COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting

May 26, 2016

9AM

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Call to Order: Ellen Shinaberry, Committee Chairman	
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• Approval of Agenda	
Call for Public Comment	
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• Consider 2017 Legislative Proposal for Requiring Temperature Monitoring Devices	49-71
• Consider 2017 Legislative Proposal for Addressing Compounding Best Practices	72-78
Adjourn	

****The Committee will have a working lunch at approximately 12pm. ****

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board as of May 10, 2016

Action: None – provided for information only

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] NOIRA - *At Governor's Office for 12 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *Register Date: 11/30/15* *Re-proposed – June meeting*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Outsourcing facilities [Action 4452] Proposed - *DPB Review in progress* [Stage 7508]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Proposed - *DPB Review in progress* [Stage 7515]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Repackaging at PACE sites [Action 4453] Fast-Track - *Register Date: 3/7/16* *Effective: 4/21/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Inclusion of diazepam rectal gel in emergency kits [Action 4536] Fast-Track - *DPB Review in progress* [Stage 7510]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemicals in Schedule I [Action 4535] Final - *Register Date: 5/16/16* *Effective: 6/15/16*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Permits for facilities [Action 4451] Proposed - *DPB Review in progress* [Stage 7507]

Agenda Item: Consideration for Convening a Regulatory Advisory Panel and Discussion of Emergency Regulations for Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil

Included in your agenda package are:

A copy of SB701

A copy of Regulation 18VAC110-11-70 regarding allowance to appoint a regulatory advisory panel

Links to marijuana regulations and frequently asked questions in Connecticut, Minnesota, and New York

Letter from GW Pharmaceuticals

Board action:

Determine if regulatory advisory panel should be formed.

Preliminary discussion of what concepts must be included in the emergency regulations.

ENROLLED

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, relating to cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

Approved [S 701]

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.).

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is guilty of a misdemeanor and shall be confined in jail not more than 30 days and fined not more than $500, either or both; any person, upon a second or subsequent conviction of a violation of this section, is guilty of a Class 1 misdemeanor.

B. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

C. In any prosecution under this section involving marijuana in the form of cannabidiol oil or THC-A oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the individual's intractable epilepsy or (ii) if such individual is the parent or legal guardian of a minor *or of an incapacitated adult as defined in § 18.2-369*, such minor's *or incapacitated adult's* intractable epilepsy. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification.

§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil to treat intractable epilepsy.

A. As used in this section:

"Cannabidiol oil" means a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine who is a neurologist or who specializes in the treatment of epilepsy.

"THC-A oil" means a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

B. A practitioner ~~of medicine or osteopathy licensed by the Board of Medicine~~ in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of a patient's intractable epilepsy.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no

later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's intractable epilepsy pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number of patients to whom a practitioner may issue a written certification.

F. A patient who has been issued a written certification shall register with the Board or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian shall register and shall register such patient with the Board.

G. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, the patient being treated by the practitioner, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a prohibition for the patient to be issued a written certification by more than one practitioner during any given time period.

H. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House and Senate Committees for Courts of Justice, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor involved in the treatment of a registered patient, or (v) a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

Article 4.2.

Permitting of Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil.

§ 54.1-3442.5. Definitions.

As used in this article:

"Cannabidiol oil" has the same meaning as specified in § 54.1-3408.3.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian for the treatment of intractable epilepsy.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; and (x) the secure disposal of plant remains.

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist

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on the premises of the pharmaceutical processor.

E. No person who has been convicted of a felony or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1) of Chapter 7 of Title 18.2 shall be employed by or act as an agent of a pharmaceutical processor.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the pharmaceutical processor shall verify that the practitioner issuing the written certification, the patient, and if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board. No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of cannabidiol oil or THC-A oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor pursuant to § 54.1-3442.6 with the court at least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

2. That, except as provided in the third enactment of this act, the provisions of the first enactment of this act shall not become effective unless reenacted by the 2017 Session of the General Assembly.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act within 280 days of its initial enactment. Such regulations shall not become effective unless the provisions of the first enactment of this act are reenacted by the 2017 Session of the General Assembly.

18VAC110-11-70. Appointment of Regulatory Advisory Panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

Statutory Authority

§§ 2.2-4007.02 and 54.1-2400 of the Code of Virginia.

Historical Notes

Derived from Volume 25, Issue 02, eff. October 29, 2008.

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Discussion of Emergency Regulations for Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil

- Connecticut Regulations on Palliative Use of Marijuana:

https://eregulations.ct.gov/eRegsPortal/Browse/RCSA/%7B24D7E54F-7516-4C12-B49C-C3F50DDF2CDE%7D

- Connecticut FAQs:

http://www.ct.gov/dcp/cwp/view.asp?a=4287&q=531642&dcpNav=|&dcpNav_GID=2109

- Minnesota Regulations on Medical Cannabis:

https://www.revisor.mn.gov/rules/?id=4770&version=2015-07-07T08:02:24-05:00&format=pdf

- New York Medical Marijuana Program Regulations:

https://www.health.ny.gov/regulations/medical_marijuana/docs/regulations.pdf

- New York FAQs:

https://www.health.ny.gov/regulations/medical_marijuana/faq.htm

GW pharmaceuticals

April 25, 2016

Caroline Juran
Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Ms. Juran,

Please allow me to introduce myself. I am the Vice President of U.S. Professional Relations for GW Pharmaceuticals. GW is the developer of Epidiolex®, a pure cannabidiol (CBD) investigational product that is being studied as a potential anti-convulsive treatment for children with certain types of childhood-onset, medication-resistant epilepsies, including Dravet Syndrome and Lennox Gastaut Syndrome (LGS).

We have just announced that the results of our first study in Dravet Syndrome were highly statistically significant in favor of Epidiolex® over placebo. Epidiolex® achieved the primary endpoint of a significant reduction in convulsive seizures assessed over the entire treatment period compared with placebo (p=0.01). The results from our two trials in LGS will become available over the next few months, and the results from our second Dravet study will be available in the second half of the year. I include the press release announcing the first Dravet study results. Epidiolex® has both Orphan Drug Designation and Fast Track Designation from the U.S. Food and Drug Administration (FDA) in the treatment of Dravet syndrome and also Orphan designation for LGS.

Dravet Syndrome is a severe infantile-onset and highly treatment-resistant epileptic syndrome. Over time, people with Dravet Syndrome can develop multiple types of seizures and are prone to prolonged seizures called status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden expected death in epilepsy) is elevated in people with Dravet Syndrome. Additionally, the majority will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care. **There are currently no FDA-approved treatments**, and nearly all patients continue to have uncontrolled seizures and other medical needs throughout their lifetime.

Patients with Lennox Gastaut Syndrome commonly have frequent seizures of a wide variety, including convulsive, atonic seizures, which can cause abrupt falls and serious injury. LGS is also highly medication resistant. Most children with LGS experience some degree of impaired intellectual functioning or

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information processing, as well as developmental delays and behavioral disturbances. As you can see, there is a pressing need for new treatment options for patients with Dravet Syndrome and LGS. These syndromes have serious consequences for both the patients and for their families.

GW intends to file a New Drug Application with the FDA as soon as possible within the next year. Since Epidiolex has Fast Track status, we hope that the FDA will afford it a Priority Review cycle, which could result in approval within eight months of submission. Because CBD is a purified derivative of the cannabis plant, it is currently classified in Schedule I of the U.S. Controlled Substances Act (CSA). If Epidiolex® were approved by FDA, it would then be rescheduled by DEA to a lower schedule so that it could be prescribed. Under recent federal legislation, that rescheduling should be accomplished within 90 days of FDA approval. Almost all states have their own state controlled drug laws, and CBD is a Schedule I substance under those laws. ***Therefore, despite being approved by FDA and rescheduled by DEA, Epidiolex® could not be made available to patients in your state until it is also rescheduled under state law.*** In summary:

- Late 2016/beginning of 2017 - GW files a New Drug Application with FDA
- Potential FDA approval within 8 months of submission - based on Fast Track status and Priority Review Cycle
- 90 days after FDA approval - DEA reschedules Epidiolex® from Schedule I to lower schedule.
- Subsequently, the state reschedules Epidiolex® under state law similarly to DEA rescheduling.

We understand that your agency is responsible for implementing the administrative process that must occur in order for such rescheduling to take place. Therefore, we are reaching out to you with this information in order to minimize any delays in patient access in your state to a much-needed treatment option.

We would very much like to speak with you in the very near future to provide you with additional information about our research and answer any questions you might have about the development path of Epidiolex®. Thank you so much for considering our request.

Best wishes,

Alice P Mead

Alice P. Mead
Vice President, U.S. Professional Relations
GW Pharmaceuticals

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Agenda Item: Fast-track Regulations for amending regulations for "Public Participation Guidelines (PPG)"

Included in your agenda package are:

A copy of the Administrative Process Act relating to PPG's

A copy of the fast-track regulations for consideration by the Regulation Committee

Board action:

Recommendation to the full Board to adopt by a Fast-track action

Code of Virginia
Title 2.2. Administration of Government
Chapter 40. Administrative Process Act

§ 2.2-4007.02. Public participation guidelines.

A. Public participation guidelines for soliciting the input of interested parties in the formation and development of its regulations shall be developed, adopted, and used by each agency pursuant to the provisions of this chapter. The guidelines shall set out any methods for the identification and notification of interested parties and any specific means of seeking input from interested persons or groups that the agency intends to use in addition to the Notice of Intended Regulatory Action. The guidelines shall set out a general policy for the use of standing or ad hoc advisory panels and consultation with groups and individuals registering interest in working with the agency. Such policy shall address the circumstances in which the agency considers the panels or consultation appropriate and intends to make use of the panels or consultation.

B. In formulating any regulation, including but not limited to those in public assistance and social services programs, the agency pursuant to its public participation guidelines shall afford interested persons an opportunity to (i) submit data, views, and arguments, either orally or in writing, to the agency, to include an online public comment forum on the Virginia Regulatory Town Hall, or other specially designated subordinate and (ii) be accompanied by and represented by counsel or other representative. However, the agency may begin drafting the proposed regulation prior to or during any opportunities it provides to the public to submit comments.

2007, cc. 873, 916; 2012, c. 795.

Project 4719 - none

BOARD OF PHARMACY

Conform to APA

Part III

Public Participation Procedures

18VAC110-11-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to (i) submit data, views, and arguments, either orally or in writing, to the agency; and (ii) be accompanied by and represented by counsel or other representative. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.

Agenda Item: Adoption of Re-Proposed Regulations on setting certain conditions on work hours for pharmacists

Included in your agenda package are:

Staff recommendation for a re-proposed amendment

Staff note:

Based on questions and interpretation of proposed language, staff is concerned that the language adopted by the Board does not accurately represent its intent in this action. The recommended re-proposed amendment is in brackets [ ] with the current language stricken.

Since this could be considered a substantive change, it is recommended that the amendment be "re-proposed" and sent for an additional 30-day comment period.

Board action:

Recommendation to the full Board on re-proposed amendment

Part IV

Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day [~~without being allowed~~ and shall allow] at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

~~B.~~ C. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

~~C.~~ D. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

~~D.~~ E. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

~~E.~~ F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with

no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

~~F.~~ G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

~~G.~~ H. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

~~H.~~ I. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

Statutory Authority

§ 54.1-2400 and Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 3.1, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 12, Issue 21, eff. August 7, 1996; Volume 15, Issue 8, eff. February 3, 1999; Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009.

Agenda Item: Fast-track action on fees for nonresident medical equipment suppliers

Staff Note:

This action cannot be adopted by the Board until after July 1st

Included in your package are copies of:

- Copy of legislation passed in 2016 General Assembly
- Draft regulatory action to be recommended by the Committee to the Board in September.

Action:

Motion to recommend fee amendments to the full Board

CHAPTER 88

An Act to amend the Code of Virginia by adding a section numbered 54.1-3435.3:1, relating to registration of nonresident medical equipment suppliers.

[H 527]

Approved March 1, 2016

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-3435.3:1 as follows:

§ 54.1-3435.3:1. Registration of nonresident medical equipment suppliers; renewal; fee.

A. Any person located outside the Commonwealth other than a nonresident pharmacy registered pursuant to § 54.1-3434.1 that ships, mails, or delivers to a consumer in the Commonwealth any hypodermic syringes or needles, medicinal oxygen, Schedule VI controlled device, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, sterile water and saline for irrigation, or solutions for peritoneal dialysis pursuant to a lawful order of a prescriber shall be registered with the Board as a nonresident medical equipment supplier. Registration as a nonresident medical equipment supplier shall be renewed by March 1 of each year. Applicants for registration or renewal of a registration shall submit a fee specified by the Board in regulations at the time of registration or renewal. A nonresident medical equipment supplier registered in accordance with this section shall notify the Board within 30 days of any substantive change in the information previously submitted to the Board.

B. The nonresident medical equipment supplier shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located, if required by the resident state, and shall furnish proof of such license, permit, or registration upon application for registration or renewal. If the resident state does not require a license, permit, or registration to engage in direct consumer supply of the medical equipment described in subsection A, the applicant shall furnish proof that it meets the minimum statutory and regulatory requirements for medical equipment suppliers in the Commonwealth.

C. Records of distribution of medical equipment described in subsection A into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distribution into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

Project 4718 - none

BOARD OF PHARMACY

Nonresident medical equipment suppliers

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Nonresident medical equipment supplier	$180
~~7.~~8. Humane society permit	$20
~~8.~~9. Nonresident pharmacy	$270
~~9.~~10. Controlled substances registrations	$90
~~10.~~11. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
~~11.~~12. Approval of a pharmacy technician training program	$150
~~12.~~13. Approval of a continuing education program	$100
~~13.~~14. Approval of a repackaging training program	$50

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy permit – due no later than April 30	$270
5. Physician permit to practice pharmacy – due no later than February 28	$270
6. Medical equipment supplier permit – due no later than February 28	$180
7. Nonresident medical equipment supplier – due no later than February 28	$180
~~7.~~8. Humane society permit – due no later than February 28	$20
~~8.~~9. Nonresident pharmacy – due no later than the date of initial registration	$270
~~9.~~10. Controlled substances registrations – due no later than February 28	$90
~~10.~~11. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~11.~~12. Approval of a pharmacy technician training program	$75 every two years
~~12.~~13. Approval of a repackaging training program	$30 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90

5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Nonresident medical equipment supplier	$60
~~7.~~8. Humane society permit	$5
~~8.~~9. Nonresident pharmacy	$90
~~9.~~10. Controlled substances registrations	$30
~~10.~~11. Approval of a pharmacy technician training program	$15
~~11.~~12. Approval of a repackaging training program	$10

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210

d. Nonresident medical equipment supplier	$210
~~d.~~e. Humane society permit	$30
~~e.~~f. Nonresident pharmacy	$115
~~f.~~g. Controlled substances registration	$180
~~g.~~h. Approval of a pharmacy technician training program	$75
~~h.~~i. Approval of a repackaging training program	$50

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	$150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

Request from VPhA to Deem Promethazine with Codeine a Drug of Concern

Background: VPhA offered comment at the March 2016 full board meeting that the board should consider deeming promethazine with codeine a drug of concern which would require dispensers to report dispensations of this drug to the Prescription Monitoring Program. The board did not deliberate on this matter.

Possible actions:

- Recommend to the full board that it adopt a Notice of Intended Regulatory Action to deem promethazine with codeine as a drug of concern which will require dispensers to report dispensations of this drug to the Prescription Monitoring Program, **or**
- Recommend to the full board that it recommend to the PMP Advisory Committee that it consider a legislative proposal to expand the definition of "covered substance" to include drugs in Schedule V, or
- Take no action.

§54.1-2519

"Covered substance" means all controlled substances included in Schedules II, III, and IV and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter.

"Drug of concern" means any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

§ 54.1-2520. Program establishment; Director's regulatory authority.

A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program. Covered substances shall include all Schedule II, III, and IV controlled substances, as defined in the Drug Control Act (§ 54.1-3400 et seq.), and any other drugs of concern identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.

E. The Director shall also establish an advisory committee within the Department to assist in the implementation and evaluation of the Prescription Monitoring Program.

- December 1, 2015 Full Board Meeting
- December 1, 2015 Public Hearing for Hours of Continuous Work by Pharmacists
- December 15, 2015 Special Conference Committee
- December 29, 2015 Pilot Informal Conference Committee
- January 5, 2016 Regulation Committee
- March 21, 2016 Special Conference Committee

MOTION:

The Board voted unanimously to approve the minutes as presented for the meetings held between November 23, 2015 and March 21, 2016. (motion by Allen, second by Saenz)

PUBLIC COMMENTS:

Tim Musselman, Executive Director for the Virginia Pharmacists Association, provided a request by membership input for the Board to consider adding promethazine with codeine as a drug of concern so that it may be reported to the Prescription Monitoring Program. *

Michael Rush, Executive Director of Global Health Policy at Temptime Corporation requested the Board consider legislative or regulatory changes to require temperature sensitive medications that are shipped via mail to be accompanied with a device to monitor temperature during shipping. He indicated Georgia recently passed such a law. Mr. Rush provided background on how this type of temperature monitoring has vastly reduced waste in third world countries, specifically in terms of vaccines. Mr. Rush provided examples of factors contributing to drug waste in today's society which included delays in patients receiving mailed packages containing temperature-sensitive drugs. Mr. Rush stated the temperature devices that his corporation provides fall within USP guidelines.

DHP DIRECTOR'S REPORT:

Dr. David Brown introduced the recently appointed Chief Deputy Director, Lisa Hahn. He then provided a summary of the report generated by the Pharmacy Benefits Manager Workgroup, stating that he believes Virginia is in a good position having now completed this work should legislators need information on the subject of the oversight of pharmacy benefit managers. The report summarizes the discussion on several issues identified by the workgroup and provides potential policy options. He stated there was consensus among the workgroup members that:

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Juran, Caroline (DHP)

Subject: FW: Drug of concern question

From: Orr, Ralph (DHP)
Sent: Friday, April 29, 2016 2:08 PM
To: Juran, Caroline (DHP)
Subject: FW: Drug of concern question

FYI

Ralph A. Orr
Director
Virginia's Prescription Monitoring Program
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4566
Fax: 804-527-4470
www.dhp.virginia.gov/pmp/

From: Carter, Barbara A (HLB) [mailto:Barbara.A.Carter@state.mn.us]
Sent: Friday, April 29, 2016 1:56 PM
To: Orr, Ralph (DHP)
Subject: Re: Drug of concern question

Ralph,
In MN it is a schedule III and therefore reported. After a quick google search I see it is a schedule II in KY. Since federally it is a V then I would expect that it is reported in states who collect schedules II-V.

Hope that is helpful.

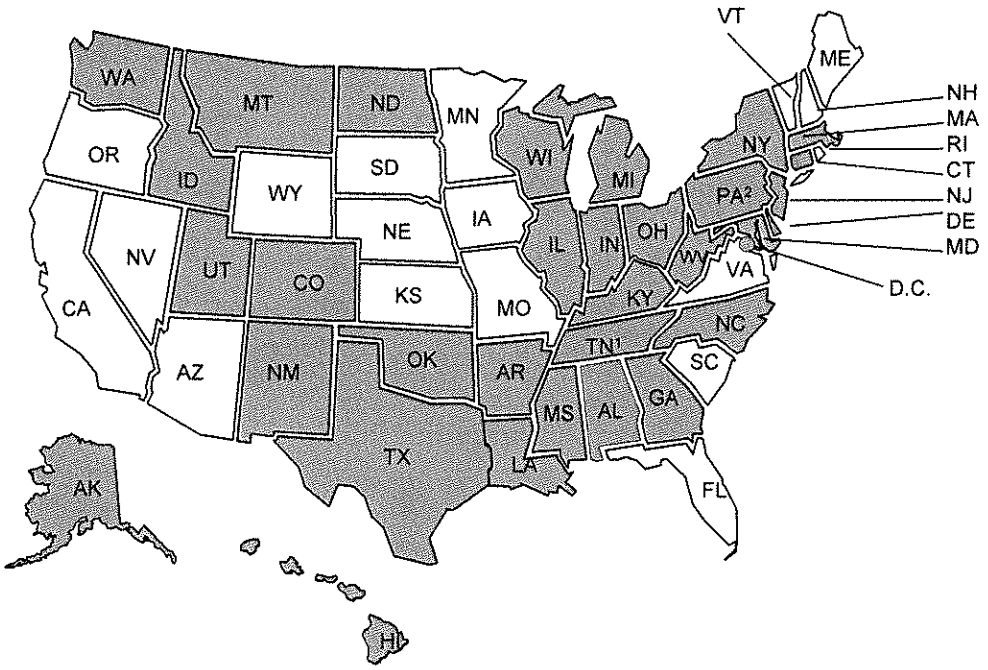
Barb

On Apr 29, 2016, at 12:05 PM, Orr, Ralph (DHP) <Ralph.Orr@DHP.VIRGINIA.GOV> wrote:

> Are you aware if other states are requiring promethazine with codeine to be reported to their PMP?
>
> Thanks!
>
> Ralph
>
> Ralph A. Orr
> Director
> Virginia's Prescription Monitoring Program
> 9960 Mayland Drive, Suite 300

25

Prescription Drug Monitoring Programs
States With Authority to Monitor Schedule V Substances



¹Tennessee's law authorizes the monitoring of Schedule V substances which have been identified by the controlled substances database advisory committee as demonstrating a potential for abuse. ² Pennsylvania will begin collecting data on Schedule V substances on June 30, 2015.

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives

White Bagging/Brown Bagging

Background:

Pharmacy Benefit Manager Workgroup agreed that the Board of Pharmacy should address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes. Full board in March agreed that Regulation Committee should discuss issues of white bagging and brown bagging at its May meeting.

Possible actions:

- Recommend to the full board that it adopt a Notice of Intended Regulatory Action to amend regulations to address white bagging and brown bagging, **or**
- Recommend to the full board that it table this issue pending the outcome of possible discussions on this subject through the National Association of Boards of Pharmacy during the next year, **or**
- Take no action.

"White bagging and brown bagging"

These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient's residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans

Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

Prior authorizations

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare "donut hole" faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management,

Specialty drugs
There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:
Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

Prescribing and Dispensing of Naloxone

recommended that the Board consider amending the naloxone protocol to include this third drug option. She indicated the amendments as presented had been discussed with and agreed upon by representatives of the Board of Medicine, Department of Behavioral Health and Developmental Services, the Virginia Department of Health, and the Department of Criminal Justice Services.

MOTION:

The Board voted unanimously to amend the naloxone protocol as presented by adding reference to the recent FDA-approved Narcan nasal spray as a third naloxone delivery system. (motion by Allen, second by Shinaberry)

- Consideration for "white bagging, brown bagging" and "specialty drugs"

Ms. Juran provided an overview of the practices involving "white bagging" and "brown bagging" and indicated the practices don't appear to operate in compliance with current regulations. She referenced comments on the subject within the Pharmacy Benefit Managers (PBM) Workgroup Report. There was a unanimous recommendation from the PBM workgroup that the Board discuss promulgating regulation for these practices. Ms. Shinaberry commented that this topic will be discussed at the NABP meeting in California in May as there is a resolution for consideration. Ms. Cathcart and Mr. Saenz agreed that this is a large public health issue that needs to be addressed. Ms. Juran stated that Colorado has addressed white bagging and brown bagging in regulation, but that the regulation only addresses reconstitution by the receiving pharmacy, not compounding by the receiving pharmacy.

A question was asked if the Board has the authority to define a "specialty drug". Counsel opined that the Board does not presently have the authority to define "specialty drug" in regulation. He recommended the term be defined in statute or that the General Assembly could give the Board of Pharmacy the authority to define "specialty drug" in regulation. Ms. Allen provided statistics about the approval of specialty drugs and that CMS is often times changing the definition of specialty drugs as well as the cost of some specialty drugs.

ACTION ITEM:

There was consensus that the Regulation Committee should further discuss the issues of white bagging, brown bagging, and the defining of specialty drug at its May meeting.

- Amend Guidance Document 110-29 *Physician Dispensing Drugs*

Ms. Juran provided background regarding the changes in statute and regulation requiring the practitioners of the healing arts to sell controlled substances to obtain a permit for the location from which they dispense or sell drugs. Thus, there is a need to conform language in the guidance document to this new oversight. Additionally, the suggested amendments reflect counsel's advice resulting from an opinion of the Attorney General as to under what circumstances a physician may dispense a prescription written by a mid-level practitioner. Suggested amendments further address counsel's advice that a physician may also dispense a refill of a prescription written by another physician licensed to sell controlled

Oregon's Final Rule

3.00.27 Outlet to Outlet Drug Reconstitution. A pharmacist at a prescription drug outlet may reconstitute a prescription originally dispensed in an unreconstituted form pursuant to a patient-specific order at another prescription drug outlet or nonresident prescription drug outlet provided the following conditions are met:

a. The prescription is delivered directly from the originating outlet to the receiving outlet;

b. The prescription is at no time in the physical possession of the patient until after the prescription has been reconstituted;

c. The prescription is reconstituted according to the corresponding manufacturer's directions;

d. The prescription is not a controlled substance;

e. The pharmacist at the receiving outlet does not alter the prescription or its original labeling in any way other than to reconstitute, re-label for re-dispensing for administration, and properly store the prescription; and

f. The originating outlet is ultimately accountable to the Board for the accurate dispensing of the original prescription, and the receiving outlet is ultimately accountable for the accurate reconstitution and re-dispensing of the prescription.

Specialty Drug

Background:

Pharmacy Benefit Manager (PBM) Workgroup members representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported the Board of Pharmacy considering the issue of specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug. PBM Workgroup members representing health plans and PBMs did not support this policy option. Board counsel opined at the March 2016 full board meeting that the Board does not presently have the authority to define "specialty drug" in regulation. He recommended the term be defined in statute or that the General Assembly could give the Board the authority to define the term in regulation.

Possible actions:

- Recommend to the full board that it adopt a legislative proposal authorizing the Board of Pharmacy to define "specialty drug" in statute, **or**
- Take no action.

Prescribing and Dispensing of Naloxone

recommended that the Board consider amending the naloxone protocol to include this third drug option. She indicated the amendments as presented had been discussed with and agreed upon by representatives of the Board of Medicine, Department of Behavioral Health and Developmental Services, the Virginia Department of Health, and the Department of Criminal Justice Services.

MOTION:

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Report of the Pharmacy Benefit Managers Workgroup

Virginia Department of Health Professions

March 4, 2016

Workgroup Participants

Virginia Department of Health Professions (David E. Brown, D.C., Director, Chairman)
Virginia Board of Pharmacy (Ellen B. Shinaberry, member; Caroline D. Juran, Executive Director)
Virginia Board of Medicine (Kenneth J. Walker, MD, member; William L. Harp, MD, Executive Director)
National Community Pharmacists Association (John Beckner)
Anthem Blue Cross and Blue Shield (Geoffrey S. Ferguson)
Virginia Association of Health Plans (Douglas Gray)
Virginia Department of Health, Division of Disease Prevention (Diana Jordan)
Virginia Department of Health, Office of Licensure and Certification (T.C. Jones, IV)
Medical Society of Virginia (Michael Jurgensen)
Virginia Association of Chain Drug Stores (Rusty Maney)
Pharmaceutical Care Management Association (Jessica S. Mazer, Esq)
Virginia Pharmacists Association (Timothy S. Musselman)
Virginia Department of Medical Assistance Services (Donna Proffitt)
Express-Scripts (John Sisto)
Virginia Bureau of Insurance (Van Tompkins)
Virginia Department of Human Resource Management (Sara Wilson)

Alternates

Virginia Association of Chain Drug Stores (Bill Cropper)
Virginia Board of Pharmacy (Cynthia Warriner)
Virginia Department of Human Resource Management (Walter E. Norman)
Medical Society of Virginia (Kirsten Roberts)

Staff

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

from mail order pharmacies often owned by PBMs. The Committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage as this may be considered the practice of pharmacy and these individuals generally are unlicensed persons. Based on the significant amount of public comment received, complexity of issues, and impact on multiple healthcare professions, David Brown, D.C., Director of the Department of Health Professions (DHP), and Caroline Juran, Executive Director of the Board of Pharmacy, recommended that Dr. Brown discuss with William A. Hazel Jr., MD, Secretary of Health and Human Resources, the possibility of forming a workgroup of various stakeholders to review the possible lack of oversight of PBMs. At the June 15, 2015 Board of Pharmacy full board meeting, Dr. Brown reported that Secretary Hazel agreed that a broad-based workgroup should be convened and led by DHP. Any recommendations would be relayed to Secretary Hazel.

Current Oversight:

Current oversight distinguishes between self-insured and fully-insured health plans. An example of a self-insured plan is the plan offered to state employees through the Department of Human Resources Management. There is no state oversight for self-insured (Employee Retirement Income Security Act, aka ERISA) health plans. They are regulated federally. Self-insured plans may require patients to use mail order pharmacies.

Fully-insured health plans are regulated by state and federal law. The Bureau of Insurance (BOI) has the authority to oversee the administration of benefits by fully-insured health plans but does not have authority to directly oversee the PBMs with which the health plans may contract to fulfill certain functions. Oversight of PBMs is indirect, through the contracting fully-insured health plan. Fully-insured health plans may offer financial incentives to patients to use mail order pharmacies but may not require it unless the health plan deems the drug a specialty drug which the health plan may require to be obtained from a specialty pharmacy. The Virginia Department of Health Office of Licensure and Certification (VDH OLC) issues a certificate of quality assurance to fully-insured health plans and focuses more on the quality of services provided by the plan, such as reviewing whether the plan has a clear and strong utilization management/review program, its tracking of clinical performance data (for health maintenance organizations), network adequacy, and a complaint system in place. VDH OLC does not oversee PBMs. Additionally, while the Board of Pharmacy regulates the practice of pharmacy and mail order pharmacies, including specialty pharmacies, which may be associated with a PBM, it does not have direct oversight of PBMs. Oversight of PBMs is limited to the health plan being responsible for its contract PBMs as is the case with other subcontractors the health plan has contracted with to deliver health care benefits to beneficiaries, e.g., behavioral health, vision, and dental.

Role of a PBM and Specialty Pharmacy:

There is no legal definition for a pharmacy benefit manager in Virginia law. PBMs act as a third-party administrator for employers and health plans, managing the pharmacy benefits and negotiating favorable prices with pharmaceutical manufacturers and providers, e.g., pharmacies. The largest PBMs currently include Express Scripts, CVS Caremark, and OptumRx. In the last

decade, large businesses have merged, and many PBMs now have financial relationships with specialty pharmacies, mail order pharmacies, and community pharmacies. Health plans make decisions as to formulary management, plan design, and cost-sharing. The PBM administers the plan per the contract with the client. PBMs' clients include the federal government, state governments, large employers, and health plans. Common approaches in the industry for PBMs to mitigate the high costs of drugs include requiring prior authorizations of certain drugs, requiring certain drugs to be dispensed from a specialty pharmacy or mail order pharmacy, the development of pharmacy networks, disease management, and claims processing. In the 2013 National Association of Boards of Pharmacy *Report of the Task Force on the Regulation of Pharmacy Benefit Managers*, which updated and broadened information from the 1999 Task Force on Licensing of Pharmacy Benefit Managers, the following activities performed by a PBM were identified as activities which may encompass the practice of pharmacy: disease state management; disease compliance management; drug adherence management; drug interaction management; drug utilization management; formulary management; generic alternative program management; generic incentive program management; medical and/or drug data analysis; patient drug utilization review services; prior authorization services; provider profiling and outcomes assessment; refill reminder program management; therapy guidelines management; stop therapy protocol management; wellness management; maintenance of confidential patient information; and, direction or design of the clinical programs for a pharmacy or a group of pharmacies.

While there is no legal definition for a specialty pharmacy, these are mail order pharmacies that have historically been used to dispense drugs that are extremely expensive, have a restricted or limited distribution, or are complex and require special storage, handling, or ongoing monitoring for safety and efficacy. However, there appears to be an increasing trend in the industry to expand the role of specialty pharmacies and require more commonly used drugs that are not complex or expensive to be dispensed from specialty pharmacies. The plan design determines which drugs qualify as a specialty drug and therefore, must be dispensed from a specialty pharmacy. There are no standard criteria for a specialty drug; and the specialty pharmacies may have a financial relationship with the PBMs or may be operated by an independent pharmacy, chain pharmacy or a Health System.

Drugs which require prior authorization cannot be dispensed to the patient until approval is received from the health plan or the PBM, unless the patient is willing to pay the cash price. The purposes of prior authorization are decreasing overall healthcare costs as well as managing health and safety by ensuring the patient is receiving the least expensive, yet most effective drug therapy. Health plans determine which drugs require prior authorization, and this status can vary based on contractual agreements the PBM may have in place with the drug manufacturer or health plan. Patients are often informed by the dispensing pharmacist if a drug requires prior authorization. The pharmacist then notifies the prescriber who must provide the required information to the PBM for processing of the approval request.

Workgroup Activities:

The Workgroup met on October 19, 2015, November 13, 2015, and December 16, 2015. Public comment was received at each meeting; discussion focused primarily on the subjects listed below.

Specialty drugs

There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:

Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

One Prescription per Blank Prohibition

Background:

Constituent of Senator Ebbins requested Board of Pharmacy to remove the one prescription per blank prohibition. Ms. Juran informed the Senator and constituent that it would require an amendment of §54.1-3408.01 and that she would bring the issue to the Board's attention.

Possible actions:

- Recommend to the full board that it adopt a legislative proposal to amend §54.1-3408.01 by removing the prohibition that a written prescription shall not include more than one prescription, **or**
- Take no action.

2017 DRAFT Legislative Proposal

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

~~No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.~~

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

Collaborative Practice Agreements

Background:

The statement in §54.1-3300.1 that "Nothing in this section shall be construed to supersede the provisions of §54.1-3303." appears to legally conflict with the authorization in the law for a pharmacist to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols and therefore, has led to questions as to how a pharmacist may legally perform these activities. The amendment does not intend to expand on the pharmacist's authority to participate in collaborative practice agreements, but to clarify and support the existing authority in law.

Possible actions:

- Recommend to the full board that it adopt a legislative proposal to amend §54.1-3300.1 to clarify, notwithstanding the provisions of §54.1-3303, that a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols within a collaborative practice agreement **or**
- Take no action.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

Bills amending this Section

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

No patient shall be required to participate in a collaborative procedure without such patient's consent. A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

~~Nothing in this section shall be construed to supersede~~ Notwithstanding the provisions of § 54.1-3303, a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols within a collaborative practice agreement.

Consider 2017 Legislative Proposal for Requiring PTCB Certification for Initial Pharmacy Technician Registration

Included in agenda package:

A copy of the draft legislative proposal adopted by the Board in 2015

A copy of an email from PTCB providing an update on PTCB's 2020 Initiative

Possible actions:

- Recommend to the full board that it adopt a legislative proposal requiring PTCB certification for initial pharmacy technician registration, **or**
- Take no action.

Board of Pharmacy

2016 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by amending section § 54.1-3321 pertaining to registration of pharmacy technicians.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3321 of the *Code of Virginia* is amended as follows:

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

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B. To be initially registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and ~~has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he~~ holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

F. The Board shall waive the initial registration fee ~~and the first examination fee for the Board-approved examination~~ for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. ~~If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination.~~ A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

2. That the provisions of this act shall become effective on July 1, 2017.

Juran, Caroline (DHP)

Subject: FW: Executive Message - PTCB's 2020 Initiative To Require Accredited Education - from the Pharmacy Technician Certification Board

From: Everett McAllister, PTCB Executive Director & CEO [mailto:ptcb@ptcb.org]
Sent: Wednesday, May 11, 2016 3:29 PM
To: Board of Pharmacy
Subject: Executive Message - PTCB's 2020 Initiative To Require Accredited Education - from the Pharmacy Technician Certification Board

Click here if you are having trouble viewing this message.

Message from Executive Director & CEO Everett McAllister

PTCB's 2020 Initiative: Accredited Education Requirement

Dear Caroline,

I want to share some important news about changes in PTCB's Certification Program, including the 2020 initiative. As you know, beginning in 2020, technicians applying for certification for the first time will be required to complete an education program accredited by the American Society of Health System Pharmacists and the Accreditation Council for Pharmacy Education (ASHP/ACPE).

Success So Far

You may recall that in 2013 PTCB announced the 2020 Initiative and a number of other changes we would make in our requirements over 7 years. These are significant changes that require careful implementation to ensure our program provides continued value. I am pleased to report the process has been successful so far; we implemented updates in our continuing education (CE) requirements in 2014, 2015, and 2016 according to the phase-in schedule as planned. These include requiring 20 hours of technician-specific CE, with 1 hour of patient/medication safety CE, and a reduced number of acceptable CE hours that can be earned from college credit and in-service CE. These changes are intended to ensure technicians are educated through programs that are specific to their workplace knowledge and responsibilities.

Accredited Education Requirement in 2020

2020 is 4 years away, and PTCB continues to prepare to implement required accredited education for initial applicants. As pharmacists provide more direct patient care, technicians are being given more responsibility as they assume new and expanding roles; PTCB's new requirement reflects this evolution and is the result of years of collaboration and collective thinking among stakeholders in the pharmacy community. (Please note this requirement will not apply to already certified pharmacy technicians, only to initial certification applicants.)

Your Input: PTCB is Listening

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PTCB regularly interacts with state boards of pharmacy, and with employers, educators, and state associates. We are committed to providing various opportunities for you to inform the implementation process. PTCB also conducts regular surveys to allow our stakeholder community to have input into our program decisions.

We have hosted forums, including the 2014 stakeholder meeting which brought the community together to discuss perspectives on the ASHP/ACPE accreditation process. In 2011, we hosted a summit focused on Consumer Awareness, Resources, Education, State Policy, and Testing (CREST) which led to PTCB's decision to strengthen our certification requirements. We look forward to future events to convene stakeholders to continue to build consensus and share information. The more information we share, the better prepared the community will be for the accredited education requirement.

Preparing for Change: Growing Capacity

We have heard some concerns that the 2020 effective date may not allow enough time for the number of accredited pharmacy technician training programs to reach the level necessary to meet anticipated demand. As evidenced by the chart below, access to accredited programs continues to expand. It is important to note that a number of online education programs are taking steps toward becoming accredited. These programs show promise for employers and technicians by offering potential cost savings, increased capacity, and expanded access, particularly for technicians in rural and remote areas. PTCB will work with you to help ensure your planning allows time to prepare for the new requirement. The PTCB Board anticipated this major change would take time to implement, and thus recommended the gradual 7-year implementation.

Your Impact: Updates in Accredited Education Program Standards

The importance of participating in discussions with PTCB and other stakeholders is illustrated by the December 2015 decision by ASHP/ACPE (collaborating as the Pharmacy Technician Accreditation Commission, PTAC) to adjust the standards for accreditation of technician programs, effective January 1, 2016. These updates include expanded flexibility for training programs to meet requirements regarding the number and types of student experiential activities that must be performed, requiring at least one and encouraging two different contemporary pharmacy practice experiences. The updates, in large part, resulted from stakeholders voicing their views.

Your Participation: Please Contact Us

As always, PTCB requests your input to guide us. The transition to accredited education calls for your involvement and participation. We recently welcomed Miriam Mobley Smith, PharmD, FASHP as PTCB's new Director of Strategic Alliances. Please reach out to her at any time to share your questions or comments at: mmobleysmith@ptcb.org.

Dr. Mobley Smith and/or I are available to meet with you or present at meetings. If you would like us to participate in your conference or lead an information session, please contact Dr. Mobley Smith. We look forward to joining you.

Thank you for your interest. Please share this message with other decision-makers in your organization.

Best regards,

Everett

Everett B. McAllister, MPA, RPh
Executive Director & CEO

Growth in ASHP/ACPE-Accredited Pharmacy Technician Education Programs

(Source: ASHP)

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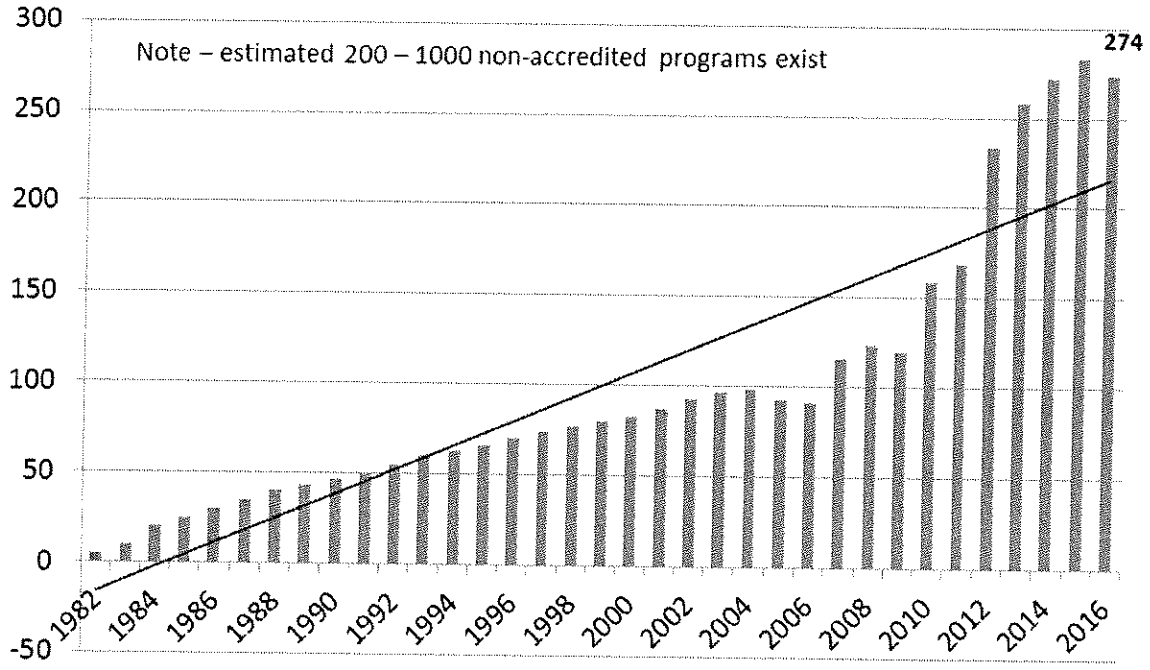


Note: 2016 decrease is due in large part to Corinthian College closures

Join PTCB's Group and follow PTCB's Company Page on LinkedIn.
Like PTCB on Facebook.
Follow PTCB on Twitter!

Pharmacy Technician Certification Board
2215 Constitution Avenue, NW
Suite 101
Washington, DC 20037
www.ptcb.org

Consider 2017 Legislative Proposal for Requiring Temperature Monitoring Devices

Included in agenda package:

A copy of the draft minutes from the March 2016 full board meeting

Information on TransTracker CF provided by TempTime

HB 132 Passed in the Georgia House and Senate – provided by TempTime

A copy of USP Chapter <1079>, Good Storage and Distribution Practices for Drug Products

Possible actions:

- Recommend to the full board that it adopt a legislative proposal requiring temperature sensitive medications to be accompanied with a device to monitor temperature during shipping, **or**
- Take no action.

- December 1, 2015 Full Board Meeting
- December 1, 2015 Public Hearing for Hours of Continuous Work by Pharmacists
- December 15, 2015 Special Conference Committee
- December 29, 2015 Pilot Informal Conference Committee
- January 5, 2016 Regulation Committee
- March 21, 2016 Special Conference Committee

MOTION:

The Board voted unanimously to approve the minutes as presented for the meetings held between November 23, 2015 and March 21, 2016. (motion by Allen, second by Saenz)

PUBLIC COMMENTS:

Tim Musselman, Executive Director for the Virginia Pharmacists Association, provided a request by membership input for the Board to consider adding promethazine with codeine as a drug of concern so that it may be reported to the Prescription Monitoring Program.

Michael Rush, Executive Director of Global Health Policy at Temptime Corporation requested the Board consider legislative or regulatory changes to require temperature sensitive medications that are shipped via mail to be accompanied with a device to monitor temperature during shipping. He indicated Georgia recently passed such a law. Mr. Rush provided background on how this type of temperature monitoring has vastly reduced waste in third world countries, specifically in terms of vaccines. Mr. Rush provided examples of factors contributing to drug waste in today's society which included delays in patients receiving mailed packages containing temperature-sensitive drugs. Mr. Rush stated the temperature devices that his corporation provides fall within USP guidelines.

DHP DIRECTOR'S REPORT:

Dr. David Brown introduced the recently appointed Chief Deputy Director, Lisa Hahn. He then provided a summary of the report generated by the Pharmacy Benefits Manager Workgroup, stating that he believes Virginia is in a good position having now completed this work should legislators need information on the subject of the oversight of pharmacy benefit managers. The report summarizes the discussion on several issues identified by the workgroup and provides potential policy options. He stated there was consensus among the workgroup members that:

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

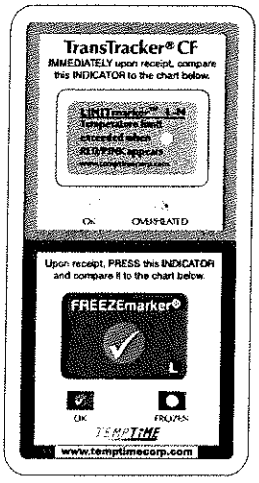
TransTracker® CF

Performance and Use

Heat and Freeze indicators for Monitoring Multiple Unit Boxes

Temptime's TransTracker® indicators can be combined so that heat excursions and freeze events) can be monitored during shipping. TransTracker indicators change color to signal a freeze event, a threshold heat excursion, or that a customer defined cumulative exposure has occurred. TransTracker dual indicators are placed inside multiple units secondary packages or shipping boxes to monitor temperature events during transportation.

Leading medical product manufacturers and distributors use TransTracker dual devices to ensure compliance with regulatory guidelines (e.g. Freeze events and threshold heat events), extend their quality systems into the distribution system and communicate their commitment to cold chain best practices.



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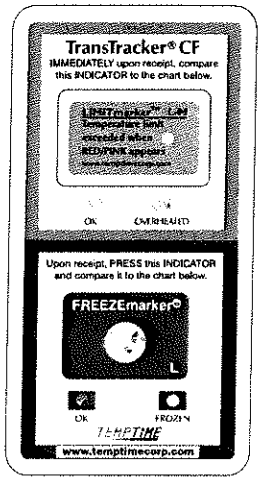

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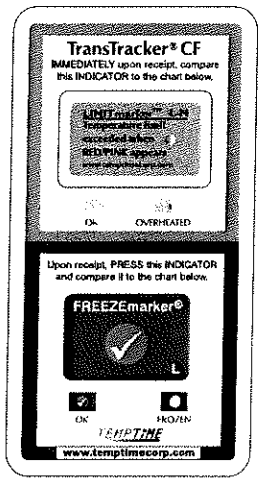

OVERHEATED

Features

- Irreversible
- Single-use
- Easy to read
- Easy to understand
- Time-delay heat excursion
- Range of monitoring capabilities
- Combined indicators
- Superior monitoring reliability
- Device activation not required
- Nontoxic materials used in product

Benefits

- Cost effective versus all electronic and chemical indicators
- Environmentally friendly (no battery or hazardous waste disposal)
- Easily integrated into the existing packing process
- Reduce unnecessary waste - limit the destruction of products incorrectly suspected of temperature damage
- Identify and avoid administration of heat damaged medications to patients
- Enhance quality risk management and support continual quality improvement
- Strengthen conformance to International Code on Harmonization (ICH) Q9 and Q10

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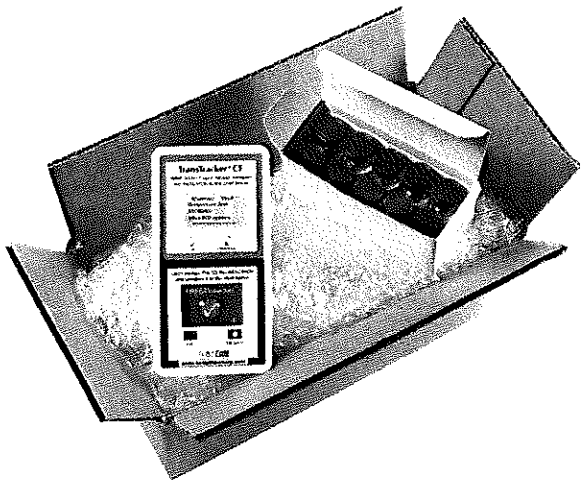
TransTracker® CF

Performance and Use

- Response Temperatures
  - Heat: 25°C(±1)
  - Freeze: -1°C(±1) 0°C(±1) -6°C(±2)
- Response Time:
  - Heat: Short Delay within 2 hours or Long Delay in 5-10 hours
  - Freeze: Within 30 minutes
- Storage Temperature: Refrigerated Storage (2°C to 8°C)
- Shelf Life: 18 months to 4 years determined by category
- Usage: Single use
- Temperature Monitoring: Continual
- Device Size: 56mm x 108mm
- Additional Features: Adhesive backing available / card design customization

Quality System

- Temptime's quality management system is consistent with FDA Quality System Requirement (QSR) 21 CFR 820 (GMP for medical devices).
- ISO 9001:2008
- ISO 13485:2003



Temptime is the world leader in time-temperature indicators that protect patients by alerting the user that a medical product has been exposed to potentially damaging temperatures. Temptime performs a vital role in the improvement of global health by providing manufacturers and distributors with heat and freeze indicators that monitor each medical product or multiple unit packages.

Temptime Corporation, 116 The American Road, Morris Plains, NJ 07950

TT-CF-001

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House Bill 132 (AS PASSED HOUSE AND SENATE)

By: Representatives Hawkins of the 27th, Rogers of the 29th, Watson of the 166th, Channell of the 120th, Lindsey of the 54th, and others

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 4 of Title 26 and Chapter 11 of Title 43 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies and dentists, dental hygienists, and dental assistants, respectively, so as to provide that the Georgia State Board of Pharmacy and the Georgia Board of Dentistry are transferred from being administratively attached to the Secretary of State to being divisions of the Department of Community Health; to provide for the powers and duties of each board; to authorize each board to employ an executive director; to provide for the powers and duties of such executive directors; to provide that the Georgia Drugs and Narcotics Agency may employ personnel who are not special agents and may contract with licensing boards for purposes of conducting investigations; to provide for a census of dentists and dental hygienists; to revise provisions relating to qualifications of applicants to practice dentistry; to provide for notice of felonies by licensees; to revise provisions for purposes of conformity; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

PART I

SECTION 1-1.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended in Code Section 26-4-5, relating to definitions, by revising paragraph (11.1) and by adding new paragraphs to read as follows:

"(3.1) 'Cognizant member' means that member of the Georgia State Board of Pharmacy who is charged with conducting investigative interviews relating to investigations involving licensees, registrants, and permit holders."

~~"(11.1) 'Division director' means the division director of the professional licensing boards division, as provided in Chapter 1 of Title 43."~~

"(15.1) 'Executive director' means the executive director appointed by the Georgia State Board of Pharmacy pursuant to Code Section 26-4-20."

(8) Being ~~adjudicated to be mentally ill or insane~~ adjudged mentally incompetent by a court of competent jurisdiction within or outside this state; any such adjudication shall automatically suspend the license of any such person and shall prevent the reissuance or renewal of any license so suspended for as long as the adjudication of incompetence is in effect;

(9) Violating any rules and regulations promulgated by the board;

(10) Promoting to the public in any manner a drug which may be dispensed only pursuant to prescription;

(11) Regularly employing the mails or other common carriers to sell, distribute, and deliver a drug which requires a prescription directly to a patient; provided, however, that this provision shall not prohibit the use of the mails or other common carriers to sell, distribute, and deliver a prescription drug directly to:

(A) A patient or directly to a patient's guardian or caregiver or a physician or physician acting as the patient's agent for whom the prescription drug was prescribed if:

(i) Such prescription drugs are prescribed for complex chronic, terminal, or rare conditions;

(ii) Such prescription drugs require special administration, comprehensive patient training, or the provision of supplies and medical devices or have unique patient compliance and safety monitoring requirements;

(iii) Due to the prescription drug's high monetary cost, short shelf life, special manufacturer specified packaging and shipping requirements or instructions which require temperature sensitive storage and handling, limited availability or distribution, or other factors, the drugs are not carried in the regular inventories of retail pharmacies such that the drugs could be immediately dispensed to multiple retail walk-in patients;

(iv) Such prescription drug has an annual retail value to the patient of more than $10,000.00;

(v) The patient receiving the prescription drug consents to the delivery of the prescription drug via expedited overnight common carrier and designates the specialty pharmacy to receive the prescription drug on his or her behalf;

(vi) The specialty pharmacy utilizes, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(vii) The specialty pharmacy establishes and notifies the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner

or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs;

(B) An institution or to sell, distribute, or deliver prescription drugs, upon his or her request, to an enrollee in a health benefits plan of a group model health maintenance organization or its affiliates by a pharmacy which is operated by that same group model health maintenance organization and licensed under Code Section 26-4-110 or to a patient on behalf of a pharmacy. Any pharmacy using the mails or other common carriers to dispense prescriptions pursuant to this paragraph shall comply with the following conditions:

(i) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which reasonably determines whether the medications distributed by the mails or other common carriers have been received by the enrollee and through which a pharmacist employed by the group model health maintenance organization or a pharmacy intern under his or her direct supervision is enabled to offer counseling to the enrollee as authorized by and in accordance with his or her obligations under Code Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant to subsection (e) of such Code section. In addition, the enrollee shall receive information indicating what he or she should do if the integrity of the packaging or medication has been compromised during shipment;

(ii) In accordance with clinical and professional standards, the State Board of Pharmacy shall promulgate a list of medications which may not be delivered by the mails or other common carriers. However, until such list is promulgated, the group model health maintenance organization shall not deliver by use of the mails or other common carriers Class II controlled substance medications, medications which require refrigeration, chemotherapy medications deemed by the federal Environmental Protection Agency as dangerous, medications in suppository form, and other medications which, in the professional opinion of the dispensing pharmacist, may be clinically compromised by distribution through the mail or other common carriers;

(iii) The pharmacy shall utilize, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(iv) The pharmacy shall establish and notify the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs.

⟨1079⟩ GOOD STORAGE AND DISTRIBUTION PRACTICES FOR DRUG PRODUCTS

INTRODUCTION

This general information chapter describes good storage and distribution practices to ensure that drug products (medicines) reach the end user (practitioners and patient/consumers) with quality intact.

In the context of this chapter, the following definitions are used.

Definitions

Adulteration: FDA FDC Act, SEC. 501 (351), A drug or device shall be deemed to be adulterated, if (2)(A) It has been prepared, packed, or held under insanitary conditions it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identify and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Continuous improvement: Recurring activity to increase the ability to fulfill requirements (see *Quality Management Systems—Fundamentals and Vocabulary. ISO Standard 9000:2005*).

Distribution: Refers to elements such as shipping and transportation activities that are associated with the movement and supply of drug products.

Distribution Management System: A program that covers the movement, including storage and transportation, of drug products.

Documentation: Recorded information.

Drug products: Medicines, including marketed human and veterinary prescription finished dosage medications, in-process/intermediate/bulk materials, drug product samples, clinical trial materials, over-the-counter products (OTC).

End user: The patient as well as the healthcare provider administering the drug product to the patient.

Environmental Management System: A management system that allows for the identification of quality critical environmental aspects (such as temperature , humidity, and/or other environmental factors) for the drug product and ensures that adequate processes to maintain that environment are in place.

Hazardous materials and/or dangerous goods: Any item or chemical which, when being transported or moved, is a risk to public safety or the environment, and is regulated as such under any of the following: Hazardous Materials Regulations (49 CFR 100–180); International Maritime Dangerous Goods Code; Dangerous Goods Regulations of the International Air Transport Association; Technical Instructions of the International Civil Aviation Organization; or the U.S. Air Force Joint Manual, *Preparing Hazardous Materials for Military Air Shipments* .

International Conference on Harmonization (ICH) Guidance for Industry, *Q10 Pharmaceutical Quality System; ICH Q9, Quality Risk Management; and, ICH Q1A R2, Stability Testing of New Drug Substances and Products*: Internationally harmonized documents intended to assist the pharmaceutical industry.

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Mean Kinetic Temperature (MKT): The single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

Preventive actions: The measures to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Quality: The physical, chemical, microbiological, biological, bioavailability, and stability attributes that a drug product should maintain in order to be deemed suitable for therapeutic or diagnostic use. In this chapter, the term is also understood to convey the properties of safety, identity, strength, quality, and purity.

Quality Management System (QMS): In the context of this chapter, minimally a set of policies, processes, and procedures that enable the identification, measurement, control, and improvement of the distribution and storage of drug product. It is the management system used to direct and control a company with regard to quality (see ICH Q10 model and *Quality System—Fundamentals and Vocabulary, ISO Standard 9000:2005*).

Risk Management System: A systematic process used to assess, control, communicate, and review risks to the quality of a drug product across the product lifecycle. Integral to an effective pharmaceutical quality system, it is a systematic and proactive approach to identifying, scientifically evaluating, and controlling potential risks to quality as described in ICH Q10. It facilitates continual improvement of process performance and product quality throughout the product lifecycle. ICH Q9 Quality Risk Management provides principles and examples of tools that can be applied to different aspects of pharmaceutical quality.

Written Agreement or Contract (commonly referred to as a Quality Agreement, Technical Agreement, Service Level Agreement, or other): A negotiated, documented agreement between the drug product owner and service provider that defines the common understanding about materials or service, quality specifications, responsibilities, guarantees, and communication mechanisms. It can be either legally binding or an information agreement. A Service Level Agreement may also specify the target and minimum level of performance, operation, or other service attributes.

Storage Management System: A program that is used to control the storage of drug products.

Supply chain: The continuum of entities spanning the storage and distribution lifecycle of a product to the end user.

Temperature **stabilizer:** A material or combination of materials that stores and releases thermal energy used to maintain a specified temperature range within an active or passive packaging container or system (e.g., water-, chemical-, or oil-based phase change material, such as carbon dioxide solid/dry ice and liquid nitrogen).

Transport vehicles: Vehicles used in the supply chain including semitrailer trucks, vans, trains, airplanes, sea vessels, and mail delivery vehicles. Other vehicles, when used to transport drug products are included here, such as emergency medical service vehicles and industry representatives' automobiles.

SCOPE

Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the following:

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- Manufacturers of drug products for human and veterinary use where manufacturing may involve operations at the application holder's facilities (i.e., facilities that belong to the holder of an approved New Drug Application or Abbreviated New Drug Application) or at those of a contractor for the applicant holder
- Packaging operations by the manufacturer or a designated contractor for the applicant holder
- Repackaging operations in which the drug product may be owned by an organization other than the primary manufacturer
- Laboratory operations at the manufacturer's or at the contractor's site
- Physician and veterinary offices
- Pharmacies including but not limited to retail, compounding, specialty, mail order, hospital, and nursing home pharmacies
- Importers and exporters of Record
- Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services
- Third-party logistics providers, freight forwarders, and consolidators
- Health care professional dispensing or administering the drug product to the end user
- Mail distributors including the U.S. Postal Service (USPS) and other shipping services including expedited shipping services

The information is intended to apply to all drug products regardless of environmental storage or distribution requirements.

It is recognized that conceivably there are special cases and many alternative means of fulfilling the intent of this chapter and that these means should be scientifically justified. Although this chapter is not intended to address the storage and distribution of active pharmaceutical ingredients (APIs), excipients, radioactive products, reagents, solvents, medical devices, medical gases, or clinical trial materials for which storage requirements may not yet be defined (e.g., Phase I clinical trial drug products), the general principles outlined here may be useful if applied selectively or comprehensively.

This general information chapter does not supersede or supplant any applicable national, federal, and/or state storage and distribution requirements, or USP monographs. General Chapter *(659) Packaging and Storage Requirements* contains definitions for storage conditions. This chapter is not intended to cover counterfeiting, falsified medicines, drug pedigrees, or other supply chain security, including chain of custody issues.

BACKGROUND INFORMATION

Storage and distribution processes may involve a complex movement of product around the world, differences in documentation and handling requirements, and communication among various entities in the supply chain. The translation of best practices into good storage and distribution meets these challenges and sets forth a state of control.

The good storage and distribution practices described in this chapter should facilitate the movement of drug products throughout a supply chain that is controlled, measured, and analyzed for continuous improvements and should maintain the integrity of the drug product in its packaging during storage and distribution.

RESPONSIBILITIES

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The holder of the drug product application, the drug product manufacturer (in the case of many OTCs, where there is no application) and the repackager bear primary responsibility and accountability including but not limited to the following:

- The decision for regulatory submissions, where applicable, relative to the contents of this chapter for the storage and distribution of drug products. If breaches occur in any of the QMS systems and cannot be justified or documented with scientific evidence, the appropriate entity should consider action with the product to ensure the public safety.
- Determining proper storage and handling practices
- Communicating storage and distribution practices through the supply chain
- Drug product stability profiles or the associated stability information from the holder, inclusive of distribution conditions and excursions that may be allowable should they occur. These stability profiles include the approved storage conditions for the shelf life of the drug product and, where appropriate, supporting data for the distribution conditions, if these differ from the storage conditions.
- Appropriate firms, such as an applicant holder, are to convey relevant environmental requirements (e.g., when appropriate, product-specific lifecycle stability data), when needed to support deviations or temperature excursions . If stability data cannot be reviewed or is not shared, an assessment may be needed to consider regulatory review or other appropriate actions (e.g., destruction of product or additional stability testing).
- Recalling the drug product if it is found to be adulterated in any part of the supply chain

However, all organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the drug product identity, strength, quality, purity, or safety.

Each holder of drug product is responsible and accountable for the receipt from an entity and transfer out of the drug product to the next entity.

LABELING CONSIDERATIONS FOR DRUG PRODUCTS

The environmental requirements for drug product storage conditions should be indicated on the drug product primary container–closure system. If space on the immediate container is too small (e.g., an ampule) or is impractical for the container–closure system (e.g., blister package), this information can be placed on the most immediate container of appropriate size (e.g., carton). Environmental storage conditions and/or environmental warning statements should be evident, securely fixed, and indelible on the outermost container (generally the shipping container).

Products classified as hazardous materials and/or dangerous goods by the U.S. Department of Transportation or other relevant authorities or bodies should be labeled, stored, and handled in accordance with applicable federal/state/local regulations. Drug products classified as controlled substances by the U.S. Drug Enforcement Administration or by individual state requirements should be labeled and handled in accordance with applicable regulations.

Good practices and controls for labeling should provide the receiver with instructions for the correct handling of the drug product upon receipt. When a drug product's storage conditions are not readily available, use the storage conditions described in USP's *General Notices and Requirements* or the applicable USP monograph; or, contact the drug manufacturer for further information.

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Product labels with expanded information beyond the single long-term storage temperature ensure ease of transport and use for shippers, distributors, healthcare professionals, and patients. Product labels should clearly define the storage temperature range, and broader distribution or in-use temperature ranges where allowable. Products labeled "Keep in a cold place" or "Do not freeze" are subject to interpretation and are discouraged if used without accompanying temperature ranges. USP storage definitions and temperature ranges are defined in *General Notices and Requirements*.

During international transport, the proper language(s) should be used to ensure that handlers understand the requirements set forth on drug product labeling. The use of symbols that are recognized by international organizations is advisable.

Drug products can be transported at temperatures outside of their labeled storage temperatures if stability data and relevant scientific justification demonstrate that product quality is maintained. The length of the stability studies and the storage conditions for a drug product should be sufficient to cover the shipment, distribution, and subsequent use of the drug product. The data gathered from ICH, Q1A R2, accelerated testing or from testing at an ICH intermediate condition may be used to evaluate the effect of short-term excursions outside of the label storage conditions that might occur during storage and/or distribution.

QUALITY MANAGEMENT SYSTEM

Good storage and distribution practices require that entities involved in the storage and/or distribution of drug products maintain a Quality Management System (QMS) that is based on standard quality concepts, includes good manufacturing practice (GMP) in compliance with the appropriate regulatory agency(s), and is complementary to the ICH quality guidances, including ICH *Q10 Pharmaceutical Quality System* and ICH *Q9 Quality Risk Management*. In the context of this chapter, the QMS includes the following management system programs: (1) *Storage Management System*, (2) *Distribution Management System*, (3) *Environmental Management System*, and (4) *Risk Management System*.

The storage and distribution QMS should, at minimum, cover the following elements: corrective and preventive actions (CAPA), change management, deviation/investigation management, and the management review process.

Written agreements (e.g., Quality Agreement, Technical Agreement, Service Level Agreements) should be in place between applicable organizations involved in the drug product supply chain. This means that the originating manufacturer may not be required to hold a Written Agreement with all parties in the supply chain. The use of written agreements ensures clarity and transparency, and delineates the responsibilities of each organization in the supply chain.

Good Documentation Practices

Good documentation practices should be practiced in the QMS. This documentation includes standard operating procedures and corporate policies and standards, as well as protocols and other written documents that delineate the elements of the QMS. The QMS programs should describe events and actions that must be documented as well as the proper verbiage to be used, the copies required, and any other items that will ensure adequate processing of the drug product and prevent delays. The documentation process should use a standard such as a

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quality manual or other practice and, should include routine assessment for review and update as needed.

Written procedures should ensure that drug products are held in accordance with their labeling instructions and associated regulatory requirements. Procedures should provide the written steps needed to complete a process and ensure consistency and standard outcomes. The following elements should be included: (1) how and when a product should be moved from one transport container/vehicle into another, (2) how products are handled when equipment malfunctions or when there are delays in distribution due to Customs hold, and (3) how to communicate with the necessary parties.

The QMS should require monitoring of processes to demonstrate that a state of control is being maintained, where the set of controls consistently provides assurance of continued process performance and product quality (ICH Q10).

If deviations occur, a nonconformance should be documented, and investigation should be performed and documented as appropriate. The investigative process should determine the root cause(s) of the deviation. For example, the following should be determined: whether the drug product experienced stress, damage, delays, or environmental lapses, or whether there were errors in documentation. The associated supply quality management staff should have final responsibility for approving or rejecting the investigation. The investigation process should be linked to the risk management program to ensure that proper mitigation occurs and preventive measures are put in place.

For example, a written investigation should be performed if the receiving and/or transferring processes result in a drug product being subjected to unacceptable temperature conditions or contamination (e.g., pests, microorganisms, or moisture). Any breach of standard operating procedures should be documented with a risk justification as needed. This information should be forwarded to the appropriate organization responsible for the drug product. The drug product should be quarantined, and final disposition should be based on good science with appropriate evidence to justify the decision(s).

Manufacturers should develop written procedures for recording the security process that confirms container–closure integrity for drug products that require special handling, such as security seals for controlled substances. Returned and salvaged goods records should address how the drug product is assessed through a written procedure. In addition, training on such procedures should be part of the QMS.

Records should be retained for purchases and sales of drug products and should show the date of purchase or supply; the name of the drug product and the amount; the name and address of the supplier or consignee; and the associated lot numbers. These records should allow for the traceability of a drug product in the supply chain.

All records and documents should be maintained in accordance with a traceable records-retention program and should be made available upon request to regulatory agencies. These documents should be approved, signed, and dated by the department responsible for the QMS.

Storage Management System

STORAGE LOCATIONS AND PROCESSES

It is important that each entity define their appropriate storage locations to ensure that adequate controls are in place. These locations include buildings and facilities for drug product storage (e.g., warehouse, storage or hold area, the original manufacturer's warehouses,

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contractor warehouses, wholesale distribution warehouses, mail order or retail pharmacy storage area, hospital or nursing home pharmacy storage areas; and border Customs storage areas).

In these locations, two basic processes can occur. First, receiving for storage is the act of bringing a drug product into a facility, while transferring refers to the moving of a drug product internally within a facility or into or out of a vehicle. Second, storing and holding refers to the act of maintaining temporary possession of a drug product in the supply chain process, during which no movement of the product will occur.

STORAGE IN BUILDINGS AND FACILITIES

Drug product storage areas are required to maintain the product temperature between the limits as defined on the product label. Buildings and facilities used for the warehousing, storage, and/or holding of drug products should be of adequate size for their intended use. These facilities should be adequate to prevent overcrowding. The building and facility should be designed to control environmental conditions where necessary and should be made of readily or easily cleanable materials. Sanitation and pest control procedures should be written, indicating frequency of cleaning and the materials and methods used. The pest-control program should ensure the prevention of contamination as well as the safe use of pesticides. Records of all cleaning and pest-control activities should be maintained.

Storage should be orderly and should provide for the segregation of approved, quarantined, rejected, returned, or recalled drug product. If computerized systems are used for the control of storage conditions, the software should be appropriately qualified for its intended purposes. Facilities should have controls that mitigate risks such as fire, water, or explosion. Certain drug products may cause these risks and should be stored accordingly. Storage areas, when not computerized, should be appropriately visually labeled.

Storage facilities themselves, unless thermostatically controlled, cannot be validated; however, they can be qualified via a mapping process. The generator back-up power supply should be qualified.

RECEIVING AND TRANSFERRING DRUG PRODUCTS

Storage of a drug product includes not only the period during which the drug product is held in the manufacturer's storage areas but also time spent at the receiving bay area. When drug products arrive at warehouse loading docks and other arrival areas, they should be transferred as quickly as possible to a designated storage or within a time period that is consistent with the risk and exposure of the product in the receiving area to a designated storage environment to ensure minimal time outside specified storage conditions as described in a written procedure.

Relative to the incoming receipt of drug product, it is recognized that the process of product reaction to ambient conditions begins immediately and may occur quickly (e.g., reach temperature equilibrium within minutes to a few hours depending on details such as the product mass, volume, and packaging density taking into account secondary and tertiary packaging)[1]. Time spent in a transport vehicle is considered to be part of the distribution process and is not a storage location.

Receiving docks should protect drug product deliveries from inclement weather during unloading. Any storage area, including loading and unloading docks for receipt and distribution of drug products, should be clean, cleanable, and free from pests. The incoming receiving area

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should limit access to authorized persons. Where appropriate, the delivery vehicle/container should be examined before unloading to ensure that adequate protection from contamination was maintained during transit. Deliveries should be examined at receipt in order to check that containers are not damaged and that the consignment corresponds to the order. The results of this examination should be documented.

Areas should be designated to provide an adequate space in which containers of drug products can be cleaned and opened for sampling. If sampling is performed in the receiving area, it should be done in a manner that prevents contamination and cross-contamination and ensures that environmental requirements for the drug product are not breached.

Adequate precautions should be taken to prevent theft and diversion of drug products. Drug products that have been identified as counterfeit should be quarantined to prevent further distribution. The appropriate regulatory agencies should be contacted according to established procedures.

Appropriate delivery records (e.g., as applicable, transport vehicle movement papers, receiving/delivery records, data logging records, temperature recorders and similar devices, bill of lading, house air waybill, master air waybill, etc.) should be reviewed by each receiving entity in the supply chain to determine if the product has been subjected to any transportation delays or other events that could have exposed the product to undesirable conditions. Each entity should ensure that their respective Service Level Agreement documents and supporting documents such as SOPs cover delivery and receiving responsibilities of the transactional parties.

Smoking, eating, and drinking should not be permitted in any storage/hold areas.

REFRIGERATORS AND FREEZERS

Refrigerators and freezers used to store drug products are required to maintain the product temperature between the limits as defined on the product label. Typically, a refrigeration unit specification would be set to 5° with an allowable range of ±3° to store products labeled 2°–8°. Freezer temperatures may vary and typically range from −25° to −10°. Some frozen drug products, however, require lower temperatures, e.g., dry ice or liquid nitrogen temperatures.

Regular operating procedures and maintenance protocols should be in place along with written contractual agreements for all maintenance and evaluation procedures including the following:

1. Items should be stored in the units in a manner that allows adequate air flow to maintain the specified conditions.
2. Units should be positioned in the facility so that they are not subjected to environmental extremes that could affect their performance. If this cannot be prevented, the mapping protocol should include a provision for testing during the anticipated environmental extremes.
3. Large commercial units such as walk-in cold rooms are qualified via a temperature mapping study or other type of qualification process to determine the unit's suitability for storing drug products. A suitable number of temperature -recording devices should be utilized to record temperatures and to provide temperature area maps. Thereafter, the units should be monitored as determined by the results of the mapping

study. Refer to the *Temperature Monitoring* section under *Environmental Management System*.

4. Units should utilize recording systems to log and track temperatures. Alarm systems should be an integral part of the monitoring system for both refrigerators and freezers. While automated systems monitor units continuously, manual checks should be performed as appropriate to the validation program. When automated systems are not available, manual systems may be used.

Distribution Management System

Distribution of drug products occurs within a facility or location such as a manufacturer, wholesaler, pharmacy dispensing area, retail site, clinic/hospital/nursing home pharmacy, and the physician's practice. Distribution of drug products occurs as point-to-point movement within the supply chain between distribution facilities via semitrailer trucks, vans, emergency medical service vehicles, industry representatives' automobiles, trains, aircraft, sea vessels, and mail delivery vehicles.

Communication within the supply chain should be coordinated to determine proper timing for drug products to be transported and received, taking into account holiday schedules, weekends, or other forms of interruption. When international distribution is required, alerts should be made in advance and proper language should be used to ensure understanding of the requirements set forth on drug product labeling.

PACKAGING FOR THE DISTRIBUTION AND TRANSPORTATION PROCESSES

Pharmaceutical manufacturers should consider primary, secondary, and tertiary packaging that best protects the drug product during storage and distribution. Package performance testing should be documented as part of a manufacturer's QMS. Several standard test procedures are available for evaluating package performance for factors such as shock, vibration, pressure, compression, and other transit events. Organizations with standard test methods include the following: the American Society for Testing and Materials (ASTM) *Standard Practice for Performance Testing of Shipping Containers and Systems*, and the International Safe Transit Association (ISTA) specifications for various types of transit modes such as less-than-truckload, small package, rail car, and air freight.

It is important to be aware that removal or modification of the original packaging may subject the product to unacceptable conditions.

The packaging (tertiary or thereafter) for the distribution of the drug product should be selected and tested to ensure that product quality is maintained and to protect the contents from the rigors of distribution including environmental or physical damage.

All drug products have storage requirements that may contain specific controls. The container used for transporting the drug product should be qualified on the basis of the labeled conditions of the product as well as anticipated environmental conditions. Consideration should be made for seasonal temperature differences, transportation between hemispheres, and the routes and modes of transport.

The type, size, location, and amount of the temperature stabilizers required to protect the product should be based on documented studies of specific distribution environments including domestic and international lanes, mode(s) of transport, duration, temperature , and other potential environmental exposures or sensitivities that may impact product quality. Transportation container materials such as warm/cold packs and materials used to control

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temperature conditions should be properly conditioned before use. Barrier protection may be important in helping to determine the position of materials such as gel packs in order to avoid direct contact with the drug product. It should be determined if studies are required to ensure that the dry ice and its vapors do not adversely affect the drug product, including the drug product labeling.

VALIDATION AND THERMAL PERFORMANCE QUALIFICATION FOR TRANSPORT SYSTEMS

Drug product transport systems should be continuously monitored by calibrated monitoring systems, (continuous verification), or shipping systems should be qualified and based on historical data relative to the process. However, it may be acceptable to use product stability data and supply chain risk assessment to justify shipping without either continuous monitoring or qualification of the shipping system.

Operational and performance shipping studies should on a generic level be part of a formal qualification protocol that may use controlled environments or actual field testing, depending on the projected transport channel. These studies should reflect actual load configurations, conditions, and expected environmental extremes. Testing should be performed on both active and passive thermal packaging systems.

Environmental Management System

While storage and distribution temperature ranges for drug products are labeled on the packaging, relative humidity effects occur over a much longer time frame. The primary container is designed and tested to protect the product from moisture; therefore, humidity monitoring should be considered when a product will be stored in an uncontrolled facility.

TEMPERATURE MONITORING

Environmental conditions are important parameters to consider in the storage and distribution of all drug products and may require monitoring depending on the requirements. When specific storage conditions are required and transportation qualification has not been performed, and in the absence of active or passive containers, environmental recorders or devices should be used to confirm that an acceptable range has been properly maintained during each stage in the supply chain.

Temperature is one of the most important conditions to control, and requirements for each drug product should be based on stability data. Temperatures should be tracked using a monitoring system, and the monitoring devices used should be included in a calibration and/or preventive maintenance program. Environmental monitoring devices should be calibrated for their range of operation. The monitoring devices used should provide an alert mechanism if the preset ranges are breached. The following practices and controls are examples of appropriate measures that should be put in place to ensure environmental control (see also *Monitoring Devices—Time, Temperature , and Humidity* ⟨1118⟩):

- Temperature -monitoring equipment, a monitoring device, a temperature data logger, or other such device that is suitable for its intended purpose should be used.
- An appropriate number of temperature monitors or some other form of recordation or proof of temperature control. Temperature monitor(s) should be used with every distribution process unless another process has been put in place to ensure specified temperature ranges.
- Electronic temperature monitors should be calibrated to National Institute of Standards and Technology (NIST) or other suitable standard.

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- Chemical temperature indicators may be used as appropriate.
- Predetermined temperature ranges should be set for all applicable areas, as well as a plan of action in the event of an unacceptable excursion.

TEMPERATURE MAPPING

The basis of any temperature mapping in a temperature controlled space (e.g., facility, vehicle, shipping containers, refrigerator, freezer) is the identification and documentation of a sound rationale used for a given mapping procedure. The temperature variability associated with mapped locations and the level of thermal risk to the product should be defined, unless another process has been put in place to ensure environmental control.

A temperature mapping study should be designed to assess temperature uniformity and stability over time and across a three-dimensional space. Completing a three-dimensional temperature profile should be achieved by measuring points at not less than three dimensional planes in each direction/axis—top-to-bottom, left-to-right, front-to-back, where product will be present.

When temperature mapping is necessary, it should begin with an inspection of the facility, equipment and/or vehicle and should be re-evaluated as appropriate. Environmental mapping also should be performed after any significant modification to the distribution system that could affect drug product temperature .

Facility temperature mapping: The following factors, which may contribute to temperature variability, should be considered during the process of temperature mapping storage locations: (1) size of the space; (2) location of HVAC equipment, space heaters, and air conditioners; (3) sun-facing walls; (4) low ceilings or roofs; (5) geographic location of the area being mapped; (6) airflow inside the storage location; (7) temperature variability outside the storage location; (8) workflow variation and movement of equipment (weekday vs. weekend); (9) loading or storage patterns of product; (10) equipment capabilities (e.g., defrost mode, cycle mode); and (11) SOPs.

The recording of temperatures during the thermal mapping of a warehouse or cold room should be sufficient in time frame to capture workflow variation that may impact air flow and the resulting temperature fluctuation (i.e., a period of one week is recommended for data collection and should capture workflow cycles).

Equipment (container/trailer) temperature mapping: To minimize risk of product exposure to damaging temperatures during transport, dedicated containers/vehicles cargo space should be mapped. When complete fleet mapping (i.e., wholesaler or distributor vehicles) is not realistic or appropriate, minimally at least one container/vehicle from the fleet must be mapped. Thereafter, the following conditions should be considered: (1) SOPs, including loading and unloading procedures; (2) route-specific operation of the temperature control equipment; (3) seasonal effects encountered on expected routes; (4) loading patterns; and (5) transport durations.

When nondedicated (i.e., mail carriers) transport containers/vehicles and equipment are used, they should be designed to minimize the risk of contamination of the product being handled. If environmental mapping of such vehicles is not performed, some other means of control should be in place to ensure that the drug product is adequately protected. Mapping by the shipper may not be necessary if the shipper uses a transport container that is properly insulated and has been previously qualified for the duration of the distribution

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process by the transport container manufacturer via a mapping study or if drug products are continuously monitored by calibrated monitoring systems (continuous verification).

The vehicle in which drug products are transported should be mapped to determine the appropriate placement of temperature -recording devices and to confirm that the load configuration is not restricting air flow. The following are recommended practices and controls for vehicles that receive and transfer drug products:

1. Transport containers/vehicles and equipment used to store and transport drug products should be suitable for their intended function.
2. Procedures should be established that describe how to operate, clean, and maintain transport containers/vehicles and equipment used in the storage and distribution of drug products.
3. Transport containers/vehicles should be designed to prevent damage to the drug product, and pharmaceutical manufacturers should collaborate with their transporter to determine contingency response plans for how drug products are handled when equipment malfunction.
4. When drug product must be moved from one transport container/vehicle into another, the proper load configuration should be followed.
5. It should be understood how communication is made to the necessary entities when such transfer occurs.
6. Subcontracted vehicles should be considered in contractual agreements and audits, and documentation should be maintained for their use.

Temperature mapping should account for maximum and minimum loads to capture temperature variability resulting from variations in temperature mass of the payload. Performance of equipment under extreme scenarios including door open, door closed, and simulated equipment failure should be taken into account.

Thermal mapping of vehicles should be representative of the fleet with the intention of capturing variability across the range of vehicles (type of vehicle including non-refrigerated equipment, use, heating and/or cooling system). A periodic requalification program should be documented.

Mapping for both facilities and transportation containers/vehicles should be done in a way that confirms their fitness for operation during periods of expected extreme weather (e.g., summer and winter). Facilities should be mapped under varying operating conditions—ideally during periods of greater variability, accounting for and capturing the result of any seasonal fluctuations of inventory movement, equipment movement, or workflow variation.

The temperature -mapping protocol and associated number of temperature data loggers used to map a three dimensional space should meet the intent of demonstrating three-dimensional uniformity and compliance with product requirements. For both facility and trailer/container temperature mapping, the ambient conditions should be recorded and correlations between ambient conditions and potential thermal risks inside the controlled space should be identified. Drug products should not be stored in areas where a thermal risk has been identified as a result of the temperature mapping. Areas identified as being unsuitable for storage should be clearly labeled as such to ensure that they are not used.

Temperature data loggers should be used for temperature mapping and PQ testing of facilities, equipment, and transportation containers used for storage or transportation of

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temperature -sensitive medicinal products. Temperature data loggers and any associated software applications should be appropriately validated. Certificates of calibration to an NIST or other international traceable standard should be available for individual monitoring devices.

EXCURSIONS

The mapping process will help determine when excursions could occur and are useful when pharmaceutical manufacturers develop a plan for dealing with them. Alarms should be used to reveal environmental excursions during operations. Temperature excursions for brief periods outside of respective storage label conditions may be acceptable provided stability data and scientific/technical justification exists demonstrating that product quality is not affected (see Health Canada's GUI 0069 entitled, *Guidelines for Temperature Control of Drug Products During Storage and Transportation,* 2011).

MEAN KINETIC TEMPERATURE (MKT) CALCULATION

The MKT is the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. MKT may be considered as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature variation. It is not a simple arithmetic mean.

The temperatures used for calculating MKT can be conveniently collected using electronic devices that measure temperatures at frequent intervals (e.g., every 15 minutes). MKT can be calculated directly or the data can be downloaded to a computer for processing. Software to compute the MKT is available commercially.

For dispensing sites, such as pharmacies and hospitals, where the use of such instruments may not be feasible, devices such as high-low thermometers capable of indicating weekly high and low temperatures may be employed. The arithmetic mean of the weekly high and low temperatures is then used in the calculation of MKT. MKT is calculated by the following equation (derived from the Arrhenius equation):

$$T_k = \frac{\Delta H/R}{-ln\left(\frac{e^{-\Delta H/RT_1} + e^{-\Delta H/RT_2} + \ldots + e^{-\Delta H/RT_n}}{n}\right)}$$

where T_k is the mean kinetic temperature ; ΔH is the heat of activation, 83.144 kJ·mole^{-1} (unless more accurate information is available from experimental studies); R is the universal gas constant, 8.3144 × 10^{-3} kJ·mole^{-1}·degree^{-1}; T_1 is the value for the temperature recorded during the first time period, e.g., the first week; T_2 is the value for the temperature recorded during the second time period, e.g., second week; and T_n is the value for the temperature recorded during the *n*th time period, e.g., *n*th week, n being the total number of storage temperatures recorded during the observation period. [NOTE—All temperatures, T, are absolute temperatures in degrees Kelvin (K).]

MKT DURING STORAGE AND DISTRIBUTION

The holding of a drug may occur as part of storage and distribution practices. Drug products in the distribution supply chain may be held at temperatures outside their labeled storage

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requirements as determined by an appropriate stability study. Drug products stored either in warehouse conditions or in transportation modes may experience excursions from their acceptable temperature ranges. Each product excursion must be evaluated to determine the final product effect. The means of evaluation must be scientifically sound with documented technical justification that the integrity of the drug product has not been affected. One method of analysis for drug product stored outside its respective label storage conditions is the use of an MKT calculation.

Because MKT expresses the cumulative thermal stress a drug product experiences, it is considered an acceptable practice for storage, and it follows that it should be considered for transit excursions in the process of distribution. The calculation must be justified for use with distribution excursions by confirming that the stability limiting characteristic of the product follows first order kinetics over the temperature range encountered. The ICH stability-testing guidelines define MKT as a "single" derived temperature , which, if maintained over a defined period, would afford the same thermal challenge to a pharmaceutical product as would have been experienced over a range of both higher and lower temperatures for an equivalent defined period.

The MKT analysis must be based on good science and should take into account the integrity of the product. The calculated MKT is not sensitive to the impact of excursions that may occur if the baseline is a long period of time such as a storage segment or the entire lifetime of the drug product. For shorter baseline periods of time, such as transport segments, an excursion can have a significant impact on the resulting MKT for that segment; however, this would not necessarily have a significant impact on product quality.

The MKT analysis may be used for storage conditions that have exceeded the acceptable parameters for a drug product, for a short period of time and is not intended to be a measure for long-term storage.

Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. Although higher temperatures are given greater weight in the calculation, the calculation of MKT for nonfrozen product that becomes frozen for any amount of time may not result in an acceptable temperature although the product may not be adulterated. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur; at lower temperatures (near freezing) a phase change may occur that is known to have a negative impact on the quality of some drug products (e.g., some proteins and vaccines). For an example of a calculation, see *Pharmaceutical Calculations in Prescription Compounding* (1160).

Emergency Medical Service Vehicles, Automobiles, and Van Transportation

Road vehicles used to transport drug products (e.g., ambulances and other emergency response vehicles, vans, or automobiles, including those used by sales representatives to transport physicians' samples) should be suitable for their purpose. Monitoring devices should be placed in different areas of the trunk or cabin where the drug product will be positioned during seasonal extremes (e.g., summer and winter). The monitor should be secured so that it is immobile, and there should be no ambiguity about its exact position within the payload so that the monitor is always placed in the same position. Monitoring devices used on or in

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packages or on containers may also be used. Suitable measures should be taken to maintain the drug product within the allowable limits of the labeled storage requirements. Storage of physician drug product samples by sales representatives is regulated under 21 CFR Part 203.34 (b)(4).

Mail Order Pharmacy Distribution

The mailing party is accountable for the appropriate mailing process. Mail distributors including the U.S. Postal Service (USPS) and other shipping services including expedited shipping services are responsible to provide the service contracted.

In the event that the package cannot be delivered as scheduled, the package should be returned to the mailing pharmacy.

Risk Management System

Risk Management System strategies should ensure that each organization's best interests are served by adhering to proper practices, controls, and procedures, including but not limited to the following: the nature of the drug products; distribution requirements on the readable container labeling; exposure to adverse environmental conditions; number of stages/receipts in the supply chain; manufacturer's written instructions; contractors; and drugs at risk from freezing (vaccines, insulin, and biological products) or elevated temperatures (fatty-based suppositories, vaccines, insulin, and biological products).

Examples of risks include the following: (1) vibration that can cause aggregation of some drug products such as proteins and peptide-based drugs; (2) temperature excursions that may lead to phase changes (melting or freezing); (3) loss of container–closure integrity in transit that could cause glass fractures or loss of sterility in sterile drug product containers; and (4) ingress of water or oxygen that could lead to an increase in degradation products. Appropriate firms such as applicant holders are recommended to convey relevant environmental requirements when needed to support deviations or excursions . There may be alternate ways of determining acceptable environmental conditions and these should be documented and justified.

Pharmaceutical manufacturers should ensure that suppliers of drug product transportation are monitored. Auditing transportation firms should be carried out routinely to ensure adequate product handling. The manufacturer's change control system should capture and evaluate changes in logistic factors such as warehouse or receiving areas and vehicle changes.

CONCLUSION

The practices and processes set forth in this general information chapter apply to storage and distribution as part of the life-cycle management of drug products. All involved should ensure the product to its point of use, creating a contiguous supply network that is collaborative and emphasizes preventive measures to protect drug product quality. The increase in global processes coupled with products requiring special environmental controls highlights the need for a strong QM program. QM should provide the foundation for maintaining the storage and distribution practices in a continual improvement program and part of an overall management system review by each entity, as appropriate, in the supply chain.

It is equally important to stay current and be ready to change as new solutions evolve. These new technologies should be considered in developing strategies for good distribution practices, controls, and procedures.

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[1] JP Emond, *Study for Temperature Sensitive Product: Preliminary Testing*, October 2009, University of Florida.

Auxiliary Information— Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
General Chapter	Desmond G. Hunt, Ph.D. Senior Scientific Liaison (301) 816-8341	(GCPD2015) General Chapters-Packaging and Distribution

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Consider 2017 Legislative Proposal for Addressing Compounding Best Practices

Included in agenda package:

A copy of the Appendix from the Pew Charitable Trusts report summarizing Best Practices for State Oversight of Drug Compounding

Possible actions:

- Recommend to the full board that it adopt a legislative proposal for any identified possible gaps in oversight, e.g., recalls, seizures of drug, quarantine **or**
- Take no action.

Appendix

Best Practices for State Oversight of Drug Compounding

Quality standards

States should require traditional compounding pharmacies to comply, at minimum, with all applicable U.S. Pharmacopeial (USP) Convention standards, including general chapters <795> and <797>, new chapter <800> when complete, and other referenced chapters.

States should hold out-of-state traditional compounding pharmacies that ship into the state to USP standards at a minimum.

States should ensure that revisions of USP standards are reflected in state requirements.

Equipment certification and lab accreditation

States should require that all sterile compounding facilities and critical air control devices be certified by a qualified individual at least every six months (as required by USP <797>) using standard testing protocols such as those endorsed by the Controlled Environment Testing Association (CETA).

States should require that sterile compounders use only external testing labs that are clinical or environmental labs with appropriate accreditation.[*] Labs should also meet the International Organization for Standardization and the International Electrotechnical Commission 17025:2005[†] quality standard, General Requirements for the Competence of Testing and Calibration Laboratories.

Pharmacist training

In addition to USP <797> training expectations, states should require pharmacists who perform or supervise sterile compounding to receive regular specialized training in the practice, whether through continuing education or certification programs.

Training must include classroom and practical components and must cover core elements of USP <797> (see section on quality standards).

States should require compounders to document that all personnel engaging in or supervising sterile compounding are qualified and have had appropriate training. Compounders should provide such documentation upon request.

Recommendation for other stakeholders: Accreditation Council for Pharmacy Education (ACPE) should adopt core curriculum standards for schools of pharmacy that include training on nonsterile and sterile compounding, in conformance with USP requirements.

[*] Appropriate accreditation for clinical labs could include, for example, Clinical Laboratory Improvement Amendments accreditation or College of American Pathologists accreditation. Appropriate accreditation for environmental labs could include, for example, review by the American Association for Laboratory Accreditation, American Industrial Hygiene Association's Laboratory Accredited Programs LLC, or National Environmental Laboratory Accreditation Conference accreditation.

[†] The nonprofit International Organization for Standardization creates standardized international specifications for numerous types of business operations and products across many industry sectors.

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Inspections

Frequency

States should inspect nonsterile compounding facilities at least every two years and sterile compounding facilities yearly. States should have sufficient staff and funding to achieve these frequencies.

When resources are constrained, states should use a risk-based assessment to prioritize inspections, emphasizing high-risk compounding (e.g., preparing sterile drugs from nonsterile ingredients). States may also review documents to supplement in-person inspections.

States should also conduct facility inspections if the compounding pharmacy remodels or relocates, and such changes must be reported to the state. Before sterile products can be released from a remodeled or relocated facility, a successful inspection should be required.

Out-of-state pharmacies should be subject to the same frequency of inspections as in-state pharmacies, whether conducted by the state or a third party.

Process

Inspections should be conducted by the state or by a trusted, qualified third party approved by the state.

Inspections should include examinations specific to the compounding activity, such as sterile or high-risk compounding, with sterile compounding activities assessed for minimum core components of USP <797> (see section on quality standards).

States should utilize a formalized inspection document that adequately describes what was observed on an inspection to ensure compounder adherence to appropriate quality standards for the activities being conducted.

Inspections should be unannounced.

Inspections should be long enough (or include return visits) to permit direct observation of the highest risk compounding activity performed at the site. If this is not possible, states should require compounders to simulate, or compound for observation, the sterile products most challenging to make. States should also review the results of prior media fill (compounding simulations) tests that simulate the compounder's most challenging sterile product processes.

States should have the ability to take and test samples of sterile compounded drugs when needed, such as for inspections or investigations. States should have sufficient funding and, if needed, authority to support these activities. States should have a relationship with a qualified lab to perform analysis.

Recommendation for other stakeholders: The National Association of Boards of Pharmacy, or other similar credible organization, should work with states to create a standardized inspection form to support harmonization of state oversight.

Inspections by regulators in other states or by third parties

If the state relies on another state or a third party to perform inspections, the inspection process must sufficiently assess, and the inspection report must demonstrate compliance with, USP standards at minimum. Inspection reports must describe the specific criteria reviewed and whether compliance was met.

States should approve in advance any third parties permitted to conduct inspections and regularly confirm that these inspectors are meeting qualification criteria.

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Third-party inspectors should provide the state with timely notification of any compliance failures and with all documentation related to the inspection.

Inspector qualifications

State and third-party inspectors should be competent to examine the type of facility they are reviewing. This includes pharmacies engaging in traditional sterile compounding or handling nuclear/radiopharmaceuticals (knowledge of and experience in inspecting for applicable USP requirements), or outsourcing facilities for those states that elect to inspect them (knowledge of and experience in inspecting for relevant current Good Manufacturing Practices). States may also choose to rely on FDA inspections of outsourcing facilities (see outsourcing facilities section).

Inspectors should receive initial training before conducting inspections and ongoing follow-up training to stay current with updated standards. Training should include a classroom component and practical experience. States should allocate sufficient financial resources to support both initial and follow-up training for state inspectors. Third-party inspectors must be able to show proof of training.

Documentation of inspections and findings

States should document all inspections and inspectional findings in writing, which should include an inspection report form or checklist clearly indicating the standards reviewed and observed; documentation may also include additional narrative as needed.

States should give compounders a written description of any problems discovered during inspections and request a written response describing how problems will be addressed. States should follow up with facilities to ensure appropriate responses and actions.

Pharmacy licensure

Pre-licensure inspection

States should conduct an inspection before initial licensure of a traditional compounding pharmacy and before compounding activity begins at a licensed traditional pharmacy.

States may rely on FDA licensure and inspections for outsourcing facilities. However, if the state elects to license and inspect outsourcing facilities before licensure, inspections must be to cGMP standards (see outsourcing facilities section).

Specific licensure requirements for sterile compounding

States should have a mechanism to identify facilities that engage in sterile compounding that ship or dispense drugs in the state and must have a targeted ability to enforce standards specific to sterile compounding. The optimal way to achieve this is through separate licensure for sterile compounders.

Licensure requirements should include quality standards for sterile compounding (i.e., USP <797>).

Out-of-state pharmacies

States should independently license out-of-state pharmacies, which should be inspected before initial licensure or before compounding activity begins at a licensed traditional pharmacy.

If the state cannot conduct an inspection before initial licensure, it may rely on an inspection report by the state where the pharmacy is located or on an inspection by a qualified third party. In either case, the inspection must have been performed in the previous year, and the report must sufficiently demonstrate compliance with USP standards at minimum and describe the specific criteria reviewed and whether compliance was met.

Outsourcing facilities

States should recognize outsourcing facilities in regulation or statute and incorporate a state law definition that is aligned with federal law.

If states wish to formally track outsourcing facilities that do business in their state via separate registration or licensure, registration with FDA should be a prerequisite.

All production at an outsourcing facility must meet applicable cGMPs. States may:

- Rely on FDA to conduct oversight.
- Require an inspection report demonstrating compliance with cGMPs.
- Conduct their own inspections. States that wish to inspect outsourcing facilities must ensure inspectors have the appropriate training to assess adherence to applicable cGMP standards.

Outsourcing facilities that conduct patient-specific compounding and dispensing must also be licensed as a pharmacy with the state, but the quality standard applied to the facility must be cGMP, not USP <797>. Records of compounded products prepared based on a patient-specific prescription must be maintained separately from records of non-patient-specific compounded products, so that these distinct records are readily retrievable.

Compounding without prescriptions, violations of federal law

Compounding without prescriptions

States should align laws and regulations with federal laws and regulations on compounding and dispensing/distributing without prescriptions.

States should prioritize enforcement oversight on higher-risk activities—such as compounding pharmacies producing products without prescriptions on a larger scale—that in the event of contamination can affect more patients.

States should establish policies that support provider purchasing of compounded drugs without prescriptions only from FDA-registered outsourcing facilities.

Compounding in violation of federal law

State regulators should identify any compounding entities that operate in violation of federal law and either require them to cease this activity or, if appropriate, register with FDA as an outsourcing facility. State regulators should report to FDA any facilities that refuse to either cease activities in violation of federal law or, if appropriate, register with FDA as an outsourcing facility.

Physician's office compounding

Physicians' offices that compound should be held to the same standards as other compounding facilities, including quality standards (e.g., USP <797>) and reporting standards.

The state should have a mechanism for knowing which doctors' offices are conducting sterile compounding and should inspect these offices to ensure compliance. This oversight can be done by the state medical board or state board of pharmacy. If by the state medical board, inspectors must receive appropriate training.

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There should be an exemption for compliance by physicians' offices with full USP <797> for immediate-use drugs (which are administered within the hour, as defined by USP). However, practitioners compounding in doctors' offices must still have training and be held to a standard of care that includes good hand hygiene and aseptic technique, per USP standards. The immediate-use exemption cannot apply to hazardous drugs.

Recommendation for other stakeholders: The Federation of State Medical Boards should work with the National Association of Boards of Pharmacy to address physician's office compounding and identify appropriate oversight systems, whether through state medical boards, state boards of pharmacy, or other appropriate entities.

Activity and adverse event reporting

Activity reporting

States should be able to track the type of compounding activities conducted by pharmacies in the state including sterile, nonsterile, and high-risk compounding. States should require compounders to report this information to the state, whether through licensure application or renewal, or through a separate activity reporting mechanism.

States should have the authority to request reports from traditional compounding pharmacies on the number and volume of compounded products sold or dispensed in the state and, for in-state pharmacies, outside the state in the previous year, including the drug's active ingredients, strength, and dosage form. States should be able to request this information outside of an inspection.

States should have the authority to request the reports outsourcing facilities give to FDA identifying the drugs compounded in the previous six months, including the drug's active ingredients, strength, and dosage form.

Adverse event and recalls reporting

Traditional compounding pharmacies should be required to report serious adverse events (as defined by FDA)[3] to the state board of pharmacy within 24 hours.

Traditional compounding pharmacies should be required to report voluntary recalls to the state and FDA within 24 hours. The state should review voluntary recalls to ensure that actions taken to communicate with providers and/or remove products from the market sufficiently mitigate risk to patients.

States that elect to license outsourcing facilities may also decide to require these facilities to report serious adverse events to the state.

[3] U.S. Food and Drug Administration, "What Is a Serious Adverse Event?" updated Jan. 10, 2014, http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm. FDA defines a serious adverse event associated with the use of a medical product in a patient as a death, life-threatening event, hospitalization, disability or permanent damage, congenital anomaly or birth defect, or an event that may require medical or surgical intervention to prevent one of these outcomes.

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State authorities and sanctions

State authorities

States should have the authority to quarantine products.

States should have the authority to seize products.

States should have the authority to suspend activity the state believes to be in violation of applicable law or regulation in advance of a hearing when the potential for serious patient harm exists.

States should have the authority to mandate recalls of compounded drugs when there is potential or confirmed harm to a patient.

States should have the authority to require compounders to notify providers and patients about recalled products to protect public health.

States should have the authority to share information with other regulators, both federal and state, to support oversight and investigations.

Sanctions and penalties

States should post sanctions and disciplinary actions on a public website.

Recommendation for other stakeholders: An independent third party, such as the National Association of Boards of Pharmacy, should establish a central resource of public enforcement actions taken against compounding pharmacies and outsourcing facilities by state regulators, as well as product recalls. FDA enforcement actions, which the agency already posts publicly, could also be incorporated.