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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Adopted Amendments: N.J.A.C. 13:39-5.7, 5.8, and 6.2

Adopted New Rule: N.J.A.C. 13:39-5.11

Control and Monitoring of Temperature of Prescription Drugs and Chemicals; Storage Conditions; Minimum Equipment and Supplies

Proposed: April 4, 2016, at 48 N.J.R. 565(a).

Adopted: October 26, 2016, by the State Board of Pharmacy, Thomas F.X. Bender, R.Ph., President.

Filed: February 7, 2017, as R.2017 d.040, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-47 and 48.

Effective Date: March 6, 2017.

Expiration Date: May 17, 2017.

Summary of Public Comments and Agency Reponses:

The official comment period ended June 3, 2016. The Board of Pharmacy (Board) received comments from:

1. Anthony Reznik, Director of Government and Public Affairs, Independent Pharmacy Alliance;

2. Michael Rush, Executive Director, Global Health Policy, Temptime Corporation;

3. Carl and Barbara Patterson, Caregiver and Patient;

4. Ronald Angoff, MD., FAAP, Clinical Professor, Yale University Medical School Department of Pediatrics and the Yale Child Study Center, Immediate Past President AAP Connecticut Chapter and Foundation for Children;

5. Elise M. Barry, M.S., CFRE, Chief Executive Officer, New Jersey Pharmacists Association; and

6. Bill Irvin, R.Ph., Director, Pharmacy Regulatory Affairs, CVS Health.

1. COMMENT: Three of the commenters expressed support for the Board's proposal. One of

these commenters noted that the proposed rules would assist pharmacists in their integral role in improving patient outcomes and safety, in addition to improving the public health of New Jersey citizens through the safe transport and monitoring of temperature-sensitive and often costly biologics and medicines. Another of these commenters noted that the Board's proposal will help to ensure that the potency of medicines and the treatment impact expected will be as intended when prescribed.

RESPONSE: The Board thanks the commenters for their support.

2. COMMENT: One of the commenters suggested that, instead of being optional, the Board should require including temperature indicators in shipments of medicines to patients. The commenter believes that temperature monitoring should be done from the time drugs are manufactured to the time patients receive them. The commenter noted that if temperature indicators are used, anyone along the distribution line can tell if the medicine has been outside the proper temperature range, so problems can be addressed.

RESPONSE: Although the Board agrees that it is important throughout the distribution process to control and monitor the temperature of prescription drugs and chemicals to ensure their integrity, stability, and efficacy, the Board has jurisdictional authority over its licensees, registrants, and permit holders, but not drug manufacturers. The Board believes that pharmacies and pharmacists should have the flexibility to choose the means for controlling and monitoring temperature, as long as the methods are scientifically supported. Accordingly, the Board declines to mandate the specific method that a pharmacy may use to maintain and monitor the temperature of prescription drugs and chemicals.

3. COMMENT: One commenter suggested requiring visual temperature indicators to be affixed to individual boxes or doses of vaccines to help physicians better manage vaccine inventory by providing a visual cue to alert providers when vaccines may have been exposed to potentially damaging temperatures. The commenter noted that low-cost, highly reliable visual heat indicators on individual vials of vaccine have been required and successfully implemented in the developing world by the World Health Organization and the United Nations Children's Fund (UNICEF) since 1996 and by the GAVI Alliance since 2003. The commenter believes that such indicators would be a critical new tool in helping United States health care providers avoid administration of temperature-damaged vaccines to patients, reduce associated risks, administrative burdens, and liabilities for Vaccines for Children providers, and significantly reduce unnecessary vaccine wastage in the United States, mirroring international vaccine storage, handling, and administration policy successes. The commenter further believes that the same would be true if the Board adopted rules to monitor temperature of medicines from the time they arrive at pharmacies to the time they are given to patients.

RESPONSE: The Board agrees that visual indicators are one method for monitoring the temperature of vaccines and other prescription drugs and chemicals. The Board, however, declines to mandate the specific method that a pharmacy may use to maintain and monitor the temperature of these products. The Board's proposed amendments and new rule gives the pharmacy the flexibility to choose the means for controlling and monitoring the temperature, as long as the method is scientifically supported.

4. COMMENT: One commenter asked how the Board proposes to monitor packages sent from mail order companies and wholesalers. The commenter noted that mail order packages go from truck to truck, and facility to facility over several days and are more likely to have temperature control issues than local pharmacies. The commenter asks whether the Board is planning to monitor all delivery trucks, such as FedEx, United Parcel Service, and United

States Postal Service, as well as warehouses.

RESPONSE: The Board's jurisdictional authority does not extend to wholesalers, commercial carriers, or the United States Postal Service. If the mail order company referenced by the commenter is a pharmacy registered with the Board, then the proposed amendments and new rule would apply. Once the pharmacy accepts custodial control for these products, the pharmacy must ensure the integrity of the product and maintain the appropriate storage conditions within the prescription area and during the entire time it has control of the product until it reaches the patient, facility, or healthcare provider providing care to the patient.

5. COMMENT: One commenter expressed concern that mail order companies and wholesalers will not be held to the same standards as independent pharmacies and asked whether the Board will ensure that the proposed rules will be applied equally no matter the size of the company.

RESPONSE: The Board believes that the proposed new rule and amendments should be uniformly applied to all licensees and permit holders to ensure public health and safety. Therefore, the rules are the same for each pharmacy registered with the Board, regardless of the size of the business. The Board notes that the rules deliberately provide for flexibility, so each pharmacy and/or pharmacist can institute controls appropriate for specific products and business models. In addition, the Board notes that it does not have jurisdiction over wholesalers.

6. COMMENT: One commenter noted that N.J.A.C. 13:39-4.19 requires that out-of-State pharmacies register with the Board and inquired whether registration requires out-of-State pharmacies to follow New Jersey's statutes and regulations. The commenter further inquired that if out-of-State pharmacies are not required to follow State statutes and regulations, how the Board will verify that these pharmacies are following New Jersey standards to protect the public health and safety.

RESPONSE: The Board has always maintained that to protect the health and safety of the public pharmacies and pharmacists are responsible for ensuring the integrity of the product dispensed to the patient. The responsibility to ensure the public health and safety of New Jersey residents applies to all permit holders. With respect to out-of-State pharmacies, the Board takes action when there are issues concerning the public health and safety of New Jersey residents. The intent of the Board's proposed amendments and new rule is to provide [page=452] further guidance with respect to the temperature control and monitoring, the actions to take when there is a temperature excursion, and to provide the pharmacy the flexibility to employ variable means to satisfy the Board's expectations.

7. COMMENT: One commenter asked whether, in light of the State's budgetary fiscal constraints, the **Division of Consumer Affairs** (Division) has the ability to properly enforce these rules.

RESPONSE: In accordance with N.J.S.A. 45:1-3.2, boards are self-funded. The Board has the resources to enforce its rules.

8. COMMENT: One commenter sought clarification as to the Board's reason for proposing the rules. Specifically, the commenter asked whether there were instances in New Jersey in which manufacturers did not specify storage and shipping conditions and, as a result, a patient's health was jeopardized.

RESPONSE: The Board has considered and dealt with issues associated with extended periods of power failures resulting from extreme weather conditions, such as Super Storm Sandy, severe winters, and hot summers. Because extreme temperatures can impact the effectiveness of medications, the Board proposed a new rule and amendments to establish standards for the control and monitoring of temperature of prescription drugs and chemicals to ensure their integrity, stability, and efficacy. The Board believes the proposed new rule and amendments, which establish standards for the control and monitoring of temperature, define a temperature excursion, and specify actions that must be taken in the event of a temperature excursion, are necessary to protect public health and safety.

9. COMMENT: One commenter noted that if there is evidence of problems with storage and shipping resolving these issues needs to start at the manufacturer level. The commenter recommended that the Board's rules require all pharmaceutical manufacturers to specify storage and shipping conditions for their prescription drug products. The commenter also recommended that language be included that requires out-of-State pharmacies and wholesalers to comply with the new rules.

RESPONSE: The Board does not have the statutory authority to regulate manufacturers and wholesalers. With respect to out-of-State pharmacies, the Board takes action when there are issues concerning the public health and safety of New Jersey residents. (See the Response to Comment 6)

10. COMMENT: One commenter noted that the most current edition of the Drug Substance Monographs and Excipients of the United States Pharmacopeia/National Formulary (USP) is the 2016 edition. The commenter recommended amending the proposed rule language to state that the most current edition is to be referenced or a volume compiled after a certain date.

RESPONSE: The Board, upon adoption, will make a technical change to update the reference to the USP in proposed N.J.A.C. 13:39-5.7 to reflect the most current edition. As discussed below in the Response to Comment 12, upon adoption, the Board will remove the reference to USP in proposed N.J.A.C. 13:39-5.11.

11. COMMENT: One commenter raised concerns about the proposed language in N.J.A.C. 13:39-5.11(a)2, which states that the pharmacist may rely on his or her professional judgment and the pharmacy's written policies and procedures to determine which methods are adequate. The commenter noted that this language may evoke multiple interpretations, which could open the pharmacist and/or pharmacy to a license infraction or violation if an inspector interprets the scope of a pharmacist's professional judgment differently from that of the practitioner.

RESPONSE: The Board intentionally created a flexible standard to allow each pharmacy and/or pharmacist to institute controls appropriate for specific products and business models. Although inspectors note their observations on the inspection report, the Board is responsible for making the ultimate findings of fact. As part of its review process, the Board takes into consideration the responses of, and any information presented by, the licensees and permit holders.

12. COMMENT: One commenter recommended that the Board remain consistent with manufacturer storage recommendations and strike proposed N.J.A.C. 13:39-5.7(b)1. The commenter believes that the proposed rule to default to USP defined "controlled room temperature" in the absence of manufacturer guidance extends beyond the intent of the manufacturer and can lead to confusion due to the complexity of the definition. The

commenter noted that the USP definition of "controlled room temperature," includes references to mean kinetic temperature calculations, varying excursion ranges and transient spikes, and ultimately refers back to manufacturer instructions. The commenter believes that, in the absence of manufacturer's guidelines, a pharmacist should have the autonomy to exercise professional judgment regarding proper storage conditions rather than relying upon a complex and confusing USP calculation.

RESPONSE: The Board declines to delete proposed N.J.A.C. 13:39-5.7(b)1. For the protection of public health and safety, the Board is ensuring that all products are maintained under appropriate storage conditions, even when the manufacturer does not specify those conditions. The Board, however, agrees that the kinetic mean temperature calculations are complex. At the time of proposal, it was not the Board's intent to require pharmacists to calculate the kinetic mean temperature for purposes of determining controlled room temperature. Therefore, upon adoption, the Board is making a change to N.J.A.C. 13:39-5.7(b)1 and 5.11(a) to remove reference to "controlled room temperature" and to specify the temperature range set forth in the definition of "controlled room temperature" in the USP. Additional public notice of this change is not required because it does not change the effect of this rule. The change does not increase the burden on pharmacies and pharmacists responsible for maintaining adequate storage conditions or maintaining the integrity and stability of the prescription drugs and chemicals, so it does not destroy the value of the original notice.

13. COMMENT: One commenter raised concerns about the requirements of proposed N.J.A.C. 13:39-5.11(a), specific to maintaining temperature control of medications to be filled, dispensed, and transported. The commenter believes that expanding temperature monitoring to these processes will be complex, subjective, and without manufacturer guidance. The commenter noted that pharmaceutical manufacturers define temperature requirements specific to medication storage only and are not intended to include or govern the shipping process. The commenter believes that this requirement appears to be more stringent than those placed on manufacturers and wholesalers in the same distribution scheme and creates an environment of inequity for dispensing pharmacies across all areas of practice. The commenter further believes that these requirements, without any scientific merit, will undoubtedly lead to higher costs to patients, pharmacy providers, and payors, including the State of New Jersey. The commenter noted that pharmacies across the State, as well as those across the United States receive medications at their respective place of business from manufacturers and wholesalers without specific packaging for commonly prescribed medications. It is understood across the pharmaceutical industry that storage requirements were not applicable to shipping medications. The commenter also stated that short-term medication excursions during transit are acceptable based on the manner in which the manufacturer shipped the product to the receiving pharmacy.

The commenter also expressed concerns with the requirement in proposed N.J.A.C. 13:39-5.11(a) to maintain "controlled room temperature" during shipping and delivery of medication. The commenter noted that this requirement will impact all non-refrigerated oral solids, which are all labeled with controlled room temperature guidance, delivered to patients outside the pharmacy. The commenter stated that the introduction of an additional temperature monitoring process coupled with the creation and implementation of special packaging required to meet these requirements, would undoubtedly place significant financial challenges and hardship upon pharmacy permit holders across the State. The commenter believes that, if the proposed rule is promulgated, it will lead to a reduction in access for home-bound patients, as well as patients in residential and in-patient care settings, such as hospice, nursing homes, and assisted living facilities.

The commenter noted that because proposed N.J.A.C. 13:39-5.11(a) does not specifically require compliance by manufacturers and/or wholesalers, there is a lack of direction for pharmacies on how to handle medications received at their pharmacies delivered outside of the rule. Specifically, the commenter noted that the compliance requirements [page=453] outlined in the prefatory language, which makes reference to a pharmacist relying on professional judgment is not aligned with the compliance requirements of the proposed rule in which professional judgment of the pharmacist is largely absent. The commenter believes that, by the plain reading of the proposed rule, a pharmacy will be forced to reject any medication received from any source that does not or cannot comply with the requirements.

The commenter recommended that the Board remain consistent with manufacturer recommendations and amend proposed N.J.A.C. 13:39-5.11(a), such that it reads as follows: "All prescription drugs and chemicals shall be stored to assure and maintain the integrity and stability of the prescription drug or chemical at temperatures as specified by the drug manufacturer."

RESPONSE: To protect public health and safety, the Board proposed a new rule and amendments to ensure the integrity, stability, and efficacy of prescription drugs and chemicals that are in the custody of the pharmacy. It is the Board's intent for pharmacies to maintain the "storage" environmental conditions of the manufacturer while the product is in the custody of the pharmacy, and to take established, proven precautions to maintain those storage conditions until the product reaches the patient. Moreover, the Board wants to ensure that all products are maintained under appropriate storage conditions, even when the manufacturer does not specify those conditions.

The Board has always maintained that a pharmacy is responsible for the products within its custody and for ensuring that the products are maintained under adequate storage conditions, including proper temperature control as recommended by the manufacturer. The Board's proposed new rule and amendments provide guidance to pharmacies when the manufacturer does not provide its own recommendation.

The Board disagrees with the commenter that maintaining temperature control of all prescription drugs and chemicals while they are within the control of the pharmacy is complex or subjective. Once a pharmacy accepts the prescription drug and chemical from the drug manufacturer or wholesaler, the storage, filling, dispensing, transportation, and/or delivery to the patient, agent of the patient, facility, or healthcare provider providing care to the patient, are all processes within the control and responsibility, of the pharmacy. Each pharmacy is able to modify and adjust its practices based upon its individual business model and the specific product(s) involved.

In addition, the Board disagrees that the proposed new rule will lead to higher costs and believes that there is evidence demonstrating that controlling and monitoring the temperature of prescription drugs reduces costs to the health care system as a result of decreased waste and reduced staff devoted to addressing patient concerns about the medications they receive.

The Board notes that it does not have jurisdiction over manufacturers or wholesalers. The Board agrees with the commenter that if a licensee or permit holder receives pharmaceuticals that, in his or her professional judgment, were not properly handled then, as deemed appropriate, the products should be rejected or quarantined. The Board believes that, once the pharmacy accepts the product, the pharmacy is responsible for the product and maintaining the proper storage conditions until the product reaches the patient.

For the foregoing reasons, the Board declines to change N.J.A.C. 13:39-5.11(a) as the commenter suggests. As discussed in the Response to Comment 12 above, upon adoption, the Board is making a change to N.J.A.C. 13:39-5.7(b)1 and 5.11(a) to remove reference to "controlled room temperature" and to specify the temperature range set forth in the definition of "controlled room temperature" in the USP.

14. COMMENT: One commenter suggested that the Board provide additional clarification to the Board's definition of a temperature excursion set forth in proposed N.J.A.C. 13:39-5.11(d)3i. The commenter believes that it is not clear whether a temperature excursion applies to medications that are received from a manufacturer or wholesaler or is exclusive to those medications stored at, or delivered from, a pharmacy. The commenter also believes that it is unclear whether the Board intends proposed N.J.A.C. 13:39-5.11(d)3 to capture those excursions that are allowed and acceptable under the manufacturer recommendations or only those excursions that go beyond the manufacturer allowances. The commenter recommended that the Board amend proposed N.J.A.C. 13:39-5.11(d)3i as follows:

"For purposes of this paragraph, a "temperature excursion" means any deviation from the manufacturer's specifications."

RESPONSE: The Board declines to change N.J.A.C. 13:39-5.11(d)3i as the commenter suggests. The Board is providing guidance to the regulated community as to what is considered a temperature excursion when the manufacturer does not specify the appropriate temperature for maintaining the integrity and stability of the prescription drug. The Board's proposed new rule and amendments are intended to ensure the integrity, stability, and efficacy of prescription drugs and chemicals that are in the custody of the pharmacy in order to protect public health and safety. It is the Board's intent for pharmacies to maintain the "storage" environmental conditions of the manufacturer while the product is in the custody of the pharmacy, and to take established, proven precautions to maintain those storage conditions until the product reaches the patient. Moreover, the Board wants to ensure that all products are maintained under appropriate storage conditions, even when the manufacturer does not specify those conditions.

15. COMMENT: One comment recommended that the Board amend the proposed N.J.A.C. 13:39-5.11(d)6 to read as follows:

"Training of all personnel that physically handle prescription drugs to ensure that the appropriate storage and delivery of all prescription drugs and chemicals, including refrigerated and frozen pharmaceuticals."

The commenter believes that specifying that the training is required of personnel that physically handle prescription drugs will lessen the burden on the pharmacy staff and allow a more efficient approach to implement the requirement.

RESPONSE: The Board believes that all personnel who handle or are responsible for overseeing the handling of prescription drugs and chemicals must be trained to ensure the appropriate storage and delivery of such products. The Board declines the commenter's suggestion to limit the training only to the staff that physically handle prescription drugs. The Board notes that each pharmacy, as appropriate for its business operations, can identify in its policies and procedures the staff who handle or are responsible for overseeing the handling of prescription drugs and chemicals. Upon adoption, the Board is making a change to N.J.A.C. 13:39-5.11(d)6 to include language that the personnel that must be trained are those who handle or who are responsible for overseeing the handling of the prescription drugs and chemicals. Additional public notice of this change is not required because it does

not change the effect of this rule. The change does not increase the burden on pharmacies.

16. COMMENT: One commenter recommended amending proposed N.J.A.C. 13:39-5.11(e) to read:

"In the event of a temperature excursion, as defined in (d)3i above, at a permitted pharmacy practice site lasting 24 hours or more, the pharmacist-in-charge shall provide notification to the Board. Notification shall be made in a manner such that the notice is received by the Board within 7 business days of becoming aware of the temperature excursion."

RESPONSE: The Board believes that seven business days is too long a period for reporting purposes because temperature excursions that are not promptly resolved impact patient health and safety.

17. COMMENT: One commenter raised questions about the Board's belief that the proposed new rule and amendments will have a positive impact upon the public as set forth in the Social Impact Statement of the notice of proposal. The commenter stated that, although it appreciates the efforts put forth by the Board regarding its commitment to the residents of the State of New Jersey by ensuring the integrity and effectiveness of the medications they take, it believes that the proposed amendments, as written, have the potential to cause patient confusion, limit access to life-saving medications, delay therapy, create unnecessary waste, and increase health care costs.

The commenter agrees that established standards for practitioners and patients should create a positive social impact. The commenter is concerned, however, that the proposed amendments create heightened standards and liability for pharmacists, when the drug manufacturers are transporting and delivering the prescription drugs in a different way than outlined by the Board. The commenter questioned the positive impact on [page=454] pharmacists in light of the creation of a regulatory environment that requires pharmacies to protect prescription drugs in a manner that exceeds the methods used by the wholesalers and manufacturers from which they receive the medications, and creates an excessive burden and unknown liability.

In addition, the commenter is concerned that, due to the proposed rule language, "temperature excursions" may occur at a frequency greater than anticipated by the Board leading to unintended consequences. The commenter stated that a spike in the number of out-of-range products will increase the amount of medications shipped back through the reverse distribution process, including the possibility of pharmacies refusing deliveries based on their perception of the temperature on a given day. The commenter believes that this has the potential to increase the wastage of safe and effective medications leading to delays in therapy and driving up the overall cost of medications and other pharmacy-related services.

RESPONSE: The Board has considered and dealt with issues associated with extended periods of power failures resulting from extreme weather conditions, such as Super Storm Sandy, severe winters, and hot summers. Because extreme temperatures can impact the effectiveness of medications, the Board believes that establishing standards for the control and monitoring of temperature, defining a temperature excursion, and specifying actions that must be taken in the event of a temperature excursion, are necessary to protect public health and safety.

The Board disagrees that the proposed amendments and new rule will create patient

confusion, limit access to medications, cause delays in therapy, result in unnecessary waste and increased health care costs. Moreover, the Board believes that there is evidence to the contrary demonstrating a decrease in cost to the health care system, including reductions in waste.

The Board's proposed new rule and amendments are intended to ensure the integrity, stability, and efficacy of prescription drugs and chemicals that are in the custody of the pharmacy in order to protect public health and safety. It is the Board's intent for pharmacies to maintain the "storage" environmental conditions of the manufacturer while the product is in the custody of the pharmacy, and to take established, proven precautions to maintain those storage conditions until the product reaches the patient. Moreover, the Board wants to ensure that all products are maintained under appropriate storage conditions, even when the manufacturer does not specify those conditions.

The Board of Pharmacy does not regulate manufacturers and wholesalers. The proposed amendments and new rules pertain to inventory that has been accepted and is now under the control and ownership of a Board permit holder or licensee. Once a pharmacy takes ownership of a product, the assurance of proper storage and distribution becomes the responsibility of the pharmacy and its management. The Board relies on the professional judgement of its licensees to refuse, segregate, and quarantine suspect product. The return of refused or damaged or suspect product are business decisions for licensees and permit holders to determine in accordance with their agreements with suppliers and trading partners.

The Board has always maintained that a pharmacy is responsible for the products within its custody and for ensuring that the products are maintained under adequate storage conditions. The Board's proposed new rule and amendments do not heighten standards or liabilities for pharmacies and pharmacists. Instead, they provide further guidance to the regulated community concerning their existing obligations.

18. COMMENT: One commenter raised questions about the Economic Impact statement of the notice of proposal. The commenter believes that the Board is minimizing the economic impact to pharmacies delivering medications in the State. The commenter stated that by extending a "manufacturer's" storage requirements to filling, dispensing, transporting, and delivery, the Board is "casting a web that would include medications commonly delivered to pharmacy or patients home without advanced methods to maintain temperature control." The commenter further stated that, while the Board acknowledges storage requirements, the proposed amendments and new rule extend those requirements to include areas outside what manufacturers address in their labeling, including areas, such as filling, dispensing, transport, and delivery. The commenter believes, therefore, that the Economic Impact statement should extend beyond the storage requirement to include all other areas covered within the proposal. The commenter further believes that the Board's conclusion that "any increased costs are outweighed by the interest in protecting public health and safety" is overly broad and requested that the Board further explain and examine the details around the specific patient safety concerns that prompted the proposed amendments and new rule, as well as a comprehensive review of the economic impact prior to making a determination that the proposed amendments and new rule result in a positive economic impact.

RESPONSE: In the notice of proposal, the Board requires pharmacies to have a refrigerator thermometer and, if applicable, freezer thermometer, or temperature monitoring device to enable control of temperature; and appropriate manual, electromechanical, or electronic temperature recording equipment and/or logs to document proper storage of prescription drugs and chemicals. Pharmacies are currently required to maintain all prescription drugs

and chemicals under adequate storage conditions, including temperature control. To the extent pharmacies do not have appropriate manual, electromechanical, or electronic temperature recordkeeping equipment or logs to document the proper storage of prescription drugs and chemicals, some additional costs will be incurred by those pharmacies to comply with the rules to ensure the efficacy of the drugs being dispensed to the public. Similarly, for those pharmacies that do not currently have a refrigerator thermometer and, if applicable, a freezer thermometer, or other temperature monitoring device, some additional costs will be incurred. The costs associated with the temperature recordkeeping equipment and thermometers will vary depending upon the pharmacy's choice of product(s).

In addition, for a pharmacy that delivers a filled prescription drug or chemical to the patient, agent of the patient, facility, or healthcare provider providing care to the patient, except when picked up directly from the pharmacy by the patient, the pharmacist must use adequate methods, in accordance with the pharmacy's policies and procedures, to ensure temperature controlled conditions are maintained during facility storage, transportation, and delivery. A pharmacy may choose to use packaging material or devices to maintain temperature control during delivery of prescription drugs or chemicals from the pharmacy to patients. The costs to the pharmacy will vary depending upon the method(s) the pharmacy chooses to use.

Based upon the Board's experience with issues associated with extreme temperatures and impact such temperatures can have on the effectiveness of medications, the Board believes that any increased costs are outweighed by the interest in protecting public health and safety.

Federal Standards Statement

A Federal standards analysis is not required because the adopted new rule and amendments do not exceed, and in some cases reference the standards set forth in the USP, which may be viewed as establishing and setting forth Federal standards and requirements for temperature control and monitoring.

Full text of the adoption follows (additions to the proposal indicated in boldface with asterisks ***thus***; deletions from the proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39-5.7 Adequate storage

(a) There shall be sufficient shelf, drawer, or cabinet space within the prescription area for the proper storage of prescription drugs and chemicals and the minimum equipment required pursuant to N.J.A.C. 13:39-5.8.

(b) All prescription drugs and chemicals shall be maintained under adequate storage conditions, including proper lighting, ventilation, and temperature control, as recommended by the drug manufacturer.

1. If storage conditions are not specified by the drug manufacturer, the prescription drug or chemical shall be maintained according to the parameters set forth in the Drug Substance Monographs and Excipients of the United States Pharmacopeia/National Formulary, *[2014]* ***2016*** edition, incorporated herein by reference, as amended and [page=455]

supplemented, and which is available for purchase at the United States Pharmacopeia/National Formulary website at www.usp.org. Where no specific directions or limitations are provided in the packaging and storage section of individual monographs or in the manufacturer specifications, the conditions of storage shall include storage at *[controlled room temperature]* ***a temperature maintained thermostatically between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit)***, protection from moisture***,*** and, where necessary, protection from light. *["Controlled room temperature" is as defined in the USP.]*

13:39-5.8 Minimum equipment and supplies; cleanliness

(a) All prescription areas shall contain the following minimum equipment and supplies, which shall be readily accessible:

1.-7. (No change.)

8. Refrigerator thermometer and, if applicable, freezer thermometer, or temperature monitoring device to enable control of temperature;

Recodify existing 8.-13. as 9.-14. (No change in text.)

(b)-(c) (No change.)

13:39-5.11 Control and monitoring of temperature of prescription drugs and chemicals

(a) All prescription drugs and chemicals shall be stored, filled, dispensed, transported, and/or delivered to the patient, agent of the patient, or facility or healthcare provider providing care to the patient to assure and maintain the integrity and stability of the prescription drug or chemical at temperatures as specified by the drug manufacturer. If the drug manufacturer has not specified the appropriate temperature, the prescription drug or chemical shall be maintained at *["controlled room temperature," as defined in the United States Pharmacopeia/National Formulary (USP), 2014 edition, incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia/National Formulary website at www.usp.org]* ***a temperature maintained thermostatically between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit)****.

1. A pharmacy shall monitor and record the temperature of the pharmacy permitted area and refrigerator and, if applicable, freezer, no less than twice daily with an interval of at least eight hours.

i. Appropriate manual, electromechanical, or electronic temperature recording equipment and/or logs shall be utilized to document proper storage of prescription drugs and chemicals.

ii. A pharmacy shall maintain documentation of the recorded temperatures for two years.

iii. A pharmacy shall calibrate thermometers or temperature monitoring devices at predetermined intervals according to the manufacturer specifications.

2. A pharmacy that delivers a filled prescription drug or chemical to the patient, agent of the patient, or facility or healthcare provider providing care to the patient by any method, except when picked up directly from the pharmacy by the patient or his or her authorized

agent, shall, in the professional judgment of the pharmacist, and in accordance with the pharmacy's policies and procedures as set forth in (d) below, use adequate methods to ensure temperature controlled conditions are maintained during facility storage, transportation, and delivery.

i. To ensure that temperature control is maintained during delivery, the shipping processes may include the use of appropriate packaging material or devices according to information provided by the manufacturer, Chapter 1079 of USP, other learned treatises, or expert qualification analysis.

ii. When packaging material or devices are used to maintain temperature control during delivery, the contents of the package shall include instructions to the recipient how to easily detect improper storage or temperature variation, and instructions how to report the storage or temperature excursion to the pharmacy.

(b) The temperature in a refrigerator and, if applicable, freezer that are used to store prescription drugs or chemicals must be maintained according to USP standards and guidelines.

(c) The pharmacist-in-charge is responsible for ensuring proper temperature controls for all prescription drugs and chemicals in the pharmacy permitted area and all prescription drugs and chemicals that are shipped, mailed, distributed, or otherwise delivered from the pharmacy.

(d) The pharmacist-in-charge shall develop and maintain written policies and procedures to ensure the proper storage in the pharmacy permitted area of all prescription drugs and chemicals, and the proper storage when prescription drugs or chemicals are delivered from the pharmacy to the patient, agent of the patient, or facility or healthcare provider providing care. The written policies and procedures shall include, at a minimum, the following:

1. Monitoring and recording the temperature of the pharmacy permitted area and refrigerator and, if applicable, freezer consistent with the requirements of this section;

2. Maintaining documentation of the recorded temperatures consistent with the requirements of this section;

3. Actions to be taken in the event of temperature excursions include, but are not limited to: notification of appropriate personnel, investigation of all temperature excursions, inspection and disposal, as applicable, of the stock in question, and corrective actions;

i. For purposes of this paragraph, a "temperature excursion" means any deviation from the manufacturer's specifications or, in the absence of manufacturer specifications, applicable USP standards.

4. Calibrating thermometers or temperature monitoring devices consistent with the requirements of this section;

5. Actions to be taken in the event that the prescription drugs and chemicals do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment or delivery; and

6. Training of all personnel ***who handle, or are responsible for overseeing the handling of, prescription drugs and chemicals*** to ensure the appropriate storage and

delivery of all prescription drugs and chemicals, including refrigerated and frozen pharmaceuticals.

(e) In the event of a temperature excursion, as defined in (d)3i above, at a permitted pharmacy practice site lasting 24 hours or more, the pharmacist-in-charge shall immediately notify the Board. Notification shall be made in a manner such that notice is received by the Board within 48 hours of becoming aware of the temperature excursion.

(f) In the event of a temperature excursion, as defined in (d)3i above, lasting 72 hours or more, a pharmacist shall not dispense any prescription drug or chemical unless the pharmacist verifies with the manufacturer of the prescription drug or chemical that as a result of the temperature excursion, the drug or chemical has not been adulterated, is safe and efficacious, and its stability has not been adversely affected.

SUBCHAPTER 6. PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

13:39-6.2 Pharmacist-in-charge

(a)-(e) (No change.)

(f) A pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

1.-7. (No change.)

8. The prescription area is maintained in an orderly and sanitary manner;

9. There are written policies and procedures to ensure the proper storage and delivery of all prescription drugs and chemicals consistent with the requirements set forth in N.J.A.C. 13:39-5.11 and that such policies and procedures are followed; and

10. (No change in text.)