that they are an emergency.

Therefore, I approve the same.

Governor's Signature	
Date of Signature	

WYOMING STATE BOARD OF PHARMACY

1712 Carey Avenue, Suite 200, Cheyenne, WY 82002
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bop@wyo.gov electronic mailbox
Matthew R. Martineau, RPh, Executive Director

WYOMING PHARMACY ACT RULES AND REGULATIONS

STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

January 2023

The Board of Pharmacy proposes to amend Chapters 2, 20, and 21 of the Wyoming Pharmacy Act Rules and Regulations in order to modernize, reorganize and simplify the chapter by removing obsolete and/or commonly understood terms and definitions; simplify and separate the requirements of a pharmacist in charge from a pharmacy license holder; simplify the requirements for non-controlled substance prescriptions, including refill authorizations, labeling requirements, and prescription transfers. Rules for shared pharmacy services are being modernized and simplified. The Board proposes to repeal chapter 20 because its proposed revisions modernize and simplify the requirements for collaborative practice and bring those simplified requirements back into chapter 2. The Board proposes to create a new chapter, chapter 21: Fees to make it easier to find the fees that the Board charges.

As required by Wyoming Statute § 16-3-103(a)(i)(G), these rules meet minimum substantive state statutory requirements.

Chapter 2: General Practice of Pharmacy Regulations

- The chapter is being modernized, reorganized, and simplified.
- Obsolete and/or commonly understood terms/definitions are being removed.
- Requirements for the pharmacist in charge are being simplified and modernized and separated from requirements for the pharmacy license holder.
- Requirements for prescriptions, including refill authorizations and labeling requirements, and transferring prescriptions are being simplified and modernized.
- Rules for shared pharmacy services are being modernized and simplified.

Chapter 20: Collaborative Practice Regulations

- The rules on collaborative practice are being modernized and simplified.
- The simplified and modernized rules are brought back into Chapter 2 because the Board believes collaborative practice to be an aspect of the general practice of pharmacy.
- Chapter 20 is repealed.

Chapter 21: Fees

- A new chapter is being created to make it easier to find the fees that the Board charges.

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SUMMARY OF COMMENTS RECEIVED REGARDING REVISIONS TO THE WYOMING PHARMACY ACT RULES AND REGULATIONS CHAPTERS 2, 20, & 21.

Chapter 2: General Practice of Pharmacy Regulations – Six (6) commenters provided comments to the Board during the public comment period relevant to this chapter. This first commenter recommended allowing pharmacies utilizing shared pharmacy services be allowed to use other types of communication, other than a toll-free number, when a patient needed to contact a pharmacist for counseling or to answer questions. Other commenters had similar comments in different areas of the chapter where the patient needed to be provided a means to contact a pharmacist for counseling or to answer questions. **The Board agreed and chose to amend the rules in response to these comments.**

The second commenter pointed out a formatting correction that was duly incorporated. This commenter also posed two questions to the Board. **The Board chose not to amend the rules in response to these two questions.**

The third commenter believed the proposed revision to require the contact information of the dispensing pharmacy to be listed on the prescription label may cause confusion. The commenter pointed out that a prescription label exists to help patients understand how to take their medication and to provide pharmacy contact information, so patients can ask further questions as may be needed. The commenter pointed out that there are some cases, e.g. with shared pharmacy services, that the originating pharmacy and not the dispensing pharmacy may be the pharmacy that can best serve the patient. **The Board agreed and chose to amend the rules in response to this comment.**

The fourth commenter provided five (5) comments on different sections throughout the chapter.

- Their first comment was similar to the first commenters comment. I.e. that opportunities for patient counseling or for patients to ask pharmacists questions should be made available in more than one format or one opportunity. **As noted previously, the Board agreed and chose to amend the rules in response to these comments.**
- Their second comment was that they believed the Board's proposed revisions unintentionally placed unnecessary administrative burdens on the Pharmacist in Charge (PIC) regarding notice of a loss of a controlled substance from a pharmacy. They recommended that the Board edit the revision to require the PIC to notify the Board when the loss of a controlled substance has been confirmed and that the notification requirement follow the DEAs requirements. **The Board agreed and chose to amend the rules in response to these comments.**
- Their third comment was that there is little evidence that maintaining all drug orders for 2 years improves the health or safety of the patient and may lead to confusion at the pharmacy or alert fatigue when reviewing the profile. They suggested updating the language to require that 18

months of drug orders be maintained. However, in Wyoming prescriptions for non-controlled substances are statutorily valid for two years. **Because of this, the Board chose not to amend the rules in response to this comment.**

- Their fourth comment sought to clarify that faxed transfers of prescriptions would continue to be an appropriate method to exchange all required information pursuant to a patient's request to transfer their prescription(s) to another pharmacy. The Board believes that the proposed revisions do allow this practice to continue and that further revisions were not needed in response to this comment.
- Their fifth comment included suggested edits on shared pharmacy services that would align with current practice in other jurisdictions and to reduce administrative burdens for pharmacies. **The Board agreed and chose to amend the rules in response to this comment.**

The fifth commenter pointed out that a definition was included in the chapter that was not subsequently used in the chapter. **The Board chose to delete that definition in response to this comment.** Their second comment recommended an edit to provide clarity to pharmacies using a shared pharmacy services agreement to determine which pharmacy would serve as the dispensing pharmacy. **The Board agreed and chose to amend the rules in response to this comment.**

The sixth commenter believed that the new section on personal responsibility needed a small addition. They were supportive of the Boards proposed revision to hold each individual accountable for their own actions and to go upstream to hold the pharmacy owner accountable if the pharmacy owners' actions contributed to or caused an error or violation. They pointed out that there may be times when the leadership or lack thereof of a pharmacist may be the root cause of the error. They suggested an addition to this subsection to include those instances when the actions of the supervising pharmacist contributed to or caused an error or violation. **The Board agreed and chose to amend the rules in response to this comment.**

Chapter 20: Collaborative Practice Regulations – The Board did not receive any comments regarding the proposed repeal of this chapter or the proposed revisions to simplify and modernize collaborative practice and bring it back into Chapter 2.

Chapter 21: Fees – One (1) commenter provided comments to the Board during the public comment period relevant to this chapter. These included formatting corrections that were duly incorporated and one comment to clarify that renewal applications electronically submitted after the deadline were similarly subject to late fees. **The Board agreed and chose to amend the rules in response to this comment.**

Written Public Comments for Rules Packet 059.011023.Pharmacy, Board of – Chpts 2, 20 &21.			
No.	Comment	Agency Response	
		Yes – Amend Rules	No – Why?
1.	Hello, My name is [redacted] and I am writing in regards to proposed changes. I am a practicing pharmacist for a hospital pharmacy in [redacted]. [1]BOP Rules Chapter 2 new subsection 13(a)(ii) and 13(b) - In order to accept and redistribute an unused or undelivered drug, how many of the criteria must be met? One, two, all? [2]BOP Rules Chapter 2 new subsection 15(c)(vi)(C) - Must the phone number be toll free? Can a virtual method be used to fulfil this requirement?	[2] The Board agrees and moves amending Chapter 2 Section 15(c)(vi)(C) From: (C) A toll-free telephone number the patient may call to contact a pharmacist for counseling or to answer questions. to: (C) The manner or method that the patient may use to contact a pharmacist for counseling or to answer questions. See commenter #4's related comments.	[1]Thank you for your comment.
2.	I am [redacted], [redacted], and would like to make comments on Chapters 2, 21, 8, and 10. Thank you. Chapter 2 [1]13(b)(v): should the wording be "not to be more" or "not more" [2]15(c)(ii): what about student interns and student technicians-in-training who are not employed. Could the "employed or under contract" statement be used? [3]18: add a comma between "homes" and "hospices" Chapter 21 [4]3(a)(xvii): add a comma between interns and pharmacy technicians [5]3(b) and following related items: should this be 3(b) followed by (i), (ii), etc rather than (c), (d), etc? [6]All items under 3(b) -- should something about electronic application be included (or a statement that electronic is not allowed)?	[2] See also commenter #4 & 5's comments. The Board moves amending Chapter 2 Section 15(c)(ii) from: (c) The dispensing pharmacy participating in shared pharmacy services shall ensure that: (ii) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to pharmacists, pharmacy interns, pharmacy	[1]Thank you for your comments.

		technicians, or pharmacy technicians in training, who are employed by the shared pharmacy services pharmacy; To: (c) The dispensing pharmacy, which shall be identified as such in the written agreement between pharmacies participating in shared pharmacy services shall ensure that: (ii) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to pharmacists, pharmacy interns, pharmacy technicians, or pharmacy technicians in training, who are employed by the shared pharmacy services pharmacy. Non-pharmacy staff may enter the drug storage area under the direct supervision of a pharmacist; [3,4,5] Corrected	

		[6] The Board moves amending the language from: postmarked or hand delivered to the Board office after DATE XX to: postmarked, electronically submitted, or hand delivered to the Board office after DATE XX for all entities except interns. Interns have been required to renew on paper because of the requirement to be in good standing with their college or school of pharmacy. This documentation comes from the college or school not the intern. **At this time, online renewal has not been set up for resident pharmacies.*	
3.	Dear Executive Director Martineau, I am writing to you in my capacity as [redacted] for [redacted], is uniquely positioned to provide diverse access points to care to patients in the state of Wyoming through our integrated offerings across the spectrum of pharmacy care. [redacted] would also like to commend the Board on their work drafting the proposed changes to Chapter 2, General Practice of Pharmacy Regulations. [redacted] understands it is quite an undertaking to edit and rewrite an entire chapter and applauds the Board on their work. We		

	appreciate the opportunity to submit comments on the proposed additions, deletions, and changes to Chapter 2. RE: Section 15. Shared Pharmacy Services [redacted] is largely supportive of the Board's changes to their shared pharmacy services regulation. We only have one concern for the Board to consider. The current proposed rule requires the dispensing pharmacy to be listed on the label, and [redacted] believes this may cause patient confusion. The label of a prescription exists to help patients and provide pharmacy contact information, so patients can ask further questions as may be needed. In some cases, when utilizing shared services, the originating pharmacy and not the dispensing pharmacy may be the pharmacy that can best serve the patient. As an example, pharmacists who work for Specialty pharmacies are highly trained, experts in specific medications, and often perform prescription counseling and prescription data-entry verification. Another dispensing pharmacy then fills the prescription, and this pharmacist performs product verification. In this example, the pharmacist located at the originating pharmacy is best suited to serve the patient's specific questions. We ask the Board to consider the below edit to your proposed regulation taken from the Arizona Board of Pharmacy Shared Services regulation, Ariz. Admin. Code R4-23-621(C)(2)(a). [Commenters proposed change to Chapter 2 Section 15(d)(iv):] (iv)The prescription label clearly indicates ~~which~~ a pharmacy ~~dispensed the prescription~~ that has access to the patient's records; RE: Section 16. Collaborative Pharmacy Practice and Section 17. Medication Therapy Management [redacted] commends the Board on the changes made to both Section 16 and 17. [redacted] believes these changes allowing population based collaborative practice will be extremely impactful in delivering patient care in Wyoming. RE: Section 23. Automated Storage and Distribution Systems [redacted] understands that the Board is deleting this section of the regulations because you have seen low utilization and would like to re-categorize this type of technology within another chapter. [redacted] believes allowing this type of automation is impactful for patients, increasing access to their prescriptions. We want to provide the Board with a copy of the Massachusetts policy allowing this automated pharmacy system pick-up to consider as they work to rewrite this language within another chapter, please find this in the addendum. [redacted] once again thanks and appreciates the opportunity to provide comments. If you have any questions or need additional information, please contact me directly at [redacted]. Sincerely,	**Adopted by the Board.**	

[redacted]

Addendum: Massachusetts Board of Pharmacy Automated Pharmacy Systems Policy
https://www.mass.gov/doc/2022-07-automated-pharmacy-systems-pdf/download
Board of Registration in Pharmacy Policy 2022-07: Automated Pharmacy Systems
The Board of Registration in Pharmacy ("Board") authorizes this policy to facilitate patient access to filled Schedule IV through VI prescriptions from automated pharmacy systems. In the case of a licensed healthcare facility, approval for use and placement must be obtained from the facility's licensing body (e.g., Bureau of Health Care Safety and Quality).
Automated Pharmacy System ("APS") means an automated patient-facing device that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications. The APS releases patient medications after correct patient identifiers are provided. The APS must have a method to collect and provide all transaction information.
NOTE: If approved by the Board, an APS meeting all the requirements of this policy is considered an extension of the pharmacy's licensed area whether its location is contiguous or non-contiguous to the pharmacy.
I. A pharmacy may dispense Schedule IV through VI controlled substances from an APS to a patient or a patient's agent during or after pharmacy hours of operation provided the following requirements are met:
A. The APS is located within the same building as the pharmacy with the same physical address.
B. The APS is secured against or within a wall or floor in a manner that prevents unauthorized access and removal.
C. The location and APS are monitored by continuous, recordable video surveillance.
D. A pharmacy may not stock medications in an APS that require refrigeration or reconstitution.
E. The APS utilizes industry standard technological verification such as bar code verification, radio frequency identification, or other similar process, to ensure the correct medication is dispensed to the correct patient.
F. If filled prescriptions for Schedule IV, V, or Schedule VI additional drugs (i.e., gabapentin) will be stored in the APS for patient pickup:
1. the identity of the person to whom the medication is released must be collected and maintained. In addition, all reporting requirements of the Prescription Monitoring Program ("PMP") must be met; and
2. the DEA must be consulted for any additional requirements.
G. The APS or the pharmacy that operates the APS maintains an electronic audit trail of all APS transactions.
H. The pharmacy allows the patient to choose whether or not to use an APS.

	I. In the case of new or changed therapy for the patient, the pharmacy must provide the offer to counsel. J. The pharmacy provides the means and opportunity for a pharmacist consultation during the pharmacy's usual hours of operation. K. Prior to use, Board-licensed pharmacies must submit a written request for approval with details including, but not limited to: 1. type of APS (e.g., brand, model, etc.); 2. hours the APS will be available for use; 3. schedules of controlled substances (limited to Schedule IV through VI); 4. security measures; and 5. completed Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage. II. A pharmacy utilizing an APS shall maintain policies and procedures pertaining to the APS that include: A. operation and maintenance; B. security; C. controlled substances accountability; D. quality assurance; E. stocking and return activities; and F. patient confidentiality.		
4.	Dear Executive Director Martineau and Members of the Board, On behalf of all pharmacies owned and operated by [redacted] in the state of Wyoming, we thank the Board for the opportunity to provide comments on the proposed rules regarding updates to Chapter 2. Overall, the changes are positive, but there are a few sections we'd like to suggest some amendments and request clarity, specifically: Section 3: Definition of Counseling Section 4: Responsibilities of the Pharmacist in Charge (PIC) Section 11: Patient Records Section 12: Transfer of Non-Controlled Substance Prescription Orders Between Pharmacies Section 15: Shared Pharmacy Services [redacted] respectfully requests that the Board have meaningful discussions on the concerns below and consider alternatives to the language proposed. **• Section 3 (k) – Definition of Counseling** Within the noticed changes for the definition of counseling, [redacted] has concern that there may be unintentional consequences of limiting patient access and increasing workload within Wyoming-licensed pharmacies. Further, this conflicts with the proposed language in shared services (WY Rule 059.0002 Sec. 15 Shared Pharmacy Services (c)(iv)(C)) which requires the pharmacy to provide toll–free access to reach the pharmacist. Adding the ability to offer printed materials will reduce the potential burden for patients who choose to receive medications via home delivery methods. Many patients in	See commenter #1 & #5's comments. The Board moves amending Chapter 2 Section 3(k) as follows to make conforming changes in response to these comments: (j) "Patient counseling" means the verbal communication by the pharmacist of information, to the	

	pharmacy deserts or with transportation challenges rely on home delivery as the primary way to receive pharmaceuticals. Requiring counseling to be completed only verbally may delay care to patients, especially in rural areas. (k) "Patient counseling" means the verbal communication by the pharmacist of information, to the patient or caregiver, in order to improve therapy by ensuring encourage proper use of drugs and devices. Patient counseling may be supplemented with printed materials. For the purposes of medications provided by delivery, patient counseling may be provided in writing with a toll-free number for patients to receive verbal counseling. **• Section 4 (d)(I) - Reporting of a controlled substance loss** Regarding this section, we believe that the Board may have unintentionally placed unnecessary administrative burdens on the Pharmacist in Charge regarding notice of a confirmed loss of a controlled substance and have placed more stringent requirements than current DEA (Drug Enforcement Agency) regulations. CFR § 1306.76(b) requires a registrant to notify of a loss within one business day, and to complete the DEA Form 106 without specifying a timeframe for completion. As written, it would be impractical for pharmacies to comply in the case of suspected employee pilferage, as often these investigations take time to be fully concluded. [redacted] encourages the board to align with current DEA regulations and require pharmacies upon discovery of a confirmed significant drug loss or any loss related to suspected drug theft of a controlled substance to report to the board within one business day this confirmed loss. Allowing the PIC, the ability to confirm the actual drug loss prior to notifying the board will ensure that accurate reporting is sent and avoid unnecessary administrative requirements for the PIC as they investigate potential loss. (i) Confirmed d~~D~~iversion, theft or significant loss of prescription drugs or controlled substances from the pharmacy within one business day of discovery. When a DEA Form 106 is submitted to the DEA in instances involving controlled substances, a copy of the completed DEA Form 106 along with a detailed explanation shall be submitted to the Board within one business day of signing the form. ~~A copy of the DEA Form 106, if applicable, shall be included with the report~~; **• Section 11 (c)(v) - Maintenance of patient information:** Regarding this section, [redacted] requests clarification on the intent of the two-year patient information requirement. Does this information need to be accessible as a part of the patient profile or just readily retrievable for the purposes of inspection? In the case that the requirement for the pharmacy software is to maintain a list of prescription records as a part of the patient profile for two years, significant IT investments may be required to update current systems, and it may be problematic for outlets to comply. There is little evidence that maintaining all drug orders for 2 years improves the health or safety of the patient and may lead to confusion at the pharmacy or alert fatigue when reviewing the profile. For the purposes of patient profile or drug utilization review [redacted] suggests updating the language to require that 18 months of drug orders are maintained.	patient or caregiver, in order to encourage proper use of drugs and devices. Patient counseling may be supplemented with printed materials. For medications provided by delivery, patient counseling may be provided in writing, and shall indicate the manner or method that the patient may use to contact a pharmacist for counseling or to answer questions. **Adopted by the Board. Note that the correct location for the revision is Section 4(e)(i).** **W.S. 33-24-101(b)(iv)(F) provides that non-controlled substances prescriptions are valid for two years. Because of this, the Board does not adopt revisions in response to this comment.**	

	(v) A list of all prescription drug orders obtained at the pharmacy during the ~~two years~~ 18 months immediately preceding the most recent entry showing the name of the drug or device, prescription number, strength of the drug, quantity, date received and the name of the prescriber; **• Section 12 Transfer of Non-Controlled Substance Prescription Orders Between Pharmacies:** Regarding this section, while not specifically addressed as proposed regulation, we seek to clarify if a fax transfer would be an appropriate manner to exchange all required information for the transfer request. **• Section 15 Shared Pharmacy Services:** Regarding this section, we thank the Board for your approach to simplifying and modernizing the regulations related to shared services. However, we do have several suggestions to align with current practice in other jurisdictions and to reduce administrative burdens for pharmacies. As drafted, this would seem to limit this practice to only be allowed to be completed from within the state. This would limit the ability of pharmacies who have the capability to provide additional services into the state to improve patient care and to alleviate workload from in-state providers. We respectfully request the following amendments. (a) Minimum requirements for shared pharmacy services: (i) A resident or non-resident pharmacy may participate in shared pharmacy services by another licensed pharmacy or pharmacist, provided involved parties: (A) Have entered into a written agreement, specifying the services to be provided and the responsibilities and accountabilities of each party or are of common ownership; (B) Have a system in place to identify the parties responsible for each aspect of prescription preparation. With the requirement to have a system in place to identify the responsible person for each aspect of the prescription, the list of names, addresses, etc. It is unnecessary and creates additional burdens on the pharmacies to keep this information in the policy and procedure manual up to date and accurate. We respectfully request that the board strike the highlighted section below in (b)(ii.) (b) A policy and procedure manual relating to shared pharmacy services shall be maintained by all involved parties and shall be available for inspection by the Board upon request. The manual shall: (i) Outline the responsibilities of each of the involved parties; ~~(ii) Include a list of the names, addresses, telephone numbers, and all license numbers of the parties involved;~~ Regarding this section, [redacted] would request the board to consider updating the language to ensure that non-licensed personnel are able to access the drug storage areas under the supervision of a	**The Board believes that the proposed revisions <u>do</u> allow this practice to continue and that further revisions are not needed in response to this comment.** **Adopted by the Board.** **Adopted by the Board and conforming changes made.**	

	licensed pharmacist. This will ensure that in the event of required maintenance, cleaning, administrative or clerical duties may continue to occur within the pharmacy by non-licensed personnel. (c) The dispensing pharmacy participating in shared pharmacy services shall ensure that: (i) Drugs stored at the pharmacy shall be stored in an area secure from unauthorized personnel; (ii) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to pharmacists, pharmacy interns, pharmacy technicians, or pharmacy technicians in training, who are employed by the shared pharmacy services pharmacy. A non-licensed person may enter the drug storage area under the direct supervision of a pharmacist. In addition to the comments already expressed. We commend and support the Board's work to modernize and expand the collaborative practice and delivery regulations. If the Board would like additional information, please feel free to contact me. Sincerely, [redacted]	**See Boards response to commenter #2's second comment. Adopted by with conforming changes from other commenters on this point.**	
5.	Dear Mr. Martineau, On behalf of [redacted] at [redacted], we thank the Wyoming Board of Pharmacy ("Board") for the opportunity to comment on the amended rules for the General Practice of Pharmacy, including Shared Pharmacy Services and Collaborative Practice Agreements. We commend the Board for the work that has gone into reviewing and amending these rules to ensure they meet current practice standards but also evolve as those standards progress. The flexibility built into these amended rules is imperative for maintaining a continued focus on patient safety and health. These rules will be pivotal in improving public health, closing healthcare gaps, and increasing access to pharmacy services for patients in Wyoming. We support the adoption of both the amended Shared Pharmacy Services and Collaborative Practice Agreement sections, but recommend a few minor revisions to provide a greater better benefit to patients. **Section (3): Definitions** • Although defined, the term "Centralized Prescription Processing" is not utilized in the amended rules. • Providing "Centralized Prescription Processing" as a defined term without utilizing it in any context in rule creates confusion as the activities detailed in the definition overlap with the permitted activities identified in the amended rules in Section 15 for Shared Pharmacy Services. • While previous versions of the NABP Model Act utilized the defined term "Centralized Prescription Processing" in applicable sections in the act, the updated 2022 NABP Model Act removes all forms of the term and instead includes these activities under Shared Pharmacy Services. • To align with the current version of the NABP Model Act and to ensure pharmacies serving		

	Wyoming patients comply with the provisions as outlined in this Chapter, we recommend the board include the term "Centralized Prescription Processing" in the definition of "Shared Pharmacy Services" or remove the definition of Centralized Prescription Processing entirely. Our proposed amendment is as follows: ~~*(a) "Centralized Prescription Processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.*~~ **Section 15: Shared Pharmacy Services** • Section 15(c) describes the responsibilities of a "dispensing pharmacy" participating in a shared pharmacy services agreement; however the term "dispensing pharmacy" is not defined in the amended rules. • The definition provided for "dispense" or "dispensing" in Section 3(f) of the amended rules includes all aspects, from start to finish, of the prescription process. This definition, coupled with the absence of the definition for "dispensing pharmacy", makes it difficult to determine which pharmacy in a shared pharmacy services agreement would serve as the dispensing pharmacy. • We appreciate the board's intent to leave the language broad, allowing pharmacies within a shared pharmacy services agreement to determine which pharmacy would serve as the dispensing pharmacy. However, this intent may not be immediately clear to licensees. To provide clarity we recommend the following edit: *(c) The dispensing pharmacy, which shall be identified as such in the written agreement between pharmacies participating in shared pharmacy services, shall ensure that:* *(i)-(vi)* [redacted] thanks the Board for your time and consideration of our comments on this matter. I can be reached at [redacted] or [redacted] for any questions. Sincerely, [redacted]	**Adopted by the Board.** **Adopted by the Board.**	
6.	Dear Collogues at the Wyoming Board of Pharmacy, I am writing in regard to the recent rules revisions that were posted. [redacted] is overall pleased with the changes being proposed; however, we do have a few recommendations that we would like to bring to the Boards attention: 3. The changes to Chapter 2 are extensive and well thought out. We do feel that there is one section that could use a small addition. Chapter 2, section 7 deals with personal responsibility and accountability; we appreciate the Board is allowing each individual to be accountable for their own actions. However, we do feel that there may be times when the leadership or lack	**Adopted by the Board.**	

	thereof of a pharmacist may lead to error. To remedy this, we feel that it would be prudent to add subsection b stating: a. If any action of the supervising pharmacist is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the pharmacy license holder may be held responsible. We would then recommend changing the current subsection (b) to a new subsection (c). I appreciate the Boards consideration of these recommendations and look forward to the rules revisions being adopted. If [redacted] can be of any help, please feel free to reach out. Warmest Regards, [redacted]		

GENERAL PRACTICE OF PHARMACY REGULATIONS

CHAPTER 2

Section 1. Authority.

These regulations are promulgated pursuant to the Wyoming Pharmacy Act W.S. § 33-24-101 et seq.

Section 2. Scope.

This chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy within the state.

Section 3. Definitions.

(a) "Collaborative pharmacy practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners in collaboration to provide patient care services to achieve optimal medication use and desired patient outcomes.

(b) "Collaborative practice agreement" is a written and signed agreement between one or more pharmacists and one or more practitioners that defines a collaborative practice.

(c) "Compounding" means the preparation, mixing, assembling, altering, packaging, or labeling of a drug, drug-delivery device, or device, unless performed in a Food and Drug Administration (FDA)-registered outsourcing facility in conformance with Federal law, in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

(i) Preparation of drug dosage forms for both human and animal patients;

(ii) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; and

(iii) Manipulation of commercial products for patient-specific needs beyond FDA-approved labeling.

(iv) Compounding does not include mixing, reconstituting, adding flavoring or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with the labeling.

(d) “Deliver” or “delivery” means the actual, constructive or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(e) “Dispense” or “Dispensing” means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

(f) “Fill date” means the date that a new or refilled prescription was prepared, verified and labelled. It may or may not be the date the medication was received by the patient.

(g) “Labeling” means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, packager or distributor.

(h) “Medication refill consolidation” means a component of medication therapy management that recognizes the authority of the pharmacist, at the patient’s directions, to proactively adjust the medication quantity or refill schedule and to manage a patient’s maintenance medications by coordinating the refill schedules, not to exceed the total quantity prescribed, to improve patient outcomes.

(i) “Medication therapy management” (MTM) is a distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist’s scope of practice.

(j) “Patient counseling” means the verbal communication by the pharmacist of information, to the patient or caregiver, in order to encourage proper use of drugs and devices. Patient counseling may be supplemented with printed materials. For medications provided by delivery, patient counseling may be provided in writing, and shall indicate the manner or method that the patient may use to contact a pharmacist for counseling or to answer questions.

(k) “Pharmacist care” are those patient care activities provided by a pharmacist, with or without the dispensing of drugs or devices, that are intended to achieve positive clinical outcomes and to optimize the patient’s health-related quality of life.

(l) “Pharmacist-in-Charge” (“PIC”) means a licensed pharmacist has the authority to direct the pharmacy’s operations and staff.

(m) “Prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient.

(n) “Readily retrievable” means records kept in such a manner that they can be separated out from all other records and produced for review within forty-eight (48) hours.

(o) "Reasonable effort" means that degree of effort which a pharmacist of ordinary prudence and accepted professional duty would exercise in similar circumstances.

(p) "Shared pharmacy services" means a pharmacy or pharmacist performing functions at the request of another pharmacy.

(q) "Supervise" means to direct the execution of pharmacy related functions or tasks.

Section 4. Responsibilities of the Pharmacist-in-Charge (PIC).

(a) Every resident pharmacy shall designate one pharmacist, who is licensed by the Board, as the PIC.

(b) Every non-resident pharmacy shall designate one registered pharmacist as the PIC.

(c) A pharmacist may not serve as PIC for more than one pharmacy at a time unless the pharmacist obtains a waiver from the Board.

(d) A PIC shall:

(i) Direct the pharmacy's operations and staff;

(ii) Ensure all pharmacy and professional staff licenses are current and on display;

(iii) Ensure all expired or recalled drug products are removed from active stock and placed in a designated quarantine area for return or destruction;

(iv) Ensure the proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed; and

(v) Maintain all pharmacy records required by state and federal law in a readily retrievable format.

(e) The PIC shall report to the Board, in writing, the following:

(i) Confirmed diversion, theft or significant loss of prescription drugs or controlled substances from the pharmacy within one business day of discovery. When a DEA Form 106 is submitted to the DEA in instances involving controlled substances, a copy of that completed DEA Form 106, along with a detailed explanation, shall be submitted to the Board within one business day of signing the form;

(ii) Security breaches within the pharmacy or pharmacy area within one business day of discovery;

Section 5. Responsibilities of the Pharmacy License Holder.

(a) The pharmacy license holder shall:

(i) Designate a PIC;

(ii) Notify the Board upon notice of the vacancy of the PIC for a period exceeding thirty (30) days.

(iii) Ensure the pharmacy operates in compliance with all state and federal laws, rules and regulations.

(iv) Ensure the pharmacy has at least one physically present licensed pharmacist on duty at all times the pharmacy is open;

(v) Ensure a sign stating "Pharmacy Closed – No Pharmacist on Duty" is conspicuously posted when there is no pharmacist present in the building;

(vi) Ensure a working environment is provided to staff that protects the health, safety and welfare of patients, which includes, but is not limited to:

(A) Sufficient staffing with pharmacists, pharmacy interns, pharmacy technicians, and/or pharmacy technicians in training as may be required to competently and safely provide pharmacy services.

(B) Appropriate opportunities for meal breaks.

(vii) Notify the Board of any of the following:

(A) Change in ownership of the pharmacy;

(B) Change in address of the pharmacy;

(C) Permanent closing of the pharmacy;

Section 6. Requirements for issuing valid prescriptions

(a) In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

(b) All non-controlled substance prescriptions and refill authorizations shall contain the following:

(i) The patient's full name and date of birth;

(ii) Name and strength of the drug;

(iii) Quantity to be dispensed, including refills, if applicable;

(iv) Directions for use;

(v) Date issued by the practitioner;

(vi) The practitioner's full name, address, telephone number; and

(vii) If a written or faxed prescription, the recognizable signature of the issuing practitioner; or

(viii) If an electronically transmitted prescription, the prescribing practitioner's electronic or digital signature; or

(ix) If a verbal order, the name of the authorized agent providing information, if other than prescriber.

(c) Prescriptions received from out-of-state practitioners are valid only to the extent a practitioner licensed in Wyoming may prescribe that medication in Wyoming.

(d) A prescription may not be dispensed to a practitioner based on an order that is not issued for one specific patient. A prescription order for "office use" is not a valid order.

(e) Upon learning that a practitioner/patient relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his or her professional judgment may honor a patient's request for remaining medication refills, for a period not exceeding twelve (12) months.

(f) The pharmacist shall determine the accuracy and authenticity of all prescriptions received. Pharmacists shall request and document verification when necessary. If verification is refused, the prescription shall not be filled.

(g) All prescription medication shall be dispensed in child-resistant packaging, in accordance with the Poison Prevention Packaging Act.

(i) The patient may request a one-time or a blanket waiver from this requirement.

(ii) The practitioner, at the patient's request, may request a one-time waiver only.

(iii) The pharmacist shall document a one-time request on the prescription or in the patient profile record.

(h) A written or electronic record of a prescription shall be maintained and available for inspection by agents of the Board for a period of two (2) years from the date it is filed, as follows:

(i) The pharmacy system shall be able to reproduce the original prescription information and maintain it in a readily retrievable format;

(ii) A pharmacy shall be authorized to maintain an exact digitized image of the prescription in an electronic record-keeping system;

(iii) A pharmacy may maintain any hard copy prescriptions in numerical or date order; and

(iv) Disposal of the hard copy must ensure privacy and confidentiality of the contents.

Section 7. Personal Responsibility and Accountability.

(a) Each pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician in training shall be responsible and accountable for their own actions performed in their practice of pharmacy.

(b) If any action of the supervising pharmacist is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the supervising pharmacist may be held responsible.

(c) If any action of the pharmacy license holder is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the pharmacy license holder may be held responsible.

Section 8. Unprofessional Conduct.

(a) It shall be unprofessional conduct for any licensed pharmacy staff member to practice pharmacy while under the influence of alcohol or drugs.

(b) It shall be unprofessional conduct for any licensed pharmacy staff member in the pharmacy to practice pharmacy with a mental or physical impairment affecting his or her ability to safely and competently practice pharmacy.

(c) It shall be unprofessional conduct for any licensed pharmacy staff member to sexually harass another licensee, employee of the pharmacy, or patient.

(d) It shall be unprofessional conduct for any licensed pharmacy staff member to not report another pharmacy staff member suspected of engaging in unprofessional conduct to the Board.

(e) It shall be unprofessional conduct for a licensed pharmacy or licensed pharmacy staff member to distribute or dispense prescription drug samples.

(f) It shall be unprofessional conduct for a resident or non-resident pharmacy, or pharmacist, to dispense, sell or offer to sell prescription drugs to persons on the basis of a prescription generated solely through an internet practitioner consultation questionnaire. All pharmacies or pharmacists included in this section are prohibited from linking an internet site with or relating a site, to any other site, business or practitioner that provides prescriptions for medications solely on the basis on an internet practitioner consultation questionnaire.

Section 9. Refill Authorization.

(a) If a refill was not authorized on the original prescription or, if no refills remain, pharmacy staff may contact the prescriber to obtain refill authorization or a new prescription at the request of a patient.

(b) When refill authorization is obtained, the name of the practitioner authorizing the prescription and, if applicable, the name of the agent transmitting the prescription, must be recorded, as well as the number of refills authorized.

(c) The following information shall be recorded in a readily retrievable manner when a prescription is refilled:

(i) Date refilled;

(ii) Quantity; and

(iii) Pharmacy staff's initials who are involved in dispensing the refill.

Section 10. Labeling Prescription Drug Containers.

(a) All original or refill prescription drug containers dispensed by a pharmacy shall be labeled with the following:

(i) The patient's full name; or

(ii) If the patient is an animal, the animal's name, species and the owner's last name;

(iii) Brand or generic name of the drug product dispensed, unless otherwise specified;

(iv) Drug strength and quantity;

(v) Directions for use;

(vi) The name, address, and telephone number of the pharmacy;

(vii) The practitioner's name;

(viii) The serialized number of the prescription;

(ix) The date the prescription was filled or refilled;

(x) The product's physical description, including any identification code that may appear on the tablets and capsules, and;

(xi) Purpose for use where appropriate

(xii) Accessory cautionary labels for patient safety, where appropriate.

(b) All single unit dose or unit of use packaging shall include the following additional information on the label:

(i) Manufacturer's lot number; and

(ii) Expiration date; which shall be the lesser of the manufacturer's expiration date or twelve (12) months from the date of pre-packaging or repackaging.

Section 11. Patient Records.

(a) A patient profile record shall be maintained by pharmacies for patients for whom prescriptions are dispensed.

(b) The profile record shall provide for the immediate retrieval of information of previously dispensed drugs and devices.

(c) The pharmacy software shall be able to maintain the following patient information for each new prescription:

(i) Patient's full name;

(ii) Patient's address and telephone number;

(iii) Patient's date of birth;

(iv) Patient's sex; and

(v) A list of all prescription drug orders obtained at the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, strength of the drug, quantity, date received and the name of the prescriber;

(d) Pharmacy staff shall make a reasonable effort to obtain, record, and maintain the following information in the patient profile record:

(i) Known allergies;

(ii) Adverse drug reactions; and

(iii) Pharmacist comments relevant to the patient or their drug therapy.

Section 12. Transfer of Non-Controlled Substance Prescription Orders Between Pharmacies.

(a) A pharmacy shall transfer prescription order information for non-controlled substances upon the request of the patient.

(b) Transfer of prescription order information for the purpose of filling or refilling a prescription is subject to the following requirements:

(i) A prescription order for a non-controlled prescription drug may be transferred from one pharmacy to another pharmacy only so long as there are refills remaining.

(ii) Both the original and transferred prescription drug orders shall be maintained and readily retrievable for a period of two years from the date of last refill at the respective pharmacy;

(iii) Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription including those requirements in W.S. § 33-24-136;

(c) The individual transferring the prescription order information shall:

(i) Document that the prescription has been transferred in the data processing system;

(ii) Record his/her name;

(iii) Record the name of the receiving individual;

(iv) Record the name, store number if a chain pharmacy, telephone number, and whether the prescription is a controlled substance; and

(v) Record the date of the transfer.

(d) The individual receiving the transferred prescription order information shall:

(i) Document that the prescription was originated by transfer in the data processing system; and

(ii) Record the original prescription's issued date and prescription number;

(iii) Record the original number of refills authorized by the prescriber;

(iv) Record the date of original dispensing;

(v) Record the number of valid refills remaining;

(vi) Record the name, store number if a chain pharmacy, and whether the prescription is a controlled substance; and

(vii) Record the name of the individual transferring the prescription.

Section 13. Return of Unused Prescription Drugs.

(a) A pharmacist may:

(i) Accept and redistribute an unused prescription drug under the Wyoming Drug Donation Program Act, W.S. § 35-7-1601 et seq or its rules; or

(ii) Accept and redistribute any unused prescription drug, or a part of it, after it has left the premises of the pharmacy if:

(A) The drug was intended for inpatients of an institutional facility and has been maintained in the custody and control of the institutional facility or dispensing pharmacy;

(B) The drug was returned to the original dispensing pharmacy;

(C) The drug is in a single unit dose or unit of use package or in the manufacturer's sealed container;

(D) In the professional judgment of the PIC of the pharmacy, the safety and efficacy of the drug has not been compromised during transportation and storage;

(E) A system is in place to track the restocked drug for purposes of a recall; and

(F) Accepting and redistributing of the drug complies with state and federal law.

(b) A prescription dispensed by a pharmacy for delivery but not delivered to the ultimate user may be returned to stock for redispensing provided:

(i) The prescription is returned to the original dispensing pharmacy;

(ii) Storage conditions during transport of the prescription to and from the pharmacy do not in any way compromise the integrity or stability of the drug;

(iii) No compounded or flavored prescription may be returned to stock;

(iv) The drugs did not require refrigeration, freezing, or special storage;

(v) The expiration date of the drug is not more than one year from the date it was dispensed, unless it was dispensed in the manufacturer's original sealed container and bears the manufacturer's original label and expiration date.

(c) A pharmacist may accept the return of a prescription for disposal or destruction if the prescription was dispensed by the pharmacy in error, was defective, adulterated, misbranded, expired, or subject to a recall.

Section 14. Therapeutic Equivalents.

(a) Therapeutic equivalents do not include therapeutic substitutions. Therapeutically equivalent is defined in W.S. § 33-24-147(a)(v). Therapeutic substitution is that class of drug having the same or similar action, but not the identical composition.

(b) Pharmaceuticals that are considered to be therapeutic substitution instead of generic substitution shall not be used by retail/non-resident pharmacies. An institutional pharmacy using a formulary may reach a written agreement with members of the medical staff under which therapeutic substitution is permitted for use of formulary drugs.

Section 15. Shared Pharmacy Services

(a) Minimum requirements for shared pharmacy services:

(i) A resident or a non-resident pharmacy may participate in shared pharmacy services by another licensed pharmacy or pharmacist, provided involved parties:

(A) Have entered into a written agreement, specifying the services to be provided and the responsibilities and accountabilities of each party, or are of common ownership;

(B) Have a system in place to identify the parties responsible for each aspect of prescription preparation.

(b) A policy and procedure manual relating to shared pharmacy services shall be maintained by all involved parties and shall be available for inspection by the Board upon request. The manual shall:

(i) Outline the responsibilities of each of the involved parties;

(ii) Acknowledge the originating and sharing pharmacy shall be jointly responsible; and

(iii) Include policies and procedures for:

(A) Notifying patients that their prescription may be outsourced to another party for shared pharmacy services

(B) Protecting the confidentiality and integrity of patient information;

(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

(D) Operating a 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, and resolve identified problems; and

(E) Provide documentation of annual review of the written policies and procedures.

(c) The dispensing pharmacy, which shall be identified as such in the written agreement between pharmacies participating in shared pharmacy services shall ensure that:

(i) Drugs stored at the pharmacy shall be stored in an area secure from unauthorized personnel;

(ii) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to pharmacists, pharmacy interns, pharmacy technicians, or pharmacy technicians in training, who are employed by the shared pharmacy services pharmacy. Non-pharmacy staff may enter the drug storage area under the direct supervision of a pharmacist;

(iii) The pharmacy maintains and uses storage or shipment containers and shipping processes that ensure drug stability and potency;

(iv) The dispensed prescriptions are shipped in containers sealed in such a manner as to show evidence of opening or tampering;

(v) Records indicate the date the prescription was shipped to the originating retail pharmacy or patient; and

(vi) If the prescription is delivered directly to the patient, the patient shall receive written notice of available counseling. Such notice shall include:

(A) The days and hours when counseling is available,

(B) The location of pharmacy, and

(C) The manner or method that the patient may use to contact a pharmacist for counseling or to answer questions.

(d) A resident pharmacy requesting shared pharmacy services shall ensure that:

(i) Records are readily retrievable and include:

(A) The date and time the request for processing was transmitted to the central fill pharmacy or remote processing pharmacy or pharmacist; and

(B) The date and time the dispensed prescription was received from the central fill pharmacy or remote processing pharmacy or pharmacist by the originating pharmacy, including the method of delivery and the name of the person accepting delivery unless shipped directly to the patient.

(ii) The original prescription is maintained at the originating pharmacy for a time period not less than two (2) years from the date last filled or refilled.

(iii) Notification is provided to patients that their prescription may be outsourced to another pharmacy prior to outsourcing the prescription unless the prescription drug is delivered to patients in institutional facilities where a licensed healthcare professional is responsible for administering the prescription drug to the patient.

(iv) The prescription label clearly indicates a pharmacy that has access to the patient's records;

(v) The pharmacy has access to each pharmacy's prescription records and patient profiles and records, as needed to safely and properly perform the shared services activities.

(e) Shared pharmacy services pharmacies shall:

(i) Comply with federal and state laws and regulations; and

(ii) Protect the confidentiality and integrity of protected health information.

(f) Nothing in this Section shall prohibit an individual pharmacist, who is an employee of or under contract with a pharmacy, or a licensed certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the Pharmacy Act, if both of the following conditions:

(i) The pharmacy establishes controls to protect the confidentiality and integrity of protected health information; and

(ii) No part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

Section 16. Collaborative Pharmacy Practice

(a) Collaborative pharmacy practice is where one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist under specified conditions.

(b) A collaborative practice agreement must be in place prior to engaging in collaborative pharmacy practice.

(c) The collaborative practice agreement must explain the scope of the pharmacist's practices and shall be updated upon any changes in the scope or agreement of practices.

(d) A copy of the signed agreement and any additional information regarding the agreement must be readily retrievable upon request by the Board.

Section 17. Medication Therapy Management

Medication Therapy Management (MTM) services may be performed without a collaborative practice agreement. These services may include, but are not limited to:

(a) Such other patient care services as may be allowed by law;

(b) Ordering, or performing laboratory assessments; and

(c) Evaluating the response of the patient to therapy, as it directly relates to MTM, provided:

(i) The pharmacy or service is certified by the US Department of Health and Human Services, as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA); or

(ii) The tests do not otherwise require a physician's order and the pharmacy or service has obtained a CLIA Certificate of Waiver from the US Department of Health and Human Services; and

(iii) The pharmacist is qualified to direct the laboratory.

Section 18. Ancillary Drug Supply for Nursing Homes, Hospices, Extended Care Facilities or Intermediate Care Facilities.

(a) Nursing homes, hospices, extended care facilities, or intermediate care facilities licensed by the Wyoming Department of Health may be issued a permit by the Board to maintain an ancillary supply of drugs, both scheduled and non-scheduled subject to approval by the Board. The drugs maintained in the ancillary drug supply shall remain the property of the pharmacy to which the permit was jointly issued.

(i) The pharmacy servicing the facility or facilities listed in this chapter shall make application to the Board, on an application form provided by the Board. The Board may issue a permit, if the conditions of this section are met, in the name of the facility and the pharmacy authorizing the storage and use of an ancillary drug supply at the facility. This registration shall be valid until June 30 of each year. The permit must be renewed annually.

(ii) The permit may be revoked by the Board, if conditions as outlined in this Section are not followed, or for other violations of the Wyoming Pharmacy Act or Wyoming Controlled Substances Act or Rules promulgated under said Acts.

(b) The ancillary drug supply shall be kept in a tamper-evident, sealed and secured container or secured automated dispensing device and used for:

(i) An emergency situation;

(ii) To temporarily replace unavailable medications; or

(iii) As a starter dose for the purpose of starting the initial therapy for a patient residing in a facility.

(c) The facility and the pharmacy servicing the facility shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, resident confidentiality and maintenance of the quality, potency and purity of the ancillary drug supply, including the formulary.

(i) Copies of the most recent drug supply policy and procedure manual shall be on file at both the facility and the pharmacy servicing the facility.

(ii) The ancillary drug supply policy and procedure manual shall be reviewed and approved annually by the Consultant Pharmacist of the facility and the facility's Director of Nursing.

(d) The ancillary drug supply stored in an automated dispensing device shall only be stocked and restocked by a pharmacist licensed by this Board or a registered pharmacy technician or pharmacy intern under his or her supervision.

(e) Drugs administered from the ancillary drug supply shall be limited to the following:

(i) A legend drug order given by the practitioner to a nurse for administration to a resident of a facility. Enough medication may be taken to cover dosing for ninety-six (96) hours or less, until the next scheduled delivery from the pharmacy. The pharmacist must be notified of the removal of medication within forty-eight (48) hours, to review the practitioner's order and resident's profile for potential contraindications and adverse drug reactions; and

(ii) Removal of any controlled substance can only be done after the pharmacist has received an order from the practitioner or verified that a prescription exists. No controlled substance can be removed from the ancillary box until the pharmacist grants access.

(f) If the pharmacy servicing the facility discontinues its service, the Board must be notified and the permit surrendered. If the new pharmacy provider desires to maintain an ancillary drug supply, the new pharmacy provider must make application to the Board.

(g) Facilities described in this section are if the pharmacy providing their ancillary drug supply is physically located at the same site as the facility and this pharmacy possesses a DEA registration and is licensed by the Board.

GENERAL PRACTICE OF PHARMACY REGULATIONS

CHAPTER 2

Section 1. Authority.

These regulations are promulgated pursuant to the Wyoming Pharmacy Act W.S. § 33-24-101 ~~through 301~~ et seq.

~~**Section 2**. Purpose.~~

~~The purpose of this regulation is to coordinate the requirements for pharmacy services by providing minimum standards, conditions, and physical guidelines for facilities and pharmacists in professional settings.~~

~~**Section 3**~~**Section 2**. Scope.

This chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy within the state.

~~**Section 4**~~**Section 3**. Definitions.

~~(a) "Active pharmacy practice" means a pharmacist who engages in the practice of pharmacy, as defined in W.S. § 33-24-124, a minimum of four hundred (400) hours per calendar year.~~

~~(b) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:~~

~~(i) A practitioner (or by his or her authorized agent); or~~

~~(ii) The patient or research subject at the direction of the practitioner.~~

~~(c) "Ancillary kit" means a tamper-evident sealed and secured container or secured automated dispensing device containing drugs.~~

~~(d) "Audit trail" means a record showing who has accessed an information technology application and what operations the user performed during a given period.~~

~~(e) "Authentication" means verifying the identity of the user prior to allowing access to the information application.~~

~~(f) "Automated Dispensing Device" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.~~

~~(g) "Board of Pharmacy" or "Board" means the Wyoming State Board of Pharmacy.~~

~~(h)~~(a) "Collaborative pharmacy practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners ~~under protocol and~~ in collaboration to provide patient care services to achieve optimal medication use and desired patient outcomes.

~~(i)~~(b) "Collaborative practice agreement" ~~means a written voluntary agreement, between a pharmacist and a prescribing practitioner~~ is a written and signed agreement between one or more pharmacists and one or more practitioners that ~~that~~ defines a collaborative practice.

~~(j)~~(c) "Compounding" means ~~and includes the preparation, mixing or assembling of a drug or device, and the packaging and labeling incident thereto for sale or dispensing:~~ the preparation, mixing, assembling, altering, packaging, or labeling of a drug, drug-delivery device, or device, unless performed in a Food and Drug Administration (FDA)-registered outsourcing facility in conformance with Federal law, in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

~~(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of his/her professional practice;~~

~~(ii) For the purpose of research, teaching, or chemical analysis; or~~

~~(iii) In anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.~~

(i) Preparation of drug dosage forms for both human and animal patients;

(ii) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; and

(iii) Manipulation of commercial products for patient-specific needs beyond FDA-approved labeling.

(iv) Compounding does not include mixing, reconstituting, adding flavoring or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with the labeling.

~~(k) "Confidential information" means information maintained by the pharmacist in the patient's records, or communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or, as the patient directs, to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being, and to such other persons or governmental agencies authorized by law to investigate controlled substance law violations.~~

~~(l) "Consultant pharmacist" means a pharmacist who establishes policies and procedures for the distribution and storage of drugs, visits the facility on a regularly scheduled basis, but is not physically present at the facility for a set number of hours on a daily basis, and conducts prospective and retrospective drug utilization reviews, including the identification of problems and recommendations for resolution of identified problems for residents of the facility.~~

~~(m) "Customized patient medication package" means a package which contains two or more drugs.~~

~~(n)~~(d) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

~~(o) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part of accessory, which is required under federal law to bear the label, "Caution: Federal law restricts this device to sale by or on the order of a physician."~~

~~(p) "Digital signature" means an electronic identifier that:~~

~~(i) Is intended by the party using it to have the same force and effect as a manual signature;~~

~~(ii) Is unique to the authorized signer;~~

~~(iii) Is capable of verification;~~

~~(iv) Is under the sole control of the authorized signer;~~

~~(v) Is linked to the prescription in such a manner, that, if the prescription information is changed, the signature is invalidated; and~~

~~(vi) Conforms to Wyoming State Statute and Board Rules and Regulations.~~

~~(q)~~(e) ~~"Dispense" means the interpretation, evaluation and implementation of a prescription drug or nonprescription drug under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject or an animal. including the preparation, final verification, and delivery of a drug or device to a patient or patient's agent in a~~

~~suitable container appropriately labeled for subsequent administration to, or use by, a patient.~~ ”Dispense” or “Dispensing” means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

~~(r) “Distribute” means the delivery of a drug or device other than by administering or dispensing.~~

~~(s) “Dosage form” means the physical formulation or medium in which the product is manufactured and made available for use including, but not limited to, tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories.~~

~~(t) “Drug” means an article recognized as a drug in any official compendium, or supplement thereto, designated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.~~

~~(u) “Drug” means:~~

~~(i) Substances recognized as drugs in official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;~~

~~(ii) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;~~

~~(iii) Substances (other than food) intended to affect the structure or any function of the body of man or animals; and~~

~~(iv) Substances intended for use as a component of any article specified in subparagraph (i), (ii), or (iii) of this paragraph. It does not include devices or their components, parts or accessories.~~

~~(v) “Drug therapy management” means the same as medication therapy management as defined in this Chapter.~~

~~(w) “Electronic prescription” means a prescription that is generated on an electronic application and transmitted as an electronic data file.~~

~~(x) “Electronic signature” means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.~~

~~(y) “Electronic transmission” means:~~

~~(i) Transmission of the digital representation of information from one computer or other similar electronic device to another computer, which is authenticated by a digital signature; or~~

~~(ii) Transmission of the electronic representation of information from one computer or other similar electronic device to a facsimile (fax) machine, which is authenticated by an electronic signature.~~

(f) "Fill date" means the date that a new or refilled prescription was prepared, verified and labelled. It may or may not be the date the medication was received by the patient.

~~(z)~~(g) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, packager or distributor.

~~(aa)~~(h) "Medication refill consolidation" means a component of medication therapy management that recognizes the authority of the pharmacist, at the patient's directions, to proactively adjust the medication quantity or refill schedule and to manage a patient's maintenance medications by coordinating the refill schedules, not to exceed the total quantity prescribed, to improve patient outcomes.

~~(bb)~~(i) "Medication therapy management" (MTM) ~~(also known as "drug therapy management")~~ is a distinct service or group of services that optimize therapeutic outcomes for individual patients. ~~Medical therapy management (~~MTM~~)~~ services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. ~~MTM services may be performed without a collaborative practice agreement. These services may include, but are not limited to, the following, according to the individual needs of the patient:~~

~~(i) Performing or obtaining necessary assessments of the patient's health status;~~

~~(ii) Formulating a medication treatment plan;~~

~~(iii) Selecting, initiating, modifying or administering medication therapy;~~

~~(iv) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;~~

~~(v) Performing a comprehensive medication review to identify, resolve and prevent medication-related problems, including adverse drug events;~~

~~(vi) Documenting the care delivered and communicating essential information to the patient's other primary care providers;~~

~~(vii) Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;~~

~~(viii) Providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens, such as medication refill consolidation;~~

~~(ix) Coordinating and integrating MTM services within the broader health care management services being provided to the patient;~~

~~(x) Such other patient care services as may be allowed by law; or~~

~~(xi) Ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, as it directly relates to MTM, provided:~~

~~(A) The pharmacy or service is certified by the US Department of Health and Human Services, as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA); or~~

~~(B) The tests do not otherwise require a physician's order and the pharmacy or service has obtained a CLIA Certificate of Waiver from the US Department of Health and Human Services; and~~

~~(C) The pharmacist is qualified to direct the laboratory.~~

~~(cc) "Paper prescription" means a prescription created on paper or computer generated to be printed or transmitted via fax that includes a manual signature.~~

~~(dd) "Patient confidences" as used in WYO. STAT. ANN. § 33-24-101(b)(4)(C) means information transmitted by the prescribing practitioner or agent to the pharmacist or agent for the purpose of treating the patient and information transmitted by the patient or agent to the pharmacist or agent for the purpose of treatment, and includes the patient's name, address, medical condition and drugs lawfully prescribed for the patient. The pharmacist may release otherwise confidential information pertaining to the patient's treatment to a minor's parent or guardian, the patient's third party payor or the patient's agent.~~

~~(ee)~~(j) "Patient counseling" means the verbal communication by the pharmacist of information, to the patient or caregiver, in order to ~~improve therapy by ensuring~~ encourage proper use of drugs and devices. Patient counseling may be supplemented with printed materials. For medications provided by delivery, patient counseling may be provided in writing, and shall indicate the manner or method that the patient may use to contact a pharmacist for counseling or to answer questions.

~~(ff)~~(k) "Pharmacist care" ~~(also known as pharmaceutical care) is~~ are those patient care activities provided by a pharmacist, with or without the dispensing of drugs or devices, that are intended to achieve positive clinical outcomes and to optimize the patient's health-related quality of life.

~~(gg) "Pharmacist's collaborative scope of practice" means those duties and limitations of duties agreed upon by pharmacists and the collaborating practitioners (subject to Board approval and applicable law), and includes the limitations implied by the specialty practiced by the collaborating practitioner.~~

~~(hh)~~(l) "Pharmacist-in-Charge" ("PIC") means a licensed pharmacist ~~currently licensed in this state~~ who ~~accepts responsibility for the operation of a pharmacy in conformance with all laws, rules pertinent to the practice of pharmacy and the distribution of drugs~~ has the authority to direct the pharmacy's operations and staff.

~~(ii) "Pharmacy intern" is described in Chapter 3 of these rules.~~

~~(jj) "Practitioner" means: an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which he/she practices to prescribe drugs in the course of professional practice.~~

~~(i) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a prescription drug or device in the course of professional practice or research in this state~~

~~(ii) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a prescription drug or device in the course of professional practice or research in this state.~~

~~(kk) "Prepackage" means to prepare a drug in a container in advance of actual, immediate need for dispensing, prior to the receipt of an order. Such packaging may be in a single unit dose or unit of use package for use in a unit dose dispensing system or in a container suitable for a traditional dispensing system.~~

~~(ll) "Prescription drug" or "legend drug" means a drug which, under federal law, is required to be labeled with one of the following statements:~~

~~(i) "Caution: Federal law prohibits dispensing without a prescription";~~

~~(ii) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or~~

~~(iii) "Rx Only."~~

~~(mm)~~(m) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

~~(nn)~~(n) "Readily retrievable" means records kept in such a manner that they can be separated out from all other records and produced for review within forty-eight (48) hours.

(o) "Reasonable effort" means that degree of effort which a pharmacist of ordinary prudence and accepted professional duty would exercise in similar circumstances.

~~(pp) "Repackage" means to prepare a single unit dose or unit of use package or traditional dispensing system package for dispensing pursuant to an existing order.~~

~~(qq) "State Board," as used in W.S. § 33-24-136(b), shall mean the boards of medicine, dental examiners, nursing, podiatry, optometry and veterinary medicine of the State of Wyoming and their similar counterpart boards of any of the states in the United States of America.~~

(p) "Shared pharmacy services" means a pharmacy or pharmacist performing functions at the request of another pharmacy.

(q) "Supervise" means to direct the execution of pharmacy related functions or tasks.

~~(tt) "Traditional dispensing system" means a drug package system in which individual doses are not packaged in single unit dose packages or unit of use packages.~~

~~(uu) "Unit dose dispensing system" means a drug distribution system that is in a pharmacy and uses single unit dose packages or unit of use packages that enable distribution of packaged doses in a manner that preserves the identity and the integrity of the drug.~~

~~(vv) "Single Unit Dose" means a package that contains one unit of medication.~~

~~(ww) "Unit of use" means a package that provides multiple units of doses separated in a medication card or other similarly designed container.~~

~~(xx) "Wholesale distributor" is defined in Chapter 8 of these rules.~~

~~Section 5~~ Section 4. Responsibilities of the Pharmacist-in-Charge (PIC).

(a) ~~Every licensed pharmacy must be in the continuous daily charge of a pharmacist. A pharmacist shall be designated as the PIC and shall have direct control of the pharmacy services of said pharmacy.~~ Every resident pharmacy shall designate one pharmacist, who is licensed by the Board, as the PIC.

~~(i) A pharmacist may not serve as the PIC unless said pharmacist is physically present in the pharmacy a minimum of thirty-two (32) hours per week, except for time periods of less than thirty (30) days when absent due to illness, family illness or death, scheduled vacation or other authorized absence, every week, or eighty percent (80%) of the time the pharmacy is open, if opened less than forty (40) hours per week.~~

(ii) A pharmacist may not serve as PIC for more than one pharmacy at a time. The name of the PIC shall be designated on the application of the pharmacy for the license and in each renewal period. A pharmacist may seek a waiver from the Board to serve as PIC for more than one pharmacy, provided those requirements for number of hours physically present in the pharmacy are met.

(iii) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy license to notify the Board immediately of the disability of the PIC for a period exceeding thirty (30) days.

(iv) A corporation or other non-pharmacist owner must comply strictly with the above provisions and provide a PIC who will have complete control of the pharmacy services of the pharmacy.

(v) Responsibilities of the PIC include requiring compliance with all federal and state pharmacy laws and regulations. It shall be the duty of the PIC to report all pharmacy violations within their facility to the Board, with the single exception that, whenever a PIC or staff pharmacist reports a pharmacist or pharmacy technician to the Wyoming Professional Assistance Program (WPAP) for suspected substance abuse, no further reporting to the Board regarding the name of the suspected substance abuse impaired pharmacist or pharmacy technician needs to be done. Any pharmacy technician-in-training or pharmacy intern suspected of substance abuse and reported to WPAP shall be reported to the Board.

(vi) Additional responsibilities of the PIC shall be to:

(A) Establish policies and procedures for the procurement, storage, compounding and dispensing of pharmaceuticals;

(B) Supervise the professional employees of the pharmacy;

(C) Supervise the non-professional employees of the pharmacy;

(D) Establish and supervise the recordkeeping for the security of all pharmaceuticals;

(E) Report any significant loss or theft of drugs to the Board and other authorities;

(F) Ensure that all professional staff, including registered pharmacists, interns, pharmacy technicians-in-training and registered pharmacy technicians, have valid licenses or registrations in good standing and that all certificates are on display. Pharmacists must report any change of address or place of employment to the Board within fifteen (15) days of the change;

~~(G) Ensure that all pharmacy licenses, including state and federal controlled substances registration, are valid and posted;~~

~~(H) Develop and implement a procedure for drug recall, including a quarantine area designated separately from other drugs awaiting return; and~~

~~(I) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit or damaged prescription drugs or prescription drugs that are otherwise unfit for dispensing.~~

~~(II) The prescription drugs found to be unacceptable shall be quarantined from the rest of the stock until examination and determination that the prescribed drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband or adulterated.~~

~~(I) Assure that all expired drug products are removed from active stock and placed in an area designated for return.~~

~~(vii) Every pharmacy shall have at least one registered pharmacist on duty and physically present in the building at all times that the pharmacy is open for the transaction of business. If the pharmacist is absent from the building where there is a licensed retail pharmacy, the prescription department must be locked and kept so until that pharmacist's return. A sign stating "Prescription Department Closed – No Registered Pharmacist on Duty" shall be conspicuously posted.~~

~~(viii) No pharmacy shall be permitted to operate without a PIC for more than thirty (30) days.~~

(b) Every non-resident pharmacy shall designate one registered pharmacist as the PIC.

(c) A pharmacist may not serve as PIC for more than one pharmacy at a time unless the pharmacist obtains a waiver from the Board.

(d) A PIC shall:

(i) Direct the pharmacy's operations and staff;

(ii) Ensure all pharmacy and professional staff licenses are current and on display;

(iii) Ensure all expired or recalled drug products are removed from active stock and placed in a designated quarantine area for return or destruction;

(iv) Ensure the proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed; and

(v) Maintain all pharmacy records required by state and federal law in a readily retrievable format.

(e) The PIC shall report to the Board, in writing, the following:

(i) Confirmed diversion, theft or significant loss of prescription drugs or controlled substances from the pharmacy within one business day of discovery. When a DEA Form 106 is submitted to the DEA in instances involving controlled substances, a copy of that completed DEA Form 106, along with a detailed explanation, shall be submitted to the Board within one business day of signing the form;

(ii) Security breaches within the pharmacy or pharmacy area within one business day of discovery;

Section 5. Responsibilities of the Pharmacy License Holder.

(a) The pharmacy license holder shall:

(i) Designate a PIC;

(ii) Notify the Board upon notice of the vacancy of the PIC for a period exceeding thirty (30) days.

(iii) Ensure the pharmacy operates in compliance with all state and federal laws, rules and regulations.

(iv) Ensure the pharmacy has at least one physically present licensed pharmacist on duty at all times the pharmacy is open;

(v) Ensure a sign stating "Pharmacy Closed – No Pharmacist on Duty" is conspicuously posted when there is no pharmacist present in the building;

(vi) Ensure a working environment is provided to staff that protects the health, safety and welfare of patients, which includes, but is not limited to:

(A) Sufficient staffing with pharmacists, pharmacy interns, pharmacy technicians, and/or pharmacy technicians in training as may be required to competently and safely provide pharmacy services.

(B) Appropriate opportunities for meal breaks.

(vii) Notify the Board of any of the following:

(A) Change in ownership of the pharmacy;

(B) Change in address of the pharmacy;

(C) Permanent closing of the pharmacy;

Section 6. Requirements for issuing valid prescriptions

(a) In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

(b) All non-controlled substance prescriptions and refill authorizations shall contain the following:

(i) The patient's full name and date of birth;

(ii) Name and strength of the drug;

(iii) Quantity to be dispensed, including refills, if applicable;

(iv) Directions for use;

(v) Date issued by the practitioner;

(vi) The practitioner's full name, address, telephone number; and

(vii) If a written or faxed prescription, the recognizable signature of the issuing practitioner; or

(viii) If an electronically transmitted prescription, the prescribing practitioner's electronic or digital signature; or

(ix) If a verbal order, the name of the authorized agent providing information, if other than prescriber.

(c) Prescriptions received from out-of-state practitioners are valid only to the extent a practitioner licensed in Wyoming may prescribe that medication in Wyoming.

(d) A prescription may not be dispensed to a practitioner based on an order that is not issued for one specific patient. A prescription order for "office use" is not a valid order.

(e) Upon learning that a practitioner/patient relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his or her professional judgment may honor a patient's request for remaining medication refills, for a period not exceeding twelve (12) months.

(f) The pharmacist shall determine the accuracy and authenticity of all prescriptions received. Pharmacists shall request and document verification when necessary. If verification is refused, the prescription shall not be filled.

(g) All prescription medication shall be dispensed in child-resistant packaging, in accordance with the Poison Prevention Packaging Act.

(i) The patient may request a one-time or a blanket waiver from this requirement.

(ii) The practitioner, at the patient's request, may request a one-time waiver only.

(iii) The pharmacist shall document a one-time request on the prescription or in the patient profile record.

(h) A written or electronic record of a prescription shall be maintained and available for inspection by agents of the Board for a period of two (2) years from the date it is filed, as follows:

(j) The pharmacy system shall be able to reproduce the original prescription information and maintain it in a readily retrievable format;

(ii) A pharmacy shall be authorized to maintain an exact digitized image of the prescription in an electronic record-keeping system;

(iii) A pharmacy may maintain any hard copy prescriptions in numerical or date order; and

(iv) Disposal of the hard copy must ensure privacy and confidentiality of the contents.

Section 7. Personal Responsibility and Accountability.

(a) Each pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician in training shall be responsible and accountable for their own actions performed in their practice of pharmacy.

(b) If any action of the supervising pharmacist is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the supervising pharmacist may be held responsible.

(c) If any action of the pharmacy license holder is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the pharmacy license holder may be held responsible.

Section 8. Unprofessional Conduct.

(a) It shall be unprofessional conduct for any licensed pharmacy staff member to practice pharmacy while under the influence of alcohol or drugs.

(b) It shall be unprofessional conduct for any licensed pharmacy staff member in the pharmacy to practice pharmacy with a mental or physical impairment affecting his or her ability to safely and competently practice pharmacy.

(c) It shall be unprofessional conduct for any licensed pharmacy staff member to sexually harass another licensee, employee of the pharmacy, or patient.

(d) It shall be unprofessional conduct for any licensed pharmacy staff member to not report another pharmacy staff member suspected of engaging in unprofessional conduct to the Board.

(e) It shall be unprofessional conduct for a licensed pharmacy or licensed pharmacy staff member to distribute or dispense prescription drug samples.

(f) It shall be unprofessional conduct for a resident or non-resident pharmacy, or pharmacist, to dispense, sell or offer to sell prescription drugs to persons on the basis of a prescription generated solely through an internet practitioner consultation questionnaire. All pharmacies or pharmacists included in this section are prohibited from linking an internet site with or relating a site, to any other site, business or practitioner that provides prescriptions for medications solely on the basis on an internet practitioner consultation questionnaire.

Section 9. Refill Authorization.

(a) If a refill was not authorized on the original prescription or, if no refills remain, pharmacy staff may contact the prescriber to obtain refill authorization or a new prescription at the request of a patient.

(b When refill authorization is obtained, the name of the practitioner authorizing the prescription and, if applicable, the name of the agent transmitting the prescription, must be recorded, as well as the number of refills authorized.

(c) The following information shall be recorded in a readily retrievable manner when a prescription is refilled:

(i) Date refilled;

(ii) Quantity; and

(iii) Pharmacy staff's initials who are involved in dispensing the refill.

Section 10. Labeling Prescription Drug Containers.

(a) All original or refill prescription drug containers dispensed by a pharmacy shall be labeled with the following:

(i) The patient's full name; or

(ii) If the patient is an animal, the animal's name, species and the owner's last name;

(iii) Brand or generic name of the drug product dispensed, unless otherwise specified;

(iv) Drug strength and quantity;

(v) Directions for use;

(vi) The name, address, and telephone number of the pharmacy;

(vii) The practitioner's name;

(viii) The serialized number of the prescription;

(ix) The date the prescription was filled or refilled;

(x) The product's physical description, including any identification code that may appear on the tablets and capsules, and;

(xi) Purpose for use where appropriate

(xii) Accessory cautionary labels for patient safety, where appropriate.

(b) All single unit dose or unit of use packaging shall include the following additional information on the label:

(i) Manufacturer's lot number; and

(ii) Expiration date; which shall be the lesser of the manufacturer's expiration date or twelve (12) months from the date of pre-packaging or repackaging.

Section 11. Patient Records.

(a) A patient profile record shall be maintained by pharmacies for patients for whom prescriptions are dispensed.

(b) The profile record shall provide for the immediate retrieval of information of previously dispensed drugs and devices.

(c) The pharmacy software shall be able to maintain the following patient information for each new prescription:

(i) Patient's full name;

(ii) Patient's address and telephone number;

(iii) Patient's date of birth;

(iv) Patient's sex; and

(v) A list of all prescription drug orders obtained at the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, strength of the drug, quantity, date received and the name of the prescriber;

(d) Pharmacy staff shall make a reasonable effort to obtain, record, and maintain the following information in the patient profile record:

(i) Known allergies;

(ii) Adverse drug reactions; and

(iii) Pharmacist comments relevant to the patient or their drug therapy.

~~**Section 6**~~**Section 12**. Transfer of Non-Controlled Substance Prescription Orders Between ~~Prescription Drug Outlets~~ Pharmacies.

~~(a) A prescription label or a written copy of a prescription order from another pharmacy may be issued for informational purposes only and shall not be considered to be a valid prescription order. A pharmacist who receives such a label or prescription order copy shall either contact the prescribing practitioner for authorization to dispense the prescription or, alternatively, shall comply with this section.~~

~~(i) A pharmacist, pharmacy technician or pharmacy intern shall transfer prescription order information for non-controlled substances upon the request of a patient. Transfer of~~

~~prescription order information for the purpose of filling or refilling a prescription is subject to the following requirements:~~

~~(A) The information is communicated verbally by one pharmacist or pharmacy intern to another pharmacist;~~

~~(B) The information is sent to the receiving pharmacy via fax by a pharmacist, pharmacy intern, or pharmacy technician with the consent of the supervising pharmacist;~~

~~(C) The information is electronically transferred between pharmacies by a pharmacist, pharmacy intern or pharmacy technician with the consent of the supervising pharmacist;~~

~~(D) A pharmacy intern may receive a transferred prescription for non-controlled substances if the transfer is initiated by a pharmacist, not another pharmacy intern or pharmacy technician; or~~

~~(E) Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription including those requirements in W.S. § 33-24-136.~~

~~(ii) The transferring pharmacist, pharmacy technician or pharmacy intern shall:~~

~~(A) Write the word "void" across the face of the original prescription order to make the order invalid or electronically document that the prescription has been voided; and~~

~~(B) Record on the reverse side of the invalidated prescription order or electronic document:~~

~~(I) His/her name;~~

~~(II) The name of the receiving pharmacist;~~

~~(III) The name of the receiving pharmacy;~~

~~(IV) The telephone number of the receiving pharmacy; and~~

~~(V) The date of the transfer.~~

~~(iii) The pharmacist or pharmacy intern receiving the transferred prescription order information shall create a written or electronic record of the prescription, write the word "transfer" or a word of similar import on the face of the transferred prescription order or electronically document that the prescription has been transferred, and provide all information required by law or regulation to be on the prescription order, including:~~

~~(A) The name of the patient, including the date of birth, if available;~~

~~(B) The name of the prescribing practitioner and DEA number, if a controlled substance;~~

~~(C) The date of issue of the original prescription order;~~

~~(D) The date of the dispensing of the original prescription order, if any;~~

~~(E) The number of refills authorized;~~

~~(F) The number of valid refills remaining;~~

~~(G) The date of the last refill of the original prescription order, if any;~~

~~(H) The prescription order number from which the prescription order information was transferred, if any;~~

~~(I) The name of the transferring pharmacist or pharmacy intern; and~~

~~(J) The name and telephone number of the transferring pharmacy.~~

~~(iv) The transferring pharmacy shall retain the original prescription order.~~

~~(v) The receiving pharmacy shall retain the transferred prescription order.~~

~~(vi) The pharmacist or pharmacy intern at the receiving pharmacy at the time of the dispensing of the transferred prescription shall inform the patient that the prescription order is now invalid at the pharmacy from which it was transferred.~~

~~(vii) A transferring pharmacy shall comply with all requirements of this regulation, including invalidation of the prescription order and deactivation of the order in the computer.~~

~~(viii) Nothing in this rule shall be deemed to permit the transfer of a prescription order for a Schedule II controlled substance.~~

~~(ix) A prescription order for a controlled substance in Schedule III through V may be transferred only one time, that transfer being from the pharmacy where the prescription was originally filled. It shall not be further transferred by, or to, any other pharmacy. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the practitioner's authorization.~~

~~(x) The transfers of Schedules III, IV and V controlled substances are subject to the following requirements:~~

~~(A) The transfer must be communicated directly between two licensed pharmacists;~~

~~(B) The transferring pharmacist must do the following:~~

~~(I) Write the word "VOID" on the face of the invalidated prescription; or for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record;~~

~~(II) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record; and~~

~~(III) Record the date of the transfer and the name of the pharmacist transferring the information.~~

~~(C) For paper prescriptions and prescriptions received verbally, and reduced to writing or an electronic record by a pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing or an electronic record all information required including:~~

~~(I) Date of issuance of original prescription;~~

~~(II) Original number of refills authorized on original prescription;~~

~~(III) Date of original dispensing;~~

~~(IV) Number of valid refills remaining and date(s) and locations of previous refills;~~

~~(V) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;~~

~~(VI) Name of pharmacist who transferred the prescription; and~~

~~(VII) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.~~

~~(D) For an electronic prescription being transferred electronically, the transferring pharmacist shall provide the receiving pharmacist with the following information in addition to the original electronic prescription data:~~

~~(I) The date of the original dispensing;~~

~~(II) The number of refills remaining and the date(s) and locations of previous refill(s);~~

~~(III) The transferring pharmacy's name, address, DEA registration number and prescription number for each dispensing;~~

~~(IV) The name of the pharmacist transferring the prescription; and~~

~~(V) The name, address, DEA registration number and prescription number from the pharmacy that originally filled the prescription, if different.~~

~~(E) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under this chapter.~~

~~(xi) The original and transferred prescription(s) of controlled substances in Schedules III, IV and V must be maintained for a period of two (2) years from the date of last dispensing.~~

~~(xii) Pharmacies electronically accessing the same prescription record for controlled substances in Schedules III, IV and V must satisfy all information requirements of a manual mode for prescription transfer.~~

~~(xiii) When a pharmacist receives a paper or verbal prescription indicating that the prescription was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription has not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.~~

~~(xiv) A prescription order for a non-controlled prescription drug may be transferred from one pharmacy to another pharmacy only so long as there are refills remaining and each pharmacy can establish that a valid refill existed at the time of dispensing.~~

~~(xv) The original and transferred prescription(s) must be maintained for a period of two (2) years from the date of last dispensing.~~

(a) A pharmacy shall transfer prescription order information for non-controlled substances upon the request of the patient.

(b) Transfer of prescription order information for the purpose of filling or refilling a prescription is subject to the following requirements:

(i) A prescription order for a non-controlled prescription drug may be transferred from one pharmacy to another pharmacy only so long as there are refills remaining.

(ii) Both the original and transferred prescription drug orders shall be maintained and readily retrievable for a period of two years from the date of last refill at the respective pharmacy;

(iii) Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription including those requirements in W.S. § 33-24-136;

(c) The individual transferring the prescription order information shall:

(i) Document that the prescription has been transferred in the data processing system;

(ii) Record his/her name;

(iii) Record the name of the receiving individual;

(iv) Record the name, store number if a chain pharmacy, telephone number, and whether the prescription is a controlled substance; and

(v) Record the date of the transfer.

(d) The individual receiving the transferred prescription order information shall:

(i) Document that the prescription was originated by transfer in the data processing system; and

(ii) Record the original prescription's issued date and prescription number;

(iii) Record the original number of refills authorized by the prescriber;

(iv) Record the date of original dispensing;

(v) Record the number of valid refills remaining;

(vi) Record the name, store number if a chain pharmacy, and whether the prescription is a controlled substance; and

(vii) Record the name of the individual transferring the prescription.

~~**Section 7**. Labeling Prescription Drug Containers.~~

(a) All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled as follows:

(i) name of the patient;

(ii) brand or generic name of the drug product dispensed, unless otherwise specified;

(iii) drug strength and quantity;

(iv) the name, address, and telephone number of the pharmacy;

(v) the practitioner's name;

(vi) the serialized number of the prescription;

(vii) the date the prescription was filled or refilled;

(viii) purpose for use where appropriate;

(ix) directions for use; including accessory cautionary information as appropriate for patient safety;

(x) the identifying initials of the dispensing pharmacist; and

(xi) any other information required by federal or state law.

(b) All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules. A waiver will be granted for new drugs for the first one hundred-twenty (120) days on the market and ninety (90) days for drugs which the national reference file has no description on file.

(c) All single-unit dose or unit of use packaging shall be labeled as follows:

(i) Brand name and/or generic name of the prescription drug;

(ii) Strength;

(iii) Manufacturer's lot number;

(iv) Manufacturer's expiration date. If prepackaged or repackaged by the pharmacy, the expiration date shall be the lesser of the manufacturer's expiration date or twelve (12) months from the date of prepackaging or repackaging;

(v) All unit of use packaging dispensed shall include the following information on the label, in addition to that required by this chapter:

(A) Name, address and telephone number of the pharmacy;

(B) Prescription number;

(C) Name of the patient;

(D) Name of the practitioner;

(E) Directions for use;

(F) Date dispensed;

(G) Initials of dispensing pharmacist;

(H) Accessory cautionary labels for patient safety; and

(I) Quantity of medication.

(vi) All unit of use packaging dispensed by a retail pharmacy to residents of long-term care facilities, as defined in Chapter 15 of these rules, as well as prescription drugs dispensed from hospital emergency room departments, as described in Chapter 12 of these rules, shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules.

Section 8. Child-Resistant Packaging.

(a) The Consumer Product Safety Commission enforces the Poison Prevention Packaging Act (PPPA), which requires that all prescription medication shall be dispensed in child-resistant packaging.

(b) Unless the prescription drug is expressly exempted from the federal regulations, the drug must be dispensed in a child-resistant package. Exceptions to this requirement do exist as follows:

(i) The purchaser may request either a one-time or a blanket waiver from the requirement. A one-time request shall be documented on the prescription or patient profile records by the pharmacist; or

(ii) The practitioner, at the request of the patient, may request a one-time waiver. However, the practitioner cannot request a blanket waiver.

~~(c) Child-resistant prescription containers cannot be reused for refills of prescriptions. However, glass containers may be reused, provided that a new safety closure is used.~~

~~**Section 9**. Record of Refills.~~

~~(a) The following information shall be recorded in a readily retrievable manner when a prescription is filled: date refilled, quantity, and pharmacist's initials. If a refill was not authorized on the original prescription or, if no refills remain, the pharmacist may contact the prescriber to obtain a new prescription. If authorization is obtained, the name of the practitioner authorizing the prescription and, if applicable, the name of the agent transmitting the prescription, must be recorded, as well as the number of refills authorized.~~

~~(b) Both the supervising pharmacist and the intern must initial any prescription or prescription refilled by the intern.~~

~~**Section 10**. Practitioner/Patient Relationship as Affecting Prescriptions.~~

~~(a) Upon learning that a practitioner/patient relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his/her professional judgment may honor a patient's request for remaining medication refills, for a period of not exceeding twelve (12) months.~~

~~(b) It shall be unprofessional conduct for a resident or non-resident pharmacy, or pharmacist, to dispense, sell or offer to sell prescription drugs to persons located within this State, or any other state, on the basis of a prescription generated solely through an internet practitioner consultation questionnaire. All pharmacies or pharmacists included in this section are prohibited from linking an internet site with or relating a site, to any other site, business or practitioner that provides prescriptions for medications solely on the basis on an internet practitioner consultation questionnaire.~~

~~**Section 11**~~**Section 13**. Return of Unused Prescription Drugs.

(a) A pharmacist may:

(i) Accept and redistribute an unused prescription drug under the Wyoming Drug Donation Program Act, W.S. § 35-7-1601 et seq or its rules; or

(ii) Accept and redistribute any unused prescription drug, or a part of it, after it has left the premises of the pharmacy if:

(A) The drug was intended for inpatients of an institutional facility and has been maintained in the custody and control of the institutional facility or dispensing pharmacy;

(B) The drug was returned to the original dispensing pharmacy;

(C) The drug is in a single unit dose or unit of use package or in the manufacturer's sealed container;

(D) In the professional judgment of the PIC of the pharmacy, the safety and efficacy of the drug has not been compromised during transportation and storage;

(E) A system is in place to track the restocked drug for purposes of a recall; and

(F) Accepting and redistributing of the drug complies with state and federal law.

~~(iii) Accept those prescription drugs that were dispensed in a manner inconsistent with the prescriber's instructions for quarantine and destruction as allowed by state and federal law.~~

(b) A prescription dispensed by a pharmacy for delivery but not delivered to the ultimate user may be returned to stock for redispensing provided:

(i) The prescription is returned to the original dispensing pharmacy;

(ii) Storage conditions during transport of the prescription to and from the pharmacy do not in any way compromise the integrity or stability of the drug;

(iii) No compounded or flavored prescription may be returned to stock;

(iv) The drugs did not require refrigeration, freezing, or special storage;

(v) The expiration date of the drug is not more than one year from the date it was dispensed, unless it was dispensed in the manufacturer's original sealed container and bears the manufacturer's original label and expiration date.

(c) A pharmacist may accept the return of a prescription for disposal or destruction if the prescription was dispensed by the pharmacy in error, was defective, adulterated, misbranded, expired, or subject to a recall.

~~**Section 12**. Validity of Prescriptions.~~

~~A prescription written outside the scope of practice of the prescribing practitioner shall not be considered a valid prescription.~~

~~**Section 13**. Prescriptions in General.~~

~~(a) To be valid, the prescription, as defined in W.S. § 33-24-136(b), shall contain the following information:~~

(i) Name of patient;

(ii) Name and strength of drug;

(iii) Quantity to be dispensed;

(iv) Directions for using the drug;

(v) Date of issuance by practitioner;

(vi) Recognizable signature of the practitioner. The signature can be digital or electronic as defined in this chapter;

(vii) Prescriptions for controlled substances shall indicate the DEA number and address of the prescribing practitioner and address of the patient; and

(viii) In the case of a verbal order, the name of the authorized agent if conveyed by other than the prescribing practitioner.

(b) All verbal orders shall be recorded on a written or electronic prescription memorandum and filed, in accordance with W.S. § 33-24-136(a).

(c) Prescriptions may be transmitted by the pharmacist in written form; verbally, including telephone; fax; and electronic transmission. Schedule II controlled substance prescriptions may be transmitted by fax if they meet the conditions as outlined in this chapter. Controlled substance prescriptions may be transmitted electronically only to the extent allowed by federal and state law.

(d) Prescriptions received from out-of-state practitioners are valid only to the extent a practitioner licensed in Wyoming may prescribe that medication in Wyoming.

(e) The patient shall have the exclusive right to freedom of choice for any pharmacy to dispense prescription orders. No collaborative practice agreement between prescriber and pharmacy shall require that prescription orders be transmitted from the prescriber to only that pharmacy.

(f) The pharmacist shall be required to determine the accuracy and authenticity of all prescriptions received. Practitioners or their agents shall provide voice verification, when requested by the pharmacist. If refused, the prescription shall not be filled.

Section 14. Transmission of Prescription by Fax Machines.

(a) Prescriptions transmitted by fax shall include the following:

(i) Practitioner's recognizable signature;

(ii) A notation that this is a fax prescription;

(iii) Telephone number and fax number of the practitioner;

(iv) Name, address, telephone number and fax number of the pharmacy to which the prescription is being faxed;

(v) Date and time of fax; and

(vi) Name of the individual acting as the practitioner's agent if other than the practitioner.

(b) The originating fax prescription shall be put into the practitioner's patient file. It shall not be given to the patient.

(c) All fax machines used in transmitting prescriptions shall be programmed with a fax identification number so that the document received will show the sender's fax identification number.

(d) The fax machine for any receiving pharmacy shall be in the prescription department to protect patient confidentiality and shall utilize non-fading paper.

(e) Prescriptions for Schedules III, IV and V controlled substances may be transmitted by fax. Schedule II controlled substance prescriptions may be transmitted by fax if the Schedule II controlled substance prescription meets one of the following conditions:

(i) A prescription written for a Schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion;

(ii) A prescription written for a Schedule II controlled substance for a resident of a long-term care facility; or

(iii) A prescription written for a Schedule II controlled substance for a "terminally ill" patient. The pharmacist shall so annotate a faxed Schedule prescription as being for a "terminally ill" patient.

(f) The fax copy received by the pharmacist shall be deemed the original prescription order and shall be maintained as required by statute.

(g) A faxed prescription may be dispensed only by the pharmacy receiving the fax.

Section 15. Prescription Refill Information.

(a) Prescription refill permission may be obtained in written fax or electronic form, or by verbal verification.

~~(b) If prescription refill authorization is obtained by fax, the authorizing practitioner shall initial the document. All other requirements for valid prescriptions shall apply, including the pharmacist's responsibility to determine authenticity of information obtained by fax.~~

~~**Section 16**. Fax Machines in General.~~

~~Using fax equipment to circumvent documentation, authenticity, verification or other standards of pharmacy practice shall be considered unprofessional conduct.~~

~~**Section 17**~~**Section 14**. Therapeutic Equivalents.

(a) Therapeutic equivalents do not include therapeutic substitutions. Therapeutically equivalent is defined in W.S. § 33-24-147(a)(v). Therapeutic substitution is that class of drug having the same or similar action, but not the identical composition.

(b) Pharmaceuticals that are considered to be therapeutic substitution instead of generic substitution shall not be used by retail/non-resident pharmacies. An institutional pharmacy using a formulary may reach a written agreement with members of the medical staff under which therapeutic substitution is permitted for use of formulary drugs.

Section 15. Shared Pharmacy Services

(a) Minimum requirements for shared pharmacy services:

(i) A resident or a non-resident pharmacy may participate in shared pharmacy services by another licensed pharmacy or pharmacist, provided involved parties:

(A) Have entered into a written agreement, specifying the services to be provided and the responsibilities and accountabilities of each party, or are of common ownership;

(B) Have a system in place to identify the parties responsible for each aspect of prescription preparation.

(b) A policy and procedure manual relating to shared pharmacy services shall be maintained by all involved parties and shall be available for inspection by the Board upon request. The manual shall:

(i) Outline the responsibilities of each of the involved parties;

(ii) Acknowledge the originating and sharing pharmacy shall be jointly responsible; and

(iii) Include policies and procedures for:

(A) Notifying patients that their prescription may be outsourced to another party for shared pharmacy services

(B) Protecting the confidentiality and integrity of patient information;

(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

(D) Operating a 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, and resolve identified problems; and

(E) Provide documentation of annual review of the written policies and procedures.

(c) The dispensing pharmacy, which shall be identified as such in the written agreement between pharmacies participating in shared pharmacy services shall ensure that:

(i) Drugs stored at the pharmacy shall be stored in an area secure from unauthorized personnel;

(ii) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to pharmacists, pharmacy interns, pharmacy technicians, or pharmacy technicians in training, who are employed by the shared pharmacy services pharmacy. Non-pharmacy staff may enter the drug storage area under the direct supervision of a pharmacist;

(iii) The pharmacy maintains and uses storage or shipment containers and shipping processes that ensure drug stability and potency;

(iv) The dispensed prescriptions are shipped in containers sealed in such a manner as to show evidence of opening or tampering;

(v) Records indicate the date the prescription was shipped to the originating retail pharmacy or patient; and

(vi) If the prescription is delivered directly to the patient, the patient shall receive written notice of available counseling. Such notice shall include:

(A) The days and hours when counseling is available,

(B) The location of pharmacy, and

(C) The manner or method that the patient may use to contact a pharmacist for counseling or to answer questions.

(d) A resident pharmacy requesting shared pharmacy services shall ensure that:

(i) Records are readily retrievable and include:

(A) The date and time the request for processing was transmitted to the central fill pharmacy or remote processing pharmacy or pharmacist; and

(B) The date and time the dispensed prescription was received from the central fill pharmacy or remote processing pharmacy or pharmacist by the originating pharmacy, including the method of delivery and the name of the person accepting delivery unless shipped directly to the patient.

(ii) The original prescription is maintained at the originating pharmacy for a time period not less than two (2) years from the date last filled or refilled.

(iii) Notification is provided to patients that their prescription may be outsourced to another pharmacy prior to outsourcing the prescription unless the prescription drug is delivered to patients in institutional facilities where a licensed healthcare professional is responsible for administering the prescription drug to the patient.

(iv) The prescription label clearly indicates a pharmacy that has access to the patient's records;

(v) The pharmacy has access to each pharmacy's prescription records and patient profiles and records, as needed to safely and properly perform the shared services activities.

(e) Shared pharmacy services pharmacies shall:

(i) Comply with federal and state laws and regulations; and

(ii) Protect the confidentiality and integrity of protected health information.

(f) Nothing in this Section shall prohibit an individual pharmacist, who is an employee of or under contract with a pharmacy, or a licensed certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the Pharmacy Act, if both of the following conditions:

(i) The pharmacy establishes controls to protect the confidentiality and integrity of protected health information; and

(ii) No part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

Section 16. Collaborative Pharmacy Practice

(a) Collaborative pharmacy practice is where one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist under specified conditions.

(b) A collaborative practice agreement must be in place prior to engaging in collaborative pharmacy practice.

(c) The collaborative practice agreement must explain the scope of the pharmacist's practices and shall be updated upon any changes in the scope or agreement of practices.

(d) A copy of the signed agreement and any additional information regarding the agreement must be readily retrievable upon request by the Board.

Section 17. Medication Therapy Management

Medication Therapy Management (MTM) services may be performed without a collaborative practice agreement. These services may include, but are not limited to:

(a) Such other patient care services as may be allowed by law;

(b) Ordering, or performing laboratory assessments; and

(c) Evaluating the response of the patient to therapy, as it directly relates to MTM, provided:

(i) The pharmacy or service is certified by the US Department of Health and Human Services, as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA); or

(ii) The tests do not otherwise require a physician's order and the pharmacy or service has obtained a CLIA Certificate of Waiver from the US Department of Health and Human Services; and

(iii) The pharmacist is qualified to direct the laboratory.

~~**Section 18**. Fees (including examination, re-examination, license, license renewal, registration, registration renewal, mailing list and late fees).~~

~~(a) The Board shall charge the following fees:~~

~~(i) Pharmacist licensure by examination or re-examination shall be seventy-five dollars ($75.00) paid to the Board, plus the NABP fee for the NAPLEX® and the MPJE® paid to NABP;~~

~~(ii) Pharmacist licensure by reciprocity shall be two hundred dollars ($200.00) paid to the Board plus the NABP fee for licensure transfer application and the MPJE® paid to NABP;~~

~~(iii) Pharmacist licensure renewal shall be one hundred dollars ($100.00) per year;~~

~~(iv) Pharmacy intern licensure shall be fifteen dollars ($15.00) and shall be renewed annually by September 30. Renewal fee shall be fifteen dollars ($15.00);~~

~~(v) Pharmacy technician licensure fee shall be fifty dollars ($50.00);~~

~~(vi) Pharmacy technician-in-training permit shall be fifteen dollars ($15.00);~~

~~(vii) Pharmacy technician renewal fee shall be fifty dollars ($50.00) per year;~~

~~(viii) Resident retail pharmacy license and renewals shall be one hundred fifty dollars ($150.00) per year;~~

~~(ix) Non-resident pharmacy license and renewals shall be three hundred dollars ($300.00) per year;~~

~~(x) A prescription drug manufacturer, distributor, reverse distributor, or wholesaler license and renewals shall be two hundred seventy-five dollars ($275.00) per year;~~

~~(xi) Medical oxygen manufacturer or distributor license and renewals shall be one hundred dollars ($100.00) per year;~~

~~(xii) Outsourcing facilities license and renewals shall be three hundred dollars ($300.00) per year;~~

~~(xiii) Third party logistics provider license and renewals shall be two hundred seventy-five dollars ($275.00) per year;~~

~~(xiv) Wholesale distributors of prescription drugs for non-human use license and renewals shall be two hundred seventy-five dollars ($275.00) per year;~~

~~(xv) Methamphetamine precursor retail distributor license and renewals shall be twenty-five dollars ($25.00) per year;~~

(xvi) Ancillary drug supply permit and renewals shall be twenty-five dollars ($25.00) per year;

(xvii) Institutional pharmacy license and renewals shall be one hundred fifty dollars ($150.00) per year;

(xviii) The Board shall charge a two hundred fifty dollar ($250.00) fee for preparing and sending mailing lists of pharmacists, pharmacy technicians, pharmacy interns pharmacy technicians-in-training, pharmacies, controlled substance registrants and drug distributors. Each list shall constitute a separate mailing list. Federal and state agencies shall be exempt from payment of fees for mailing lists;

(xix) The Board shall charge a thirty-five dollar ($35.00) fee to verify the license of any non-resident pharmacy, manufacturer, distributor, wholesaler or reverse distributor; and

(xx) Duplicate licenses may be issued upon request when a licensee's name changes or the license becomes damaged or destroyed. There shall be a twenty five dollar ($25.00) fee charged for the duplicate license.

(b) The Board shall assess a late fee, in addition to the license or registration renewal fee, of licenses or registrants, as follows:

(i) A pharmacist whose license renewal application is postmarked or hand delivered to the Board office after December 31 shall be assessed a late fee of seventy-five dollars ($75.00) in addition to the license renewal fee;

(ii) A pharmacy intern whose license renewal application is postmarked or hand delivered to the Board office after September 30 shall be assessed a late fee of fifteen dollars ($15.00) in addition to the license renewal fee;

(iii) A pharmacy technician whose license renewal application is postmarked or hand delivered to the Board office after December 31 shall be assessed a late fee of thirty five dollars ($35.00) in addition to the license renewal fee;

(iv) A resident pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(v) A non-resident pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(vi) A manufacturer, distributor, or wholesaler of prescription drug products (drugs or oxygen) whose license renewal application is postmarked or hand delivered to the Board office after

~~June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;~~

~~(vii) A medical oxygen distributor whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of one hundred dollars ($100.00) in addition to the license renewal fee;~~

~~(viii) An outsourcing facility whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;~~

~~(ix) A third party logistics provider whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00) in addition to the license renewal fee;~~

~~(x) A wholesale distributor of prescription drugs for non-human use whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00); and~~

~~(xi) An institutional pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee.~~

~~Section 19~~Section 18. Ancillary Drug Supply for Nursing Homes, Hospices, Extended Care Facilities or Intermediate Care Facilities.

(a) Nursing homes, hospices, extended care facilities, or intermediate care facilities licensed by the Wyoming Department of Health may be issued a permit by the Board to maintain an ancillary supply of drugs, both scheduled and non-scheduled subject to approval by the Board. The drugs maintained in the ancillary drug supply shall remain the property of the pharmacy to which the permit was jointly issued.

(i) The pharmacy servicing the facility or facilities listed in this chapter shall make application to the Board, on an application form provided by the Board. The Board may issue a permit, if the conditions of this section are met, in the name of the facility and the pharmacy authorizing the storage and use of an ancillary drug supply at the facility. This registration shall be valid until June 30 of each year. The permit must be renewed annually.

~~(ii) The fee for the permit shall be twenty-five dollars ($25.00) annually; and~~

~~(iii)~~(ii) The permit may be revoked by the Board, if conditions as outlined in this Section are not followed, or for other violations of the Wyoming Pharmacy Act or Wyoming Controlled Substances Act or Rules promulgated under said Acts.

(b) The ancillary drug supply shall be kept in a tamper-evident, sealed and secured container or secured automated dispensing device and used for:

(i) An emergency situation;

(ii) To temporarily replace unavailable medications; or

(iii) As a starter dose for the purpose of starting the initial therapy for a patient residing in a facility.

(c) The facility and the pharmacy servicing the facility shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, resident confidentiality and maintenance of the quality, potency and purity of the ancillary drug supply, including the formulary.

(i) Copies of the most recent drug supply policy and procedure manual shall be on file at both the facility and the pharmacy servicing the facility.

(ii) The ancillary drug supply policy and procedure manual shall be reviewed and approved annually by the Consultant Pharmacist of the facility and the facility's Director of Nursing.

(d) The ancillary drug supply stored in an automated dispensing device shall only be stocked and restocked by a pharmacist licensed by this Board or a registered pharmacy technician or pharmacy intern under his or her supervision.

(e) Drugs administered from the ancillary drug supply shall be limited to the following:

(i) A legend drug order given by the practitioner to a nurse for administration to a resident of a facility. Enough medication may be taken to cover dosing for ninety-six (96) hours or less, until the next scheduled delivery from the pharmacy. The pharmacist must be notified of the removal of medication within forty-eight (48) hours, to review the practitioner's order and resident's profile for potential contraindications and adverse drug reactions; and

(ii) Removal of any controlled substance can only be done after the pharmacist has received an order from the practitioner or verified that a prescription exists. No controlled substance can be removed from the ancillary box until the pharmacist grants access.

(f) If the pharmacy servicing the facility discontinues its service, the Board must be notified and the permit surrendered. If the new pharmacy provider desires to maintain an ancillary drug supply, the new pharmacy provider must make application to the Board.

(g) Facilities described in this section are if the pharmacy providing their ancillary drug supply is physically located at the same site as the facility and this pharmacy possesses a DEA registration and is licensed by the Board.

Section 20. Electronic Prescription Transmission.

(a) Prescriptions of electronic transmission shall fulfill these requirements to be valid:

(i) Be transmitted to a licensed pharmacy of the patient's choice, exactly as transmitted by the prescribing practitioner or designated agent;

(ii) Identify the transmitter's telephone number for verbal confirmation of the time and date of transmission and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state laws and regulations;

(iii) Be transmitted by an authorized practitioner using a digital or an electronic signature unique to the practitioner, if the transmission is from computer to computer or from computer to fax machine; and

(iv) The electronic transmission shall be deemed the original prescription drug order, provided it is readily retrievable through the pharmacy computer system and meets those requirements outlined in W.S. § 33-24-136. The electronic transmission shall be maintained for two (2) years from the date of last dispensing.

(b) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of the prescription communicated by electronic transmission consistent with existing federal or state laws and regulations;

(c) All electronic equipment for receipt of prescriptions communicated by way of electronic transmission shall be maintained to prevent unauthorized access;

(d) Hard copy prescriptions presented to the patient that are generated from electronic media utilizing an electronic signature shall be applied to paper that utilizes security features that will ensure that the prescription is not subject to any form of copying or alterations;

(e) Prescriptions may be transmitted by fax to fax, as allowed in this chapter;

(f) Prescriptions submitted by electronic transmission shall include all the features listed in this chapter;

(g) Electronic prescriptions for controlled substances shall include the requirements of 21 CFR § 1311.10, including:

(i) The practitioner may issue a prescription for a Schedule II, III, IV or V controlled substance electronically if an electronic prescription application is used that has been certified by a third party auditor to ensure that the electronic prescription application records, stores and transmits the prescription accurately and consistently and that the individual practitioner has obtained a two-factor authentication credential for signing;

(ii) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner and the contents of the prescription must not be altered during transmission between the practitioner and pharmacy; and

(iii) The pharmacy receiving the electronic prescription must determine the third-party certification has found that the pharmacy application accurately and consistently imports, stores and displays the information required for the prescription, including the number of refills and the practitioner's digital signature.

Section 21. Drug Samples.

It is unprofessional conduct for a licensee in an institutional or a retail pharmacy to distribute or dispense prescription drug samples.

Section 22. Centralized Prescription Processing.

(a) Definitions specific to this Section:

(i) "Centralized prescription processing," as used in this Section, means the processing by a pharmacy of a request from another pharmacy to refill a prescription drug order or to perform functions such as prospective or retrospective drug use review, claims adjudication, refill authorizations and therapeutic interventions.

(ii) "Dispensing pharmacy," as used in this Section, means a pharmacy that may outsource the processing of a prescription drug order to another pharmacy licensed by the Board.

(iii) "Central fill pharmacy," as used in this Section, means a pharmacy that processes a prescription drug order that was outsourced by a dispensing pharmacy licensed by the Board.

(iv) "Real-time," as used in this Section, means the transmission of information through data links so rapid that the information is available to the dispensing pharmacy and requesting pharmacy sites simultaneously.

(b) Minimum requirements:

(i) A dispensing pharmacy may outsource prescription drug order processing to another pharmacy licensed by the Board, provided the pharmacies:

(A) Have the same owner;

(B) Have entered into a written agreement, which complies with federal and state laws and regulations, specifying the services to be provided and the responsibilities and accountabilities of each pharmacy;

(C) Share a real-time database; and

(D) Maintain the original prescription at the dispensing pharmacy for a time period not less than two (2) years from the date last filled or refilled.

(ii) The PIC of the central fill pharmacy shall ensure that:

(A) The pharmacy maintains and uses storage or shipment containers and shipping processes that ensure drug stability and potency. Shipping processes shall include the use of appropriate packaging material or devices that ensure the drug is maintained at a temperature range that will maintain the integrity of the medication throughout the delivery process; and

(B) The dispensed prescriptions are shipped in containers sealed in such a manner as to show evidence of opening or tampering.

(iii) A resident dispensing or central fill pharmacy shall comply with the provisions of W.S. § 33-24-113 and this Section.

(iv) A dispensing or central fill pharmacy dispensing compounded non-sterile or sterile pharmaceuticals shall comply with the provisions of Chapter 13 or Chapter 17 of these rules.

(c) Notifications to patients. A pharmacy that outsources prescription processing to another pharmacy shall:

(i) Notify patients that their prescription may be outsourced to another pharmacy prior to outsourcing the prescription via posted signage, written notification or refill telephone message; and

(ii) If the prescription is delivered to the patient directly by the central fill pharmacy, the pharmacist employed by the central fill pharmacy shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, location of pharmacy and a toll-free telephone number the patient may utilize to contact a pharmacist for counseling or to answer questions. Such notice shall be included in each prescription delivery to a patient.

(d) Prescription labeling.

(i) The prescription label shall clearly indicate which pharmacy filled the prescription and which pharmacy dispensed the prescription; and

(ii) The prescription label shall comply with this chapter.

(e) Policies and Procedures. A policy and procedures manual relating to centralized processing shall be maintained at both pharmacies and shall be available for inspection. Each pharmacy

~~is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operation. The manual shall:~~

~~(i) Outline the responsibilities of each of the pharmacies;~~

~~(ii) Include a list of the names, addresses, telephone numbers and all license/registration numbers of the pharmacies involved in centralized prescription processing; and~~

~~(iii) Include policies and procedures for:~~

~~(A) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription processing and providing the name of that pharmacy;~~

~~(B) Protecting the confidentiality and integrity of patient information;~~

~~(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;~~

~~(D) Complying with federal and state laws and regulations;~~

~~(E) 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;~~

~~(F) Identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications to the prescription record or patient profile and the final check of the completed prescription;~~

~~(G) Identifying the pharmacist responsible for making the offer to counsel the patients as required by Chapter 9 of these rules; and~~

~~(H) Documentation of annual review of the written policies and procedures.~~

~~(f) Records.~~

~~(i) Records shall be maintained in a real-time electronic database;~~

~~(ii) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy and each pharmacist's or technician's involvement in dispensing;~~

~~(iii) The dispensing pharmacy shall maintain records which indicate:~~

(A) The date and time the request for processing was transmitted to the central fill pharmacy; and

(B) The date and time the dispensed prescription was received from the central fill pharmacy by the dispensing pharmacy, including the method of delivery (e.g., private, common or contract carrier) and the name of the person accepting delivery unless shipped directly to the patient.

(iv) The central fill pharmacy shall maintain records which indicate the date the prescription was shipped to the dispensing pharmacy or patient.

Section 23. Automated Storage and Distribution Systems.

(a) Before using an automated storage and distribution system, a PIC shall ensure that the automated storage and distribution system and the policies and procedures comply with this chapter.

(b) The PIC shall establish policies and procedures for appropriate performance and use of the automated storage and distribution system that:

(i) Ensure that the automated storage and distribution system is in good working order while maintaining appropriate recordkeeping and security safeguards. This is to include the ability to store at the required temperature;

(ii) Ensure that an automated storage and distribution system used by a pharmacy that allows access to drug or devices by a patient:

(A) Only allows patient access to prescriptions that:

(I) Do not require an offer to counsel by a pharmacist as specified in W.S. § 33-24-136(c);

(II) Are properly labeled and verified by a pharmacist before placement into the automated storage and distribution system and subsequent release to patients; and

(III) Are not a Schedule II controlled substance under the Wyoming Controlled Substances Act.

(B) Allows a patient to choose whether or not to use the system;

(C) Is located inside a building in a wall of a licensed pharmacy where the pharmacy staff has access to the device from within the pharmacy and patients have access from outside the pharmacy and is attached to the wall in such a manner that prevents unauthorized removal;

(D) Provides a method to identify the patient and only release the identified patient's prescriptions;

(E) Is secure from access and removal of drugs or devices by unauthorized individuals;

(F) Provides a method for a patient to obtain consultation with a pharmacist, if requested by the patient; and

(G) Prevents dispensing of refilled prescriptions, if a pharmacist determines that the patient requires counseling.

(iii) Ensure that an automated storage and distribution system used by a pharmacy that allows access to drugs or devices for the purposes of administration only by authorized licensed personnel based on a valid prescription order or medication order.

(A) Provides for adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices; and

(B) Ensures the filling, stocking or restocking of all drugs or devices in the system may be done only by a pharmacist, pharmacy intern or pharmacy technician.

(iv) Implement an ongoing quality assurance program that monitors compliance with the established policies and procedures of the automated storage and distribution system and federal and state law.

(c) The PIC shall:

(i) Ensure the policies and procedures for the performance and use of an automated storage and distribution system are prepared, implemented and complied with;

(ii) Review and document annually and, if necessary, revise the policies and procedures required under this Section; and

(iii) Make the policies and procedures available for employee reference and inspection by the Board within the pharmacy and at any location outside the pharmacy where the automated storage and distribution system is used.

(d) The Board may prohibit a PIC from using an automated storage and distribution system if the pharmacy licensee or the pharmacy licensee's employees do not comply with the requirements of this Section.

Section 24. Electronic Records of Prescriptions.

Pursuant to W.S. § 33-24-136, a written or electronic record of a prescription shall be maintained and available for inspection by agents of the Board for a period of two (2) years from the date it is filed, as follows:

(a) The pharmacy system shall ensure the validity and retrievability of the original prescription information;

(b) A pharmacy shall be authorized to maintain an exact digitized image of the prescription drug order in an electronic record-keeping system;

(c) Faxed prescriptions received in electronic format may be electronically stored and maintained in a readily retrievable format;

(d) Electronically transmitted prescriptions may be electronically stored and maintained in a readily retrievable format;

(e) A pharmacy may retain any hard copy prescriptions in numerical or date order; and

(f) Disposal of the hard copy must be in a secure destruction method to ensure privacy and confidentiality of the contents.

Section 25. Drug Disposal Including Controlled Substances.

Information for patients regarding disposal of their personal prescription drugs that are outdated, unusable, or no longer prescribed is hereby incorporated by reference.

Section 26. Dangerous Substance List.

Pursuant to W.S. § 33-24-127, the Board adopts the most recent edition and its supplements of section 3.1 "Prescription Drug Product List" of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, as the official listing of Dangerous Substances for the State of Wyoming is hereby incorporated by reference.

Section 27. Incorporation by Reference.

(a) Any code, standard, rule or regulation incorporated by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (c) of this section.

(i) The Board has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;

(ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section; and

The incorporated code, standard, rule or regulation is maintained at Board's office and is available for public inspection and copying at cost at the same location.

(b) Each rule incorporated by reference in these rules is further identified as follows:

(i) The standard incorporated by reference in this section of these rules is "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)," 36th Edition, 2016 as existing on January 17, 2017 including amendments adopted by the Food and Drug Administration (FDA) as of that date. The products in this list have been approved under section 505 of the federal Food, Drug, and Cosmetic Act. Copies of this standard can be obtained from the US Department of Health and Human Services, Food and Drug Administration, Office of Medical Products and Tobacco, center for Drug Evaluation and Research, Office of Generic Drugs, Office of Generic Drug Policy at the following location:
www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ApprovedDrugProductswithTherapeuticEquivalenceEvaluationsOrangeBook/default.htm.

(ii) The incorporated standard for disposal of personal prescription drugs is available on the internet at:
www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm;

(iii) The incorporated standard for disposal of controlled substances by DEA registrants is available on the internet at www.deadiversion.uisdoj.gov/fed_regs/rules/2014/2014-20926.pdf; and

(iv) The standard incorporated by reference in these rules is the Federal Register Volume 79. No. 174, Tuesday, September 9, 2014, Department of Justice, Drug Enforcement Administration, 21 CFR Parts 1300, 1301, 1304, specifically § 1317.30 through § 1317.95 disposal of Controlled Substances: Final Rule. Copies of this rule can be obtained from the DEA at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf.

COLLABORATIVE PRACTICE REGULATIONS

CHAPTER 20

This chapter is repealed.

~~COLLABORATIVE PRACTICE REGULATIONS~~

~~CHAPTER 20~~

~~Section 1.~~ ~~Authority.~~

~~These regulations are promulgated pursuant to the Wyoming Pharmacy Act W.S. § 33-24-101 through -301.~~

~~Section 2.~~ ~~Purpose.~~

~~The purpose of this regulation is to regulate the practice of pharmacists who agree to collaborate with practitioners in the care of patients.~~

~~Section 3.~~ ~~Scope.~~

~~This chapter applies to any person engaging in the practice of collaborative pharmacy practice within the state.~~

~~Section 4.~~ ~~Definitions.~~

(a) ~~"Collaborative pharmacy practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration to provide patient care services to achieve optimal medication use and desired patient outcomes.~~

(b) ~~"Collaborative practice agreement" means a written voluntary agreement, between a pharmacist and a prescribing practitioner that defines a collaborative practice.~~

~~Section 5.~~ ~~Collaborative Pharmacist Care.~~

~~(a) A pharmacist planning to engage in collaborative practice shall have on file at the pharmacist's place of practice a written, signed collaborative practice agreement approved by the Board. This collaborative practice agreement allows the pharmacist, acting within the pharmacist's collaborative scope of practice, to conduct MTM approved by a prescribing practitioner acting within the scope of the practitioner's current practice.~~

~~(b) The collaborative practice agreement shall include:~~

~~(i) The names of the prescribing practitioner and the pharmacist who are parties to the collaborative practice agreement;~~

~~(ii) The specific types of MTM decisions that the pharmacist is allowed to make, which shall include:~~

(A) The types of diseases, drugs or drug categories involved, and the extent of MTM allowed in each case;

(B) The methods, procedures, decision criteria and plan the pharmacist is to follow when conducting MTM; and

(C) The procedures the pharmacist is to follow in the course of conducting MTM, including documentation of decisions and a plan or appropriate mechanism for communication and reporting to the prescribing practitioner concerning specific decisions. Documentation of decisions shall occur in the prescribing practitioner patient medical record. If the medical record is not available at the practice site, a copy of the documentation of decisions will be sent to the prescribing practitioner.

(iii) A method for the prescribing practitioner to monitor compliance with the collaborative practice agreement and clinical outcomes when MTM by the pharmacist has occurred and to intercede when necessary;

(iv) A provision that allows the prescribing practitioner to override the collaborative practice agreement whenever deemed necessary or appropriate;

(v) A provision allowing the practitioner, pharmacist and patient or patient's agent, parent or guardian to cancel the collaborative practice agreement at any time by written notice to all parties. The pharmacist shall retain the original notice of cancellation for two (2) years; and

(vi) The signatures of the pharmacist and prescribing practitioner who are entering into the collaborative practice agreement and the dates when signed.

(c) MTM shall occur only for a particular patient pursuant to a specific written order from the prescribing practitioner. The written order shall conform to the format established by the Board and shall include the following as a minimum:

(i) Patient's name, gender, date of birth, height and weight;

(ii) Allergies;

(iii) Medical diagnosis;

(iv) All current medication(s), including current dosages (including any laboratory test);

(v) Method of communicating information between pharmacist and practitioner;

(vi) Frequency of practitioner follow-up;

(vii) Date the order will be renewed (specific order must be renewed annually); and

(viii) Signatures of the practitioner, pharmacist and patient or the patient's agent, parent or guardian, and date signed.

(d) A pharmacist providing MTM for a patient shall obtain written consent from the patient or the patient's agent, parent or guardian prior to providing this service. MTM shall not be implemented for a particular patient, if the patient or patient's agent, parent or guardian refuses to give written consent after being informed of the responsibility for payment.

(e) At a minimum, the written collaborative practice agreement shall be reviewed and renewed annually. If necessary, the collaborative practice agreement may be revised. The Board must approve all revisions, once signed by the pharmacist and the prescribing practitioner, prior to implementation. The Board shall review and approve all collaborative practice agreements, including revisions, prior to implementation. This shall be accomplished as follows:

(i) The Board shall appoint a Collaborative Practice Advisory Committee. The Committee shall be composed of five (5) members. Composition shall be two (2) pharmacists currently licensed by the Board and in active practice in Wyoming, one of whom is a current member of the Board; two (2) physicians currently licensed by the Wyoming State Board of Medicine and in active practice in Wyoming one of whom is a current member of the Board of Medicine; and the Board of Pharmacy Executive Director;

(ii) A pharmacist who has developed a collaborative practice agreement shall forward five (5) copies of the signed collaborative practice agreement to the Board. The Executive Director shall convene the Committee to review pending collaborative practice agreements. The Committee shall have authority to recommend approval or rejection of the collaborative practice agreement;

(iii) The recommendation of the Committee shall be reported to the Board at their next regularly scheduled meeting or as needed. The Board's decision will be delivered to the pharmacist and prescribing practitioner within ten (10) days of the Board's decision; and

(iv) The pharmacist submitting a collaborative practice agreement or revisions to an approved collaborative practice agreement to the Board shall not practice under the collaborative practice agreement until notified of approval by the Executive Director.

(f) A pharmacist and prescribing practitioner entering into a collaborative practice agreement must be currently licensed by their respective boards and authorized to practice in this State.

(g) Nothing in this section shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in W.S. § 33-26-402 of the Medical Practice Act and the Wyoming State Board of Medicine regulations.

FEES

CHAPTER 21

Section 1. Authority.

These regulations are promulgated pursuant to the Wyoming Pharmacy Act W.S. § 33-24-101 et seq.

Section 2. General Information.

(a) Fees shall be payable in the exact amount and shall be paid in advance of the licensing services rendered.

(b) All fees collected by the Board are non-refundable.

Section 3. Fees.

(a) The Board shall charge the following fees:

(i) Pharmacist licensure by examination or re-examination is seventy-five dollars ($75.00). This is separate from fees paid to the NABP for the NAPLEX® and the MPJE®.

(ii) Pharmacist licensure by reciprocity is two hundred dollars ($200.00). This is separate from fees paid to the NABP for the NAPLEX® and the MPJE®.

(iii) Pharmacist licensure renewal is one hundred dollars ($100.00) per year;

(iv) Pharmacy intern licensure is fifteen dollars ($15.00) per year;

(v) Pharmacy technician licensure and renewals are fifty dollars ($50.00) per year;

(vi) Pharmacy technician-in-training permit is fifteen dollars ($15.00);

(vii) Resident retail pharmacy license and renewals are one hundred fifty dollars ($150.00) per year;

(viii) Non-resident pharmacy license and renewals are three hundred dollars ($300.00) per year;

(ix) A prescription drug manufacturer, distributor, reverse distributor, or wholesaler license and renewals are two hundred seventy-five dollars ($275.00) per year;

(x) Medical oxygen manufacturer or distributor license and renewals are one hundred dollars ($100.00) per year;

(xi) Outsourcing facilities license and renewals are three hundred dollars ($300.00) per year;

(xii) Third party logistics provider license and renewals are two hundred seventy-five dollars ($275.00) per year;

(xiii) Wholesale distributors of prescription drugs for non-human use license and renewals are two hundred seventy-five dollars ($275.00) per year;

(xiv) Methamphetamine precursor retail distributor license and renewals are twenty-five dollars ($25.00) per year;

(xv) Ancillary drug supply permit and renewals are twenty-five dollars ($25.00) per year;

(xvi) Institutional pharmacy license and renewals are one hundred fifty dollars ($150.00) per year;

(xvii) The Board shall charge a two hundred fifty-dollar ($250.00) fee for preparing and sending mailing lists of pharmacists, pharmacy technicians, pharmacy interns, pharmacy technicians-in-training, pharmacies, controlled substance registrants and drug distributors. Each list shall constitute a separate mailing list. Federal and state agencies shall be exempt from payment of fees for mailing lists;

(xviii) The Board shall charge a thirty-five-dollar ($35.00) fee to verify the license of any non-resident pharmacy, manufacturer, distributor, wholesaler or reverse distributor; and

(xix) Duplicate licenses may be issued upon a licensee's request. There shall be a twenty-five-dollar ($25.00) fee charged for the duplicate license.

(b) The Board shall assess a late fee, in addition to the license or registration renewal fee, of licenses or registrants, as follows:

(i) A pharmacist whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after December 31 shall be assessed a late fee of seventy-five dollars ($75.00) in addition to the license renewal fee;

(ii) A pharmacy interns whose license renewal application is postmarked or hand delivered to the Board office after September 30 shall be assessed a late fee of fifteen dollars ($15.00) in addition to the license renewal fee;

(iii) A pharmacy technician whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after December 31 shall be assessed a late fee of thirty-five dollars ($35.00) in addition to the license renewal fee;

(iv) A resident pharmacy whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(v) A non-resident pharmacy whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(vi) A manufacturer, distributor, or wholesaler of prescription drug products (drugs or oxygen) whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(vii) A medical oxygen distributor whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of one hundred dollars ($100.00) in addition to the license renewal fee;

(viii) An outsourcing facility whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(ix) A third-party logistics provider whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00) in addition to the license renewal fee;

(x) A wholesale distributor of prescription drugs for non-human use whose license renewal application is postmarked, electronically submitted, or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00); and

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