49 N.J.R. 3761(a)

VOLUME 49, ISSUE 23, DECEMBER 4, 2017

RULE ADOPTIONS

Reporter
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NJ - New Jersey Register > 2017 > DECEMBER > DECEMBER 4, 2017 > RULE ADOPTIONS > LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS

Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > **STATE BOARD OF PHARMACY**

Administrative Code Citation

Board of Pharmacy Rules

Readoption with Amendments: N.J.A.C. 13:39

Adopted Repeals and New Rules: N.J.A.C. 13:39-3.7, 3.8, 3.9, 6.13, and 6.14

Adopted New Rules: N.J.A.C. 13:39-1.8, 6.14A, 7.22, 7.23, 11.25, and 11B

Adopted Repeals: N.J.A.C. 13:39-4.6 and 11.9

Text

Proposed: June 5, 2017, at 49 N.J.R. 1316(a).

Adopted: September 20, 2017, by the State Board of Pharmacy, Thomas F.X. Bender, R.Ph., President.

Filed: November 3, 2017, as R.2017 d.220, **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. 45:1-15.1, 45:14-47, 45:14-48.a(4), 45:14-61, and 45:14-62.

Effective Dates: November 3, 2017, Readoption;

December 4, 2017, Amendments, New Rules, and Repeals.

Expiration Date: November 3, 2024.

Summary of Public Comments and Agency Reponses:

The official comment period ended August 4, 2017. The Board of Pharmacy (Board) received comments from:

1. Anne Fellows, Regional State Director, National Association of Chain Drug Stores (NACDS) and John Holub, Executive Director, New Jersey Council of Chain Drug Stores (NJCCDS);

2. Thomas J. Wilverding, President, Central Admixture Pharmacy Services, Inc. (CAPS);

3. Kate Douglass, Vice President and Chief Learning Officer, CriticalPoint Center for Training and Research, Eric Kastango and Abby Roth, Clinical IQ, and Jim Wagner, Controlled Environment Technologies; and

4. John Long RPh, MBA, Director, Regulatory Affairs, CVS Health.

1. COMMENT: One commenter noted that the ability for pharmacies to store their records electronically not only improves the process/efficiency for recordkeeping but also enhances compliance as multiple types of records can be stored and easily retrieved as needed. The commenter further noted that, in many cases, recordkeeping is an administrative burden to the pharmacy that reduces the amount of time available for pharmacy staff to focus on patient care. The commenter recommended amending N.J.A.C. 13:39-3.1(b) and 6.7(b), which respectively concern the requirements to display the pharmacy license and pharmacy technician registration, to replace "conspicuously displayed in view of the public" with "readily available for viewing."

RESPONSE: The Board recognizes the benefit of electronic recordkeeping and amended N.J.A.C. 13:39-7.19(a) to require that an electronic patient profile system be maintained to enable immediate retrieval of current clinical information. With respect to the Board's requirements to display the pharmacist's license and pharmacy technician's registration, these requirements are consistent with those of other licensing boards within the Division of Consumer Affairs and the Board declines to amend N.J.A.C. 13:39-3.1(b) and 6.7(b) as suggested.

2. COMMENT: One commenter raised concerns about proposed N.J.A.C. 13:39-4.11(a)4, which requires pharmacies using social media to notify their patrons on the social media platforms used by the pharmacy of its closure, that they have a right to obtain copies of their prescriptions and/or a patient profile, and the location of the prescriptions and patient profile. Proposed new paragraph (a)4 also requires the pharmacy to discontinue and remove all commercial advertising from the social media sites. The commenter believes that, as written, the proposed requirements are overly superfluous and should be revised to be limited in the scope of the required postings and/or how notice of a store closing and the availability of patient records is provided. The commenter noted that it does not believe that the Board should be involved in the business aspects of pharmacies, such as advertising. In addition, the commenter believes that posting store closures for an individual state on an IT platform that operates in many states is

not helpful information for consumers. The commenter noted that, currently, many chain pharmacies utilize social media, but are not set up to provide details on individual locations. The commenter also noted that much of the social media that is used by chain pharmacies relates to products on sale, services, or other offerings that apply throughout the chain; not just at a specific location. Therefore, the commenter requested that the Board strike this language. As an alternative, the commenter recommended the following changes to paragraph (a)4:

> "For a pharmacy that uses social media, the pharmacy shall post notice on all social media platforms used by For a pharmacy that uses social media that is specific to individually identified locations, the pharmacy informing patrons of the pharmacy closure, that they have a right to obtain copies of their prescriptions and/or patient profile and the location of the prescriptions and patient profile. The pharmacy shall also discontinue and remove all commercial advertising from social media sites."

RESPONSE: The Board intended for the requirements proposed in N.J.A.C. 13:39-4.11(a)4 to apply to the website for a particular permitted pharmacy. Accordingly, upon adoption, the Board will change proposed new N.J.A.C. 13:39-4.11(a)4 to clarify that the requirements are for a permitted pharmacy that uses social media that is specific to individually identified locations. 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 that use social media, so it does not destroy the value of the original notice.

3. COMMENT: Two commenters expressed concerns about the proposed amendments to N.J.A.C. 13:39-6.2 that clarify that both the outgoing and incoming pharmacists-in-charge are required to conduct the controlled dangerous substances (CDS) inventory and require both the outgoing and incoming pharmacists-in-charge to notify the Board of the change. The commenters stated that there may be several situations in which the outgoing pharmacist-in-charge should not or is unable to complete a controlled substance inventory (that is, termination, injury, etc.). One of the commenters, therefore, believes that the Board should also include a provision that allows the permit holder to choose an alternate pharmacist if the outgoing pharmacist is unable to complete the controlled substance inventory along with a documented explanation as to the reason for choosing the alternate pharmacist. Another commenter suggested that the Board amend N.J.A.C. 13:39-6.2(d) to specify the "outgoing pharmacist-in-charge, when available."

RESPONSE: The Board agrees with the commenters that there may be circumstances in which the outgoing pharmacist-in-charge is unable to complete the CDS inventory and that, in such circumstances, the pharmacy permit holder should be allowed to designate an alternate pharmacist to conduct the inventory and must provide the Board with a documented explanation necessitating the selection of an alternate pharmacist. Therefore, upon adoption, the Board will change N.J.A.C. 13:39-6.2(d) to include language to specify that, when the outgoing pharmacist-in-charge is unable to complete the CDS inventory, the pharmacy permit holder may designate an alternate pharmacist and must provide the Board with an explanation. 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 or pharmacists-in-charge so it does not destroy the value of the original notice of proposal.

4. COMMENT: One commenter raised concerns about proposed N.J.A.C. 13:39-7.7(a). The commenter noted that under subsection (a), which requires pharmacies to immediately comply with a patient's request for copies of prescriptions and/or a patient profile, the Board is proposing to specify that "immediately" shall not exceed 24 hours. The commenter stated that, although it understands the need to ensure that there are minimal delays when a patient requests copies of his or her prescriptions and/or a patient profile, because there is no limit on the length of time for which the patient can request copies of prescriptions or the number of prescriptions that can be requested at one single point [page=3762] in time, and considering the amount of time that pharmacies are required to maintain records, this could be an exhaustive request.

The commenter further stated that, to access the prescription, copy it, and print the required verbiage of "COPY-FOR INFORMATION PURPOSES ONLY" is a very time-consuming task for pharmacists, and the commenter believes that this would require a complete information technology upgrade if copying prescriptions could be required from its New Jersey pharmacies on a frequent basis. In addition, the commenter noted that the fact that the Board is requiring the verbiage of "COPY-FOR INFORMATION PURPOSES ONLY" seems to indicate the Board's recognition of the possible misuse of copied prescriptions. The commenter recommended, however, that if the Board is going to include this option, the required verbiage be limited to only those prescriptions filled within the last calendar year from the date of the patient's request and that the time for compliance be extended to 72 hours.

The commenter believes that if there is an actual immediate and legitimate need for copies of prescriptions, instead of requesting such information from the dispensing pharmacy, the patient should contact the prescribing physician for such information and other pertinent information from his or her medical record to support use of such medications. The commenter further noted that this same type of information can be provided in a copy of the patient profile.

Accordingly, the commenter suggested that the patient's request be limited to the patient profile with a time limit not to exceed two years or a total of 15 prescriptions.

RESPONSE: The Board notes that the requirement to include the verbiage "COPY-FOR INFORMATION ONLY" is an existing Board requirement and declines to modify this requirement as the commenter suggests.

The Board believes that to assure the continuity of patient care, a pharmacy must be able to immediately provide patient prescription and/or patient profile information. The Board, however, recognizes that for prescriptions that are no longer active, that is, those older than one year and which cannot be used to fill or refill a prescription, the need to provide the prescription information is not as time sensitive as with active prescriptions. Accordingly, upon adoption, the Board will change N.J.A.C. 13:39-7.7(a) to specify that for requests for prescriptions that are one year or less from the original date of filling, "immediately" shall not exceed 24 hours, and for prescriptions that exceed this time period, "immediately" shall not exceed 72 hours. Additional public notice of this change is not required because it does not change the effect of the intent of the rule, which was to assure the continuity of patient care. The change does not increase the burden on pharmacies so it does not destroy the value of the original notice. In addition, there is no burden on the patients who are seeking the records. For those prescriptions that are active (that is, one year or less from the original date of filling), pharmacies must comply with the

patient's request within 24 hours. For those prescriptions that are no longer active, and, therefore, the information is less critical, the requests must be complied within 72 hours. Patients will continue to have immediate access to their prescriptions and/or patient profile information.

5. COMMENT: One commenter expressed concerns about the proposed amendments to N.J.A.C. 13:39-7.8(a), concerning the transfer of prescriptions between pharmacies, to specify that the pharmacy, pharmacist-in-charge, and pharmacist who receives the request for the transfer, are responsible for ensuring the timely transfer of the prescription, and that "immediately" shall not exceed four hours. The commenter stated that, given the amount of information and verification that is needed for some prescriptions, especially controlled substances, this requirement may not be feasible in all situations and may cause decreased compliance within the four-hour time limit. The commenter, therefore, recommended that the time limit be changed to not to exceed 24 hours to allow for adequate communication.

In addition, the commenter is concerned that the Board's proposed requirement may contradict the recent U.S. Drug Enforcement Agency (DEA) decision to restrict the transfer of a patient's unfilled controlled substance prescription, as well as most pharmacies' inability (due to technology) to forward an electronic controlled substance prescription. The commenter, therefore, recommended including a provision to exclude prescriptions that fall under this category. The commenter suggested including the phrase (addition to proposal in underline) "shall immediately comply with the patient's request *as allowed by law*" and a provision to exclude unfilled electronic prescriptions unless the pharmacy systems can forward the prescription securely pursuant to Federal code.

RESPONSE: The Board declines to change the rule as the commenter suggests. The Board believes that the four-hour clarification is necessary to ensure continuity of patient care. In addition, the Board notes that, in accordance with existing N.J.A.C. 13:39-7.8(b), (c), and (d), a prescription may be transferred between pharmacies, consistent with the rule's requirements, for one year from the date the prescription was written, provided refills of the prescription are available; a prescription for a Schedule II controlled substance may not be transferred; and a prescription for a Schedule III, IV, or V controlled substance must be transferred pursuant to the State's Controlled Dangerous Substances requirements at N.J.A.C. 13:45H-7.18 (as amended through this proposal at N.J.A.C. 13:39-7.8). The Board believes that the State's rule is consistent with the Federal Drug Enforcement Administration rule at 21 CFR 1306.25.

6. COMMENT: One commenter opposed the proposed amendments to N.J.A.C. 13:39-7.16, concerning return of prescription medication, because it believes that the language creates unnecessary restrictions that can lead to the wasting of safe prescription medications. The commenter recommended deleting the proposed new first sentence at N.J.A.C. 13:39-7.16(c). In addition, the commenter suggested changing the proposed amended language at N.J.A.C. 13:39-7.16(c)1 as follows:

> "1. In the professional judgment of the pharmacist, the prescription medication is eligible for re-dispensing. Eligible medications are those medications that are able to be consumed by a patient within the original time frame established for the medication's stability and expiration**, were maintained under proper storage conditions to ensure**

their integrity, and have remained under the exclusive control and custody of the pharmacy, pharmacy's agent or the patient's long-term care facility, as applicable, at all times. Products that have a limited shelf life and/or that have not been stored consistent with manufacturers' storage requirements may not be re-dispensed;"

RESPONSE: The Board declines to change the rule as suggested. P.L. 2016, c. 42, codified as N.J.S.A. 45:14-57.1, which became effective August 31, 2016, permits abandoned prescription medication to be re-dispensed for up to one year after original preparation and establishes, for purposes of re-dispensing, the circumstances in which a prescription medication is considered to be abandoned. The Board's proposed amendments conform N.J.A.C. 13:39-7.16 to N.J.S.A. 45:14-57.1.

7. COMMENT: Two commenters expressed concerns about proposed new N.J.A.C. 13:39-10.3(a), requiring pharmacies to first conduct a self-inspection and to submit the self-inspection report to the Board for approval. One commenter believes that this requirement can be potentially harmful to current evolvements in technology. One of the commenters noted that the use of automation and other technology plays a significant role in the practice of pharmacy. This commenter also believes that, as new and different technology becomes available, it is important for pharmacies to be able to utilize the most state-of-the-art equipment to meet the needs of their patients. The commenters noted that, in many cases, some automated dispensing systems are the same type of automation set up in a different location throughout the State. The commenters believe that, once a specific type of pharmacy automation is approved by the Board, requiring additional self-inspections with Board approval seems time-consuming and duplicative for both the pharmacies and the Board. The commenters believe that, once a technology or automation has been approved, additional approval is not necessary for the redeployment of the same technology or automation. The commenters, therefore, suggested that the proposed language be revised to allow proven systems to not be required to seek approval for the same technology or automation. One of the commenters recommended adding: "Pharmacies under common ownership may utilize an automated medication system that has been approved by the Board without additional Board approval for each location or system."

[page=3763] RESPONSE: The Board declines to change the rule as suggested. The Board notes that the proposed amendments to N.J.A.C. 13:39-10.3 clarify the Board's existing authorization process, which includes that the pharmacy conduct a self-inspection and submit it to the Board. The Board believes the self-assessment process is necessary for each location while facilitating easy implementation of the proposed system and maintaining an adequate mechanism for enforcement of its rules. In addition, the Board notes that it does not approve specific vendor systems or proprietary technology. The Board inspects the proposed system at a specific permitted pharmacy practice site for conformance with all aspects of the subsection requirements.

8. COMMENT: One commenter suggested that the Board change all references to "buffer area" and "ante area" to "buffer room" and "anteroom" in Subchapters 11 and 11B, which concern the compounding of sterile preparations and antineoplastic agents and other hazardous substances. The commenter stated that open architecture designs are not

allowed for compounding hazardous drugs and should not be allowed anywhere. The commenter further stated that open architecture builds have demonstrated an inability to provide room segregation. The commenter believes that changing the wording from "area" to "room" will make it clear that the space will always have doors and walls.

RESPONSE: The Board declines to change the existing wording as the commenter suggests. The Board is aware that United States Pharmacopeia (USP) 797 is undergoing review and that future changes are anticipated. Once changes are finalized and adopted, the Board intends to review Subchapters 11 and 11B to determine if changes are necessary.

9. COMMENT: One commenter suggested amending proposed new N.J.A.C. 13:39-11.3(f) to include "personnel" testing.

RESPONSE: The Board agrees with the commenter's suggestion and, upon adoption, will change N.J.A.C. 13:39-11.3(f) to include "personnel" testing. Additional public notice of this change is not needed because it does not change the effect of this rule. Personnel testing is a standard component of the protocol to help ensure the control of a sterile compounding environment. Therefore, specifically identifying "personnel testing" is a clarification that the Board will allow such testing as part of the process, equipment, and environmental testing that is allowed prior to receiving written Board approval. Such testing will help pharmacies and protect the public by ensuring the control of a sterile compounding environment. The change does not increase the burden on pharmacies so it does not destroy the value of the original notice.

10. COMMENT: One commenter recommended amending the heading of N.J.A.C. 13:39-11.4 to change the term "cleanroom" to "controlled compounding environments" because the term "cleanroom" has many meanings. The commenter stated that "cleanroom" often means buffer room and noted that the Board is using the term to reference the entire controlled compounding environment, which is made up of two rooms (buffer and anterooms) or it could be a C-SCA (containment segregated compounding area) or SCA (sterile compounding area) which, even if not ISO classified, still is a controlled compounding environment.

RESPONSE: The Board declines to change the existing wording as the commenter suggests. The Board is aware that USP 797 is undergoing review and that future changes are anticipated. Once changes are finalized and adopted, the Board intends to review Subchapters 11 and 11B to determine if changes are necessary.

11. COMMENT: One commenter proposed amending N.J.A.C. 13:39-11.4(d)2 and 3 to specify that the water column negative pressure should not be greater than 0.03 inches because too much negative pressure makes it more likely that contaminants will be pulled into the room especially as the facility ages.

RESPONSE: The Board notes that N.J.A.C. 13:39-11.4(d)2 and 3 were proposed for recodification as N.J.A.C. 13:39-11B.3(b)1 and 2 and provide that, as of July 1, 2018, room pressurization or air velocity must meet the standards set forth in USP 800. July 1, 2018, is the effective date for USP 800, which is incorporated by reference. The Board believes

that USP 800 will require the water column negative pressure to be between 0.01 and 0.03 inches relative to all adjacent areas.

12. COMMENT: One commenter recommended that N.J.A.C. 13:39-11.6 specify that the anteroom must be supplied with high efficiency particulate air (HEPA) filtered air because it is the commenter's experience that rooms, especially anterooms, when measured at rest may class out as ISO 8 but do not have HEPA supplied air.

RESPONSE: The Board requires that ISO class 8 air quality be maintained and declines to specify how the pharmacy achieves that air quality. The Board notes that, after anticipated amendments to USP 797 standards are finalized, the Board will review the rules in Subchapter 11 to determine if changes are necessary.

13. COMMENT: One commenter noted with respect to N.J.A.C. 13:39-11.7(b)2, that "nonshedding" cannot be interpreted as non-linting because no such materials exist. The commenter further noted that wipers, mop heads, and clothing can be low-linting or low-shedding, but not non-linting.

RESPONSE: The Board thanks the commenter for the information.

14. COMMENT: One commenter recommended amending N.J.A.C. 13:39-11.7(g) to remove reference to a specific minimum square footage requirement because the room must be the correct size to accommodate personnel and equipment needed to perform sterile compounding.

RESPONSE: The Board declines to change the rule as suggested. The Board believes that the existing specific square footage requirement is the minimum necessary for performing sterile compounding functions. The Board expects permit holders to ensure that the buffer area is of an appropriate size for the type of compounding performed.

15. COMMENT: One commenter recommended amending the last sentence of existing N.J.A.C. 13:39-11.8 to reflect that a perimeter line must surround the compounding aseptic containment isolator (CACI) or compounding aseptic isolator (CAI) and this area may be entered only by persons who will use the device to perform sterile compounding.

RESPONSE: The Board notes that existing N.J.A.C. 13:39-11.8 specifies that if the CAI and CACI are not located in a buffer area, they must be located in an area that is maintained under sanitary conditions and such area shall only be traveled by persons engaging in the compounding of sterile preparations. The Board does not believe it is necessary to reflect that a perimeter line must surround the CAI or CACI. In addition, the Board notes that, after anticipated amendments to USP 797 standards are finalized, the Board will review the rules in Subchapter 11 to determine if changes are necessary.

16. COMMENT: One commenter raised concerns about the proposed amendment to N.J.A.C. 13:39-11.12(b)13 requiring that the temperature be recorded twice each day. The commenter stated that it is unclear as to the reason the Board made the change from daily to twice daily and would alternatively recommend that the temperature be documented at least once daily but continuously monitored and an audible alarm placed

that will sound if the required temperature is breached. The commenter is concerned that without an audible alarm, when the temperature is documented twice each day but not looked at during the day, this requirement will prevent the detection of excursions throughout the day.

RESPONSE: The Board amended N.J.A.C. 13:39-11.12(b)13 to be consistent with the requirements of N.J.A.C. 13:39-5.11, which requires that the temperature is recorded twice each day. The Board's rules give the pharmacy the flexibility to choose the means for controlling and monitoring the temperature, as long as the method is scientifically supported.

17. COMMENT: One commenter suggested adding to proposed amended N.J.A.C. 13:39-11.16(d), the following:

"Initial Gloved fingertip/thumb sampling shall be conducted at the end of the hand hygiene and garbing procedure. Gloved fingertip samples will be taken on three consecutive and discrete occasions to verify that staff are able to don sterile gloves without contaminating. Thereafter gloved fingertip/thumb sampling must be performed at least in concert with the preparation of media fill test units."

In addition, the commenter suggested deleting the sentence requiring gloved fingertip/thumb sampling to be conducted annually for all personnel engaged in compounding low- and medium-risk level preparations and semi-annually for all personnel engaged in compounding high-risk level preparations. The commenter believes this sentence is inconsistent with the requirement that the sampling [page=3764] procedures be consistent with the standards established in USP 797 because the annual/semi-annual requirement is likely to not represent the USP standards. The commenter also asked whether the Board intended to incorporate by reference all of USP 797 or to solely incorporate the gloved fingertip/thumb sampling procedures of USP 797, and noted that the Board proposed to incorporate by reference all of the standards of USP 800.

RESPONSE: The Board believes that the gloved fingertip/thumb sampling is necessary and consistent with the Board's mandate to protect the public. In addition, the Board notes that the proposed amendments require that such procedures for the sampling be consistent with the standards established in USP 797. The Board is aware that USP 797 is undergoing review and that future changes are anticipated. After the USP 797 changes are finalized and adopted, the Board intends to review Subchapter 11 to determine if changes to its rules are necessary.

18. COMMENT: Two commenters suggested changes to the proposed amendments at N.J.A.C. 13:39-11.24(a)6 regarding the quality assurance program, which requires third-party certification of viable microbial sampling every six months. One of these commenters noted that although, in principle, it is not opposed to a third-party certification of potential microbial growth, in practice it is problematic. The commenter stated that it is not abundantly clear that third-party certification firms operate their own microbiologic laboratories. According to the commenter, as a result, microbial evaluation

will be performed by an additional party that further complicates the assessment process. The commenter suggested that requiring microbiologic sampling every six months by a third-party vendor who may outsource the laboratory services is insufficient to assess the state of control of the compounding suite and primary engineering controls. The commenter believes that microbial sampling should be performed by qualified operators on a more frequent basis as this larger body of data represents a more statistically significant assessment of the state of control. In addition, the commenter stated that a reasonable alternative might be to allow pharmacies to perform this sampling every six months and work directly with qualified laboratories for the assessment of results.

Another commenter suggested amending N.J.A.C. 13:39-11.24(a)6 to include reference to segregated compounding areas. The commenter also suggested amending this rule to replace the proposed requirement for certification by an independent certification company with that of an individual who is appropriately trained and has demonstrated competency in sampling techniques. The commenter noted that "EM" will need to be conducted at least monthly/quarterly (the commenter believes weekly/monthly) and that certification companies only started doing this because it needed to occur every six months in concert with certification. The commenter also stated that the trend is for a pharmacy to perform air and surface sampling themselves (or have a microbiology company perform it on their behalf). In addition, the commenter stated that because "EM" is not a core competency of room/equipment certification companies, it should not be encouraged.

RESPONSE: The Board believes that the commenter's use of "EM" refers to environmental monitoring. The Board believes that the commenters raised appropriate concerns about requiring microbiologic sampling every six months by a third-party vendor who may outsource the laboratory services. The Board also believes that it is necessary to further review and consider the issues raised and suggestions offered and, therefore, intends to address these issues as part of a separate rulemaking. The Board continues to expect a pharmacy permit holder to ensure that the third-party vendor it selects to perform the testing services is able to perform the required tests with a high degree of accuracy and reliability on a repeated basis. In addition, the Board notes that, although N.J.A.C. 13:39-11.24(a)6 requires air and surface sampling for microbial organisms to be conducted every six months and at any time microbial contamination is suspected, a pharmacy may conduct such sampling more frequently to mitigate the potential risks of product contamination.

19. COMMENT: One commenter recommended amending N.J.A.C. 13:39-11.24(a)10 to require the pharmacy to immediately begin a root cause investigation whenever test results indicate that the cleanroom or any primary engineering control does not meet the established standards. The commenter also suggested adding language that "issues with personnel must be investigated and remediated." In addition, the commenter recommended amending the Board's proposed new language as follows:

"The pharmacy shall notify the Board in writing within 48 hours of any environmental, air and/or surface sampling test conducted within the ISO 5 space that exceeds the predetermined action level results that are out of compliance."

The commenter stated that this is not needed for room data but understands doing it for Class 5 spaces. The commenter also stated it understands why reporting everything is important if pharmacies are sampling only twice a month.

RESPONSE: Based upon its experience with pharmacies that engage in compounding preparations and due to the potential health risks, the Board believes that it is necessary for the protection of the public and to assure the safety of the compounded drug products to require Board notification when air and/or surface sampling test results are out of compliance. The Board, however, believes the word "environmental" is superfluous and may cause confusion as to the type of test results that must be reported to the Board. Accordingly, upon adoption, the Board will remove the word "environmental." Additional public notice of this change is not required because it does not change the effect of this rule, so it does not destroy the value of the original notice. Pharmacies must still notify the Board when air and/or surface sampling test results are out of compliance.

The Board agrees that a root cause analysis of all environmental factors, including the personnel engaged in compounding, is important whenever test results indicate that the cleanroom or any primary engineering controls do not meet established standards. Accordingly, after the Board is notified of any contamination or out-of-range results, it asks the pharmacy to conduct a root cause analysis and remediate any environmental or personnel issues.

20. COMMENT: Two commenters raised concerns that the proposed amendments to N.J.A.C. 13:39-11.5 and 11.12, which respectively set forth additional cleanroom requirements and provisions and responsibilities for the pharmacist-in-charge when the pharmacy engages in sterile compounding, are not consistent with the requirements and standards established by USP 797 Standards for Compounding Sterile Preparations. Moreover, one of the commenters believes that the proposed amendments are more stringent and onerous than the current USP 797 standards. The commenter recommended keeping all requirements consistent and in-line with such standards. One commenter specifically believes that the Board's proposed amendments to N.J.A.C. 13:39-11.5(g) (cleanroom requirements), 11.12(b)13 (frequency of monitoring controlled cold storage from once daily to twice daily monitoring), 11.19 (including reference to sterility criteria), and 11.24(a)6 (requiring independent certification company to conduct air and surface sampling) and 10 (requiring notification to the Board within 48 hours) are more stringent than the standards in USP 797 and, therefore, deviate from the industry norm. The commenter believes that the proposed change to N.J.A.C. 13:39-11.19 could lead to over-reporting due to an obligation to report any small bacterial growth in addition to fungal growth. The commenter recommended that because 48 hours is a short turnaround and does not specify business hours, the Board should change the reporting time period to seven days as other states require.

RESPONSE: Based upon its experience with pharmacies that engage in compounding preparations and due to the potential health risks, the Board believes that the requirements of N.J.A.C. 13:39-11.5, 11.12, 11.19, and 11.24 are necessary for the protection of the public. As noted previously, the Board is aware that USP 797 is undergoing review and that future changes are anticipated. After the USP 797 changes are finalized and adopted, the Board intends to review Subchapter 11 to determine if changes to its rules are necessary.

21. COMMENT: One commenter noted that the reference to USP 795 at N.J.A.C. 13:39-11A.10(a)5 was not appropriate because USP removed the use of USP 795 as a stability reference because the data was only for non-sterile preparations.

RESPONSE: The Board notes that at N.J.A.C. 13:39-11A.10(a)5, USP 795 is not referenced as a stability standard and, accordingly, declines to remove the reference.

[page=3765] 22. COMMENT: One commenter recommended amending proposed new N.J.A.C. 13:39-11B.3(b) to remove reference to the air velocity meter because open architecture design is not allowed for hazardous drug compounding and, therefore, there is no reason to have a velocity meter. The commenter further stated that as doors and walls must be installed, room segregation must be maintained by pressure not velocity.

RESPONSE: The Board notes that existing N.J.A.C. 13:39-11.4 allows a pharmacy to choose to use an air velocity meter to monitor for correct room pressurization. The Board proposed to recodify this existing standard as N.J.A.C. 13:39-11B.3(b) and to retain this standard through June 30, 2018. In accordance with proposed N.J.A.C. 13:39-11B.3(f), as of July 1, 2018, pharmacies shall compound antineoplastic agents and other hazardous substances consistent with the standards set forth in USP 800. As USP 800 does not become effective until July 1, 2018, the Board is maintaining the existing requirements for compounding antineoplastic agents and other hazardous products to provide a period of transition from the existing standard to the new one.

23. COMMENT: One commenter questioned references in proposed new Subchapter 11B, which the commenter believes are duplicative of USP 800, which is proposed for incorporation by reference. Specifically, the commenter noted that proposed new N.J.A.C. 13:39-11B.3(c) is unnecessary. In addition, the commenter suggested amending proposed N.J.A.C. 13:39-11B.3(e)1 to remove reference to "When handling volatile hazardous drugs, such devices" because venting to the outside is a requirement of USP 800 for all sterile hazardous drug compounding regardless of whether or not the drug volatilizes. The commenter believes this language will bring back the confusion that led USP to remove the volatility issue altogether. The commenter also suggested deleting proposed new N.J.A.C. 13:39-11B.3(e)2, unless it is applicable until July 1, 2018. In addition, the commenter recommended deleting proposed new N.J.A.C. 13:39-11B.3(h) because it is covered by USP 800.

RESPONSE: As USP 800 does not become effective until July 1, 2018, the Board is maintaining the existing requirements for compounding antineoplastic agents and other

hazardous products to provide a period of transition from the existing standard to the new one.

24. COMMENT: One commenter noted that, currently, many pharmacies use, in their pharmacy workflow, a Centralized Prescription Handling Model. The commenter further noted that this Centralized Prescription Handling Model permits a pharmacy or pharmacies to provide services for other pharmacies. The commenter stated that these additional pharmacy services in many cases enhance the service levels of the pharmacy, thereby improving patient care and compliance. The commenter also stated that another important element of this type of model is the ability for pharmacists and technicians to access the pharmacy system from outside the licensed space. The commenter acknowledged that there are currently pilot programs in New Jersey allowing the practice, but stated that there is not a clear allowance for this practice in the rules. The commenter, therefore, requested the Board add this allowance to N.J.A.C. 13:39-4.19: Procedures for centralized prescription handling. Specifically, adding new subparagraph (f):

"(f) Nothing in this section shall prohibit a pharmacist or pharmacy technician, who is an employee of or under contract with a pharmacy, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:

1. The pharmacy establishes controls to protect the confidentiality and integrity of patient information; and

2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database."

RESPONSE: The Board declines to make the change upon adoption. However, the Board notes that for several years it has been developing a rulemaking regarding remote processing, which will be promulgated in due course.

25. COMMENT: One commenter noted that the roles, education, training, and professional opportunities are changing for both pharmacists and pharmacy technicians in the chain pharmacy environment. The commenter stated that the professional scope of the pharmacist is expanding nationally as organizations use the pharmacist-expanded drug knowledge to improve patient care and medication adherence. The commenter also stated that pharmacy technicians are expanding their supportive role as pharmacists move into more nontraditional roles in retail pharmacy. In addition, the commenter noted that the process of Tech-Check-Tech has expanded in some states to support the pharmacist's activities. The commenter stated that, when using a Tech-Check-Tech program the pharmacist must utilize an internal quality control assurance plan that assures the accuracy of dispensing. In addition, the commenter stated that the verification of the Tech-Check-Tech process remains the responsibility of the pharmacist. The commenter suggested that the Board include rule language to establish and support the adoption and implementation of a Tech-Check-Tech program in New Jersey.

RESPONSE: The Board notes that tech-check-tech programs refer generally to the checking of a pharmacy technician's order-filling accuracy by another pharmacy technician instead of by a pharmacist. Although the Board is aware of changes in the profession, the Board is constrained by N.J.S.A. 45:14-80 with respect to the duties that a New Jersey pharmacy technician may perform, and who may supervise them. The Board recently convened a sub-committee to review the qualifications for pharmacy technicians and will submit the commenter's recommendation to the sub-committee to consider whether implementing a tech-check-tech program is within the Board's statutory authority.

26. COMMENT: One commenter recommended that the Board allow for the use of electronic verification and recommended adding the following as new N.J.A.C. 13:39-10.4(a)9:

"9. Set forth methods that shall ensure the proper use of an electronic verification process.

1. Electronic verification process means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly prepared for dispensing by automated medication system;

2. The pharmacist verification requirements shall be deemed satisfied if:

i. The system utilizes an Electronic Verification Process to verify that the correct drug matches the correct prescription label;

ii. The Electronic Verification Process activities are undertaken by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist."

RESPONSE: The Board agrees that it should develop parameters for the use of electronic verification. However, such change is too substantive to make upon adoption, so the Board will propose a rulemaking regarding electronic verification to appear in a future issue of the New Jersey Register.

Federal Standards Statement

A Federal standards analysis is not required because the rules readopted with amendments, new rules, and repeals are governed by N.J.S.A. 45:14-40 et seq., and are not subject to any Federal standards or requirements. Although the rules in N.J.A.C. 13:39 are not subject to any mandatory Federal requirements or standards, where deemed appropriate, the Board has incorporated Federal standards.

Specifically, all pharmacies and pharmacy personnel must comply with all Federal laws, rules, and regulations governing the practice of pharmacy pursuant to N.J.A.C. 13:39-6.2(f)9. Pursuant to N.J.A.C. 13:39-4.15, the factors a pharmacy considers when determining whether a loss of prescription legend drugs or devices or controlled substances is significant are consistent with 21 CFR 1301.74(c).

Pursuant to N.J.A.C. 13:39-5.8, the Board requires prescription containers and child safety closures or caps to meet the standards on light resistance, tightness, and water vapor permeation of USP 661 and moisture permeability of USP 671.

The Board also notes that the requirements for the transmission of prescriptions for controlled substances set forth at N.J.A.C. 13:39-4.19, 7.4, 7.8, 7.10, 7.11, and 9.27 are consistent with the Federal Drug Enforcement Administration (DEA) standards articulated at 21 CFR 1306.11, 1306.21, and 1306.25. In addition, record retention requirements for controlled dangerous substance prescriptions set forth [page=3766] in N.J.A.C. 13:39-5.8, 7.6, and 7.15 are consistent with DEA standards set forth in 21 CFR 1306.26 and 1304.04. Institutional pharmacies must comply with the requirements of Federal and State controlled dangerous substances laws and rules and regulations with respect to maintaining records for receipt, use, and final disposition of controlled dangerous substances. N.J.A.C. 13:39-9.23 also provides that controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws, rules, and regulations. Moreover, pharmacies dispensing investigational new drugs under N.J.A.C. 13:39-7.5 and 9.10 must comply with Federal Department of Health and Human Services regulations set forth at 45 CFR Part 46.

Pharmacies that engage in compounding preparations must contain waste containers in compliance with OSHA standards as provided for in N.J.A.C. 13:39-11.7(h). N.J.A.C. 13:39-11.12 provides that storage of all materials pertinent to the compounding of sterile preparations, including procedures for procurement, must be in accordance with State and Federal laws and rules and regulations. Such pharmacies must also record all transactions as may be necessary under applicable State, Federal, and local laws and rules. Pursuant to N.J.A.C. 13:39-11.21, pharmacies that compound antineoplastic agents and other hazardous agents must include a warning on the label that is consistent with applicable Federal and State law, that antineoplastic agents and other hazardous substances products are biohazardous. In addition, the Board, at N.J.A.C. 13:39-11.15, 11.16, 11.24, and adopted new Subchapter 11B, incorporates by reference standards and requirements set forth in USP 797, USP 795, and USP 800, as applicable, which may be viewed as establishing and setting forth Federal standards and requirements for sterile and non-sterile compounding, including antineoplastic agents and other hazardous substances.

Pursuant to N.J.A.C. 13:39-12.2, nuclear pharmacies must comply with all applicable laws, rules, and regulations of Federal and State agencies including those laws, rules, and regulations governing non-radioactive drugs.

Regulations

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 13:39.

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

SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

"Address of record" means an address designated by a licensee or registrant, which is part of the public record and may be disclosed upon request. "Address of record" may be a licensee's or registrant's home, business, or mailing address, but shall not be a post office box, unless the licensee or registrant also provides another address that includes a street, city, state, and zip code.

"Biological product" means a "biological product" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. § 262(i)), and refers to a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

…

"Interchangeable" means "interchangeable" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. § 262(i)) and indicated as interchangeable by the Federal Food and Drug Administration in the "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," sometimes referred to as the "Purple Book."

…

"Pharmaceutical services" means all patient-oriented services provided by a pharmacist or other pharmacy personnel specific to their scope of practice. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labeling, distributing, and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; and teaching and counseling on the proper and safe use of drugs and medications.

…

"Professional judgment" means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge specific to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the practitioner.

"Therapeutically equivalent" means a therapeutic equivalence rating of "A" as has been listed by the Federal Food and Drug Administration in the "Approved Drug Products with Therapeutic Equivalence Evaluations," sometimes referred to as the "Orange Book."

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1.-2. (No change.)

3. For pharmacy technicians as follows:

i.-vi. (No change.)

vii. Reinstatement fee:

(1) (No change.)

(2) Administrative suspension..... $ 125.00

4.-5. (No change.)

13:39-1.7 Failure to complete application process

If an applicant for a permit, license, or registration issued pursuant to the requirements of this chapter fails to complete the application process within one year of the date of initial application, the Board shall administratively close the application. Following such action, an applicant making reapplication to the Board shall resubmit all required documentation and the applicable application fee set forth at N.J.A.C. 13:39-1.3.

13:39-1.8 Compliance with policy and procedures

A pharmacist-in-charge, pharmacist, pharmacy technician, pharmacy extern, pharmacy intern, and pharmacy permit holder shall comply with the policies and procedures required in this chapter, as applicable.

SUBCHAPTER 2. REQUIREMENTS FOR INITIAL LICENSURE

13:39-2.1 Requirements for initial licensure as a pharmacist

(a) An applicant for initial licensure as a pharmacist in New Jersey shall satisfy the following requirements:

1.-2. (No change.)

3. The applicant shall have passed the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE), consistent with the requirements of N.J.A.C. 13:39-2.2. The applicant shall take the NAPLEX and the MPJE only after providing the Board with an official transcript and receiving authorization to test from the National Association of Boards of Pharmacy (NABP). An applicant who has already taken the NAPLEX and has had his or her scores transferred to New Jersey within five years of having passed the examination consistent with N.J.A.C. 13:39-2.2, shall take the MPJE only after providing the Board with an official transcript and receiving authorization to test from NABP allowing the applicant to be admitted to the MPJE examination;

4.-5. (No change.)

(b) An applicant for initial licensure as a pharmacist in New Jersey who has graduated from a school or college of pharmacy in a foreign country that has not been accredited by ACPE or has not been deemed ACPE-equivalent by ACPE, shall satisfy the following requirements:

1.-4. (No change.)

5. The applicant shall have passed the NAPLEX and the MPJE, consistent with the requirements of N.J.A.C. 13:39-2.2. The applicant shall take the NAPLEX and the MPJE only after providing the Board with an official transcript and receiving authorization to test from NABP. An applicant who has already taken the NAPLEX and has had his or her scores transferred to New Jersey within five years of having [page=3767] passed the examination consistent with N.J.A.C. 13:39-2.2, shall take the MPJE only after providing the Board with an official transcript and receiving authorization to test from NABP allowing the applicant to be admitted to the MPJE examination. An applicant shall not be eligible to take the referenced examination until the completion of his or her internship; and

6. (No change.)

13:39-2.2 Licensure examination scores

(a) (No change.)

(b) An applicant for initial licensure shall attain a passing score of not less than 75 on the Multistate Pharmacy Jurisprudence Examination (MPJE). If an applicant fails the MPJE, he or she shall be required to repeat the examination.

(c) If an applicant fails either the NAPLEX or the MPJE three times, for each subsequent attempt at reexamination, the applicant shall not be eligible to retake the examination for licensure until one year from the date of the last examination.

1. The Board shall consider a failing score to include a "no score" and "not passing."

(d) NAPLEX and MPJE results shall be valid only for a period of five years from the date that an applicant receives a passing score on the respective examination.

13:39-2.6 Internship and externship practical experience requirements

(a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

…

"Pharmacy intern" means a person who is employed in an approved pharmacy training site for the purpose of acquiring practical experience and who has first registered for such purposes with the Board pursuant to N.J.S.A. 45:14-48b(2), and who:

1. Has graduated from an ACPE-approved school or college of pharmacy who is making an application for initial licensure as a pharmacist;

2. Has graduated from a school or college of pharmacy in a foreign country that has not been accredited by ACPE or that has not been deemed ACPE-equivalent by ACPE;

3. Has applied to the Board for reciprocal licensure and has not been engaged in the practice of pharmacy for at least 1,500 hours within the two-year period immediately preceding the date of application; or

4. Is a graduate student participating in a post-graduate pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP) and who is awaiting initial licensure.

…

(b)-(f) (No change.)

(g) An individual who works at a pharmacy outside the scope of his or her school's supervision is not deemed to be a pharmacy extern as defined in this section and shall register as a pharmacy technician in accordance with N.J.A.C. 13:39-6.6. Such an individual may perform only the duties set forth in N.J.A.C. 13:39-6.15.

SUBCHAPTER 2A. REQUIREMENTS FOR RECIPROCAL LICENSURE

13:39-2A.1 Requirements for reciprocal licensure

(a) (No change.)

(b) A pharmacist currently licensed in a mutually reciprocating jurisdiction shall satisfy the following requirements in order to obtain a license by reciprocity in New Jersey:

1.-3. (No change.)

4. The applicant shall have passed the Multistate Pharmacy Jurisprudence Examination (MPJE), consistent with N.J.A.C. 13:39-2A.5. The applicant shall take the (MPJE) only after submitting all required documentation to the Board and receiving authorization to test from the National Association of Boards of Pharmacy (NABP); and

5. (No change.)

(c) A pharmacist currently licensed in a mutually reciprocating jurisdiction who received a pharmacy degree from a school or college of pharmacy located in a foreign country that has not been accredited by ACPE or that has not been deemed ACPE-equivalent by ACPE, who wishes to obtain a license by reciprocity in this State shall satisfy the following requirements:

1.-4. (No change.)

5. The applicant shall have passed the Multistate Pharmacy Jurisprudence Examination (MPJE), consistent with N.J.A.C. 13:39-2A.5. The applicant shall take the MPJE only after submitting all required documentation to the Board and receiving authorization to test from NABP; and

6. (No change.)

(d) (No change.)

13:39-2A.5 Multistate Pharmacy Jurisprudence Examination

(a) An applicant for reciprocal licensure shall pass the Multistate Pharmacy Jurisprudence Examination. A passing score of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) If the applicant for reciprocal licensure fails the examination three times, for each subsequent attempt at reexamination, the applicant shall not be eligible to retake the examination for licensure until one year from the date of the last examination.

1. The Board shall consider a failing score to include a "no score" and "not passing."

SUBCHAPTER 3. PHARMACIST REQUIREMENTS

13:39-3.1 Authorization to practice; display of license

(a) (No change.)

(b) Upon issuance of a license, the current biennial renewal license shall be conspicuously displayed in view of the public in the pharmacist's principal place of employment.

(c) (No change.)

13:39-3.7 License renewal

(a) The Board shall send a notice of renewal to each licensee, at least 60 days prior to the expiration of the license. The notice of renewal shall explain inactive renewal and advise the licensee of the option to renew as inactive. If the notice to renew is not sent 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew provided that the license is renewed within 60 days from the date the notice is sent or within 30 days following the date of license expiration, whichever is later.

(b) A licensee shall renew his or her license for a period of two years from the last expiration date. The licensee shall submit a renewal application to the Board, along with the renewal fee set forth in N.J.A.C. 13:39-1.3, prior to the date of license expiration.

(c) A licensee may renew his or her license by choosing inactive status. A licensee electing to renew his or her license as inactive shall not engage in the practice of pharmacy, or hold himself or herself out as eligible to engage in the practice of pharmacy, in New Jersey until such time as the license is returned to active status.

(d) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee, and a late fee as set forth in N.J.A.C. 13:39-1.3. During this 30-day period, the license shall be valid and the licensee shall not be deemed practicing without a license.

(e) A licensee who fails to submit a renewal application within 30 days of license expiration shall have his or her license suspended without a hearing.

(f) A licensee who continues to engage in the practice of pharmacy with a suspended license shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to action consistent with N.J.S.A. 45:1-14 et seq., even if no notice of suspension has been provided to the individual.

13:39-3.8 License reactivation

(a) A licensee who holds an inactive license pursuant to N.J.A.C. 13:39-3.7(c) may apply to the Board for reactivation of the inactive license. A licensee seeking reactivation of an inactive license shall submit:

1. A renewal application;

[page=3768] 2. A certification of employment listing each job held during the period the license was inactive, which includes the name, address, and telephone number of each employer;

3. The renewal fee for the biennial period for which reactivation is sought as set forth in N.J.A.C. 13:39-1.3.

i. If the renewal application is sent during the first year of the biennial period, the applicant shall submit the renewal fee as set forth in N.J.A.C. 13:39-1.3.

ii. If the renewal application is sent during the second year of the biennial period, the applicant shall submit one-half of the renewal fee as set forth in N.J.A.C. 13:39-1.3; and

4. Evidence of having completed all continuing education credits that were required to be completed during the biennial period immediately prior to the renewal period for which reactivation is sought, consistent with the requirements set forth in N.J.A.C. 13:39-3A.1.

i. An applicant who holds a valid, current license in good standing issued by another state to engage in the practice of pharmacy and submits proof of having satisfied that state's continuing education requirements for that license, shall be deemed to have satisfied the requirements of this paragraph. If the other state does not have any continuing education requirements, the requirements of this paragraph apply.

(b) If a Board review of an application establishes a basis for concluding that there may be practice deficiencies in need of remediation prior to reactivation, the Board may require the applicant to submit to and successfully pass an examination or an assessment of skills, a refresher course, or other requirements as determined by the Board prior to reactivation of the license. If that examination or assessment identifies deficiencies or educational needs, the Board may require the applicant, as a condition of reactivation of licensure, to take and successfully complete any education or training or to submit to any supervision, monitoring, or limitations as the Board determines is necessary to assure that the applicant practices with reasonable skill and safety. The Board, in its discretion, may restore the license subject to the applicant's completion of the training within a period of time prescribed by the Board following the restoration of the license. In making its determination whether there are practice deficiencies requiring remediation, the Board shall consider the following non-exhaustive issues:

1. Length of time license was inactive;

2. Employment history;

3. Professional history;

4. Disciplinary history and any action taken against the applicant's license or registration by any licensing board;

5. Actions affecting the applicant's privileges taken by any institution, organization, or employer related to the practice of pharmacy or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction;

6. Pending proceedings against a professional or occupational license issued to the licensee by a professional board in New Jersey, any other state, the District of Columbia, or in any other jurisdiction; and

7. Civil litigation related to the practice of pharmacy or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction.

13:39-3.9 License reinstatement from administrative and disciplinary license suspensions

(a) A licensee who has had his or her license administratively suspended pursuant to N.J.A.C. 13:39-3.7(e) may apply to the Board for reinstatement. A licensee applying for reinstatement shall submit:

1. A reinstatement application;

2. A certification of employment listing each job held during the period of suspended license, which includes the names, addresses, and telephone number of each employer;

3. The renewal fee for the biennial period for which reinstatement is sought;

4. The past due renewal fee for the biennial period immediately preceding the renewal period for which reinstatement is sought;

5. The reinstatement fee set forth in N.J.A.C. 13:39-1.3; and

6. Evidence of having completed all continuing education credits that were required to be completed during the biennial period immediately prior to the renewal period for which reinstatement is sought, consistent with the requirements set forth in N.J.A.C. 13:39-1.3.

i. An applicant who holds a valid, current license in good standing issued by another state to engage in the practice of pharmacy and submits proof of having satisfied that state's continuing education requirements for that license, shall be deemed to have satisfied the requirements of this paragraph. If the other state does not have any continuing education requirements, the requirements of this paragraph apply.

(b) If a Board review of an application establishes a basis for concluding that there may be practice deficiencies in need of remediation prior to reinstatement, the Board may require the applicant to submit to and successfully pass an examination or an assessment of skills, a refresher course, or other requirements as determined by the Board prior to reinstatement of the

license. If that examination or assessment identifies deficiencies or educational needs, the Board may require the applicant as a condition of reinstatement of licensure to take and successfully complete any education or training or to submit to any supervision, monitoring, or limitations as the Board determines is necessary to assure that the applicant practices with reasonable skill and safety. The Board, in its discretion, may restore the license subject to the applicant's completion of the training within a period of time prescribed by the Board following the restoration of the license. In making its determination whether there are practice deficiencies requiring remediation, the Board shall consider the following non-exhaustive issues:

1. Length of time license was suspended;

2. Employment history;

3. Professional history;

4. Disciplinary history and any action taken against the applicant's license by any licensing board;

5. Actions affecting the applicant's privileges taken by any institution, organization, or employer related to the practice of pharmacy or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction;

6. Pending proceedings against a professional or occupational license/registration or certificate issued to the licensee by a professional board in New Jersey, any other state, the District of Columbia, or in any other jurisdiction; and

7. Civil litigation related to the practice of pharmacy or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction.

(c) A pharmacist who has had his or her license suspended pursuant to disciplinary action taken by the Board may apply to the Board for reinstatement of his or her license at the conclusion of the suspension period. A pharmacist applying for reinstatement from a disciplinary suspension shall submit:

1. A reinstatement application, including an affidavit of employment listing each job held during the period of license suspension, including the names, addresses, and telephone numbers of each employer;

2. A reinstatement fee set forth in N.J.A.C. 13:39-1.3;

3. The applicable renewal fee(s) set forth in N.J.A.C. 13:39-1.3; and

4. Evidence of having met all conditions imposed by the Board pursuant to the disciplinary and/or reinstatement order(s).

13:39-3.10 Steering prohibited

It shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions, or any institution, facility, or entity that provides health

care services, for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

SUBCHAPTER 3A. CONTINUING EDUCATION

13:39-3A.1 Continuing education credit hour requirements

(a) Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of [page=3769] continuing education credits for an applicant's initial license renewal. At least 10 of the continuing education credits shall be obtained through didactic instruction. For purposes of this subsection, "didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction. At least three continuing education credits shall be obtained in pharmacy law applicable to the practice of pharmacy in New Jersey. Commencing with the biennial renewal period beginning on May 1, 2017, at least one of the 30 continuing education credits shall, pursuant to P.L. 2017, c. 28, be in educational programs or topics concerning prescription opioid drugs, including alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. This one credit shall not be eligible for carry-over as described in (b) below.

1. In accordance with P.L. 2017, c. 28, if the Board deems it appropriate, on an individual basis, the Board may waive the specific one credit continuing education requirement concerning prescription opioid drugs. Any such waiver request shall be filed pursuant to N.J.A.C. 13:39-3A.5.

(b) (No change.)

(c) Each applicant for biennial license renewal who is authorized to administer vaccines and related emergency medications and who seeks renewal of Board approval granted pursuant to N.J.A.C. 13:39-4.21 shall complete the continuing education requirements set forth in that section. The Board shall consider these hours of continuing education towards the total number of credits required in (a) above.

(d) Each applicant for biennial license renewal who is granted authorization to engage in collaborative drug therapy management shall complete the continuing education requirements set forth in N.J.A.C. 13:39-13.3. The Board shall consider these hours of continuing education towards the total number of credits required in (a) above.

13:39-3A.4 Continuing education credit hour reporting procedure

(a) (No change.)

(b) A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of:

1. For programs offered by American Council of Pharmaceutical Education approved providers, a certificate of completion from the course or program or a transcript from the National Association of Boards of Pharmacy CPE Monitor;

2.-7. (No change.)

(c) (No change.)

13:39-3A.6 Responsibilities of continuing education sponsors

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

(f) The continuing education sponsor shall monitor attendance at, or ensure completion of, each approved program or course and furnish to each enrollee a verification of attendance which shall include at least the following information:

1. The title, date, start and end time, and location of the program or course offering;

2.-5. (No change.)

(g) The continuing education sponsor shall submit the fee set forth at N.J.A.C. 13:39-1.3 for each submission of program or course offerings.

(h) (No change.)

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39-4.1 New pharmacies; pharmacy departments; eligibility and application

(a)-(g) (No change.)

(h) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock. A pharmacy shall not sell, dispense, or distribute any prescription drugs or devices until the pharmacy is open for business.

(i) Within 90 days of the Board's approval of the permit application, the pharmacy shall notify the Board in writing that the pharmacy has opened for business. If additional time beyond the 90 days is needed to open the pharmacy, no less than 30 days prior to the expiration of the 90-day period, the pharmacy shall submit a written request to the Board for an extension of time. Such request shall include the reasons an extension is necessary and the amount of additional time sought. If after the expiration of the 90 days, the pharmacy has not notified the Board that it has opened for business or requested an extension, the Board shall rescind the pharmacy permit. Following such action, an applicant making reapplication to the Board shall resubmit all required documentation and the applicable application fee set forth at N.J.A.C. 13:39-1.3.

13:39-4.2 Issuance of permits; permit renewals

(a) (No change.)

(b) A permit holder shall submit to the Board, on an annual basis, within 30 days after the permit expiration, a renewal application and the renewal fee set forth in N.J.A.C. 13:39-1.3. A permit

holder that fails to submit the renewal application within 30 days after the permit expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3 in addition to the renewal fee. A permit holder that continues to engage in the practice of pharmacy with an expired permit shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(c) (No change.)

13:39-4.3 Display of permits

The current permit issued by the Board for the operation of a pharmacy shall be conspicuously displayed in view of the public.

13:39-4.4 Death of owner or partner

In the case of death of an individual owner or a partner, the permit issued to the deceased owner or to the partnership is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.10. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and/or the remaining partners shall comply with the requirements set forth at N.J.A.C. 13:39-4.5.

13:39-4.5 Change of ownership; asset acquisition

(a) When there is a change in the ownership of a pharmacy or in the ownership of the business entity holding the pharmacy permit, the following requirements shall be satisfied, as applicable:

1. If there is a complete change in ownership, the new owner(s) shall, within 30 days after the change, submit to the Board a permit application for change of ownership pursuant to N.J.A.C. 13:39-4.1, the permit application fee set forth in N.J.A.C. 13:39-1.3, and documentation evidencing the change of ownership. The new owner(s) shall perform an inventory of the pharmacy's controlled substances consistent with the requirements of N.J.A.C. 13:45H-5.4 and 5.5, which shall be made available to the Board upon request. A new permit number shall be issued if a request is made at the time of the filing of the permit application;

2. If there is a change of registered agents or officers, the business entity shall, within 30 days after the change, submit to the Board an affidavit indicating the changes that have taken place and any other information requested by the Board;

3. If there is a change of stock ownership involving 10 percent or more of the outstanding stock of a publicly traded corporation, the corporation shall, within 30 days after the change, submit to the Board an affidavit indicating the changes that have taken place and any other information requested by the Board; and

4. If a reallocation of ownership interests occurs among existing owners, the owners shall, within 30 days after the change, submit to the Board an affidavit explaining the asset reallocation.

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

13:39-4.6 (Reserved)

13:39-4.7 Change of location and/or address of licensed premises

(a) When a pharmacy permit holder intends to change the physical location and address of the permitted premises, the permit holder shall apply to the Board, at least 30 days prior to such change, for a new pharmacy permit. If the change in location and address will result in the temporary closing of the pharmacy, the permit holder shall comply with [page=3770] all requirements set forth at N.J.A.C. 13:39-4.12(c) and (d). The permit holder shall submit a new permit application pursuant to N.J.A.C. 13:39-4.1 and the new permit application fee set forth in N.J.A.C. 13:39-1.3. The Board shall issue an amended pharmacy permit reflecting the new location and address of the pharmacy. Before an amended permit may be issued to the permit holder for the new location, the Board shall inspect and approve the premises, fixtures, equipment, and inventory of the new location to ensure compliance with this subchapter and all relevant statutes, regulations, and ordinances. The permit holder shall ensure that the prescription and profile records from the pharmacy's previous location and address are maintained pursuant to N.J.A.C. 13:39-7.6 and 7.19 after the location and address change.

(b) (No change.)

13:39-4.11 Availability of records upon termination of business or change of ownership

(a) When a pharmacy ceases operation as the result of a suspension, retirement, or death of the owner, sale, or other cause including insolvency, the permit holder, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons that they have the right to obtain copies of currently valid prescriptions and/or copies of their patient profile and the location of the prescriptions and patient profile for a one-year period following notice, using all of the following methods:

1. (No change.)

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the geographic area in which the pharmacy is located, of a notice advising patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile for a one-year period following publication;

3. A sign placed in the pharmacy location informing the patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile; and

4. For a ***permitted*** pharmacy that uses social media ***that is specific to individually identified locations***, the pharmacy shall post notice on all social media platforms used by the pharmacy informing patrons of the pharmacy closure, that they have a right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile. The pharmacy shall also discontinue and remove all commercial advertising from social media sites.

(b) Upon a sale of assets or a change in ownership pursuant to N.J.A.C. 13:39-4.5(a), both the new and former pharmacy permit holders shall ensure that there is access to patient prescription

and profile records within 24 hours of the transfer of business assets, and that all telephone calls to the former pharmacy shall be forwarded to the new pharmacy.

13:39-4.15 Security of pharmacies and pharmacy departments

(a)-(b) (No change.)

(c) In addition to the requirements set forth in (b) above, the holder of a pharmacy department permit and the pharmacist-in-charge of the pharmacy department shall also ensure that:

1.-2. (No change.)

3. If the pharmacy department has a published telephone number that is the same as the one for the establishment in which the department is located, the caller is able to select the service or department to which he or she wants to be connected; and

4. (No change.)

(d) (No change.)

13:39-4.17 Steering prohibited

It shall be unlawful for a pharmacy permit holder to enter into an arrangement with a practitioner, or any institution, facility, or entity that provides health care services, for the purpose of directing or diverting patients to or from a specified pharmacy for the filling of prescriptions or restraining in any way a patient's freedom of choice to select a pharmacy.

13:39-4.19 Procedures for centralized prescription handling

(a)-(c) (No change.)

(d) Two or more of the pharmacies delineated in (c) above may engage in central prescription handling provided:

1.-3. (No change.)

4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:

i. The brand name, or if a generic, the brand name, if still available in the marketplace, and the name of the generic in the following form, with the generic name and brand name inserted as appropriate:

"---------- Generic for ----------"

If the brand name is not still available in the marketplace, the generic name.

ii.-x. (No change.)

xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist;

xii. The name, address, and telephone number of any or all of the following:

(1)-(3) (No change.)

(4) The dispensing pharmacy; and

xiii. For substituted biological products, the information required in N.J.A.C. 13:39-7.23(d).

5.-9. (No change.)

(e) (No change.)

13:39-4.20 Out-of-State pharmacy registration

(a)-(b) (No change.)

(c) An out-of-State pharmacy seeking to register with the Board shall submit a completed application for registration to the Board, which shall include the following:

1.-3. (No change.)

4. A dated copy of the most recent inspection report resulting from an inspection within the past two years of the out-of-State pharmacy conducted by the regulatory or licensing agency in the state in which the pharmacy is located;

5. (No change.)

6. The application fee specified in N.J.A.C. 13:39-1.3.

(d) (No change.)

(e) An out-of-State pharmacy registered with the Board shall submit on an annual basis, prior to the expiration of the registration, a renewal application which shall contain the information set forth in (c)1 through 5 above, and the renewal fee set forth in N.J.A.C. 13:39-1.3. A registered out-of-State pharmacy that fails to submit the renewal application within 30 days after the registration expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3 in addition to the renewal fee. An out-of-State pharmacy that continues to ship, mail, distribute, or deliver legend drugs or devices or controlled dangerous substances into the State, or continues to participate in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.19, with an expired registration shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(f) An out-of-State pharmacy registered with the Board shall submit an application for registration pursuant to (c) above and the fee set forth in N.J.A.C. 13:39-1.3, within 30 days after the following:

1. A complete change in ownership. The new owner(s) shall also submit documentation evidencing the change of ownership. A new registration number shall be issued if a request is made at the time of the filing of the application;

2. A change in the location of the licensed, permitted, or registered pharmacy; or

3. A change in the name of the licensed, permitted, or registered pharmacy.

(g) An out-of-State pharmacy registered with the Board shall submit to the Board an affidavit indicating the changes that have taken place and any other information requested by the Board within 30 days after the following, as applicable:

1. A change of registered agents or officers;

2. A change of stock ownership involving 10 percent or more of the outstanding stock of a publicly traded corporation;

3. A reallocation of ownership interests among existing owners; or

[page=3771] 4. A change in the pharmacist-in-charge. When there is a change in the pharmacist-in-charge, the affidavit shall contain the information set forth in (c)3 above.

(h) An out-of-State pharmacy may obtain a replacement registration upon payment of the fee specified in N.J.A.C. 13:39-1.3 and upon submission of an affidavit describing the loss or destruction of the registration originally issued, or upon return of the damaged permit.

Recodify existing (h)-(k) as (i)-(l) (No change to text.)

13:39-4.21 Procedures for physician ordered or government sponsored immunizations performed by pharmacists

(a) (No change.)

(b) In order to administer vaccines and related emergency medications pursuant to this section, a licensed pharmacist shall be pre-approved by the Board to perform such functions. In order to obtain such prior Board approval, a pharmacist shall submit documentation to the Board that establishes that he or she has satisfied the following education and training requirements:

1. Completion of an academic and practical curriculum that includes instruction in Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Chapter 6, Vaccine Administration, of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 13th edition, 2015. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html. The instruction shall be offered by a provider accredited by the Accreditation Council for Pharmacy Education (ACPE). The curriculum shall include the following subjects:

i. (No change.)

ii. CDC Guideline for Infection Control in Health Care Personnel (1998). The CDC Guideline for Infection Control in Health Care Personnel (1998) are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/hicpac/pdf/infectcontrol98.pdf;

iii.-xiii. (No change.)

2. Current certification in the American Heart Association Basic Life Support (BLS) protocol, the Red Cross Adult Cardiac Pulmonary Resuscitation (CPR) protocol for health care providers or in a course that complies with guidelines created by the International Liaison Committee on Resuscitation (ILCOR). The ILCOR guidelines, 2010 International Consensus on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC) Science with Treatment Recommendations, are incorporated herein by reference, as amended and supplemented, and can be found at the American Heart Association website, http://americanheart.org/presenter.jhtml?identifier=3022512, specifically, http://circ.ahajournals.org/content/122/16_suppl_2/S250; and

3. (No change.)

(c)-(m) (No change.)

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39-5.3 Pharmacy signs

(a) (No change.)

(b) Pharmacies shall post the hours that the pharmacy is open and the name of the pharmacist-in-charge in plain view of the public at all consumer entrances and consumer access points to the pharmacy, including drive-thru windows and drop-off boxes.

(c) In the case of a pharmacy department, the hours that the department is open and the name of the pharmacist-in-charge shall be posted in plain view of the public at the entrance to the department and at all consumer entrances and consumer access points to the premises, including drive-thru windows and drop-off boxes. When the premises in which the pharmacy department is located maintains different hours of operation from the pharmacy department, all advertising, announcements, signs and statements indicating hours of operation and the presence of the pharmacy department shall clearly and distinctly indicate the hours that the pharmacy department is open.

13:39-5.5 Prescription counter

Pharmacies shall contain a prescription counter or counters on which to work, including sufficient space for workstation equipment, and the free working space shall not be less than 18 inches in width and not less than 12 total feet in length. This minimum working surface shall be kept clear at all times for the processing and/or compounding of prescriptions.

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. The most recent edition of comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the pharmaceutical services provided by the pharmacy, drug interactions, drug product composition and patient counseling. Unabridged electronic versions of such reference texts shall be acceptable;

2.-11. (No change.)

12. The signage required pursuant to N.J.S.A. 24:6E-10, the 29th edition of the list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," which is incorporated herein by reference, as amended and supplemented. The Orange Book can be obtained by contacting the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954, (202) 512-1800 or toll free (866) 512-1800, and is available online at http://www.fda.gov/cder/orange/default.htm and at http://www.fda.gov/cder/ob/default.htm, and the lists of "Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," commonly known as the "Purple Book," which is incorporated herein by reference, as amended and supplemented. The Purple Book can be found online at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars;

13.-14. (No change.)

(b) All prescription areas where non-sterile compounding is performed shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1.-3. (No change.)

4. Stirring rods; and

5. Ointment tile or parchment paper.

(c) (No change.)

SUBCHAPTER 6. PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

13:39-6.2 Pharmacist-in-charge

(a)-(c) (No change.)

(d) Whenever there is a change of a pharmacist-in-charge of a pharmacy, an inventory of all controlled dangerous substances as defined in N.J.A.C. 13:45H-10.1 shall be performed by both the outgoing and incoming pharmacist-in-charge consistent with the requirements of N.J.A.C. 13:45H-5.4 and 5.5.

1. If the outgoing pharmacist-in-charge is unable to perform the inventory required in (d) above, the pharmacy permit holder shall designate an alternative pharmacist, other than the incoming pharmacist-in-charge, to perform the inventory and shall submit to the Board a documented explanation for choosing an alternate pharmacist.

(e) Whenever a pharmacist assumes or terminates the duties as a pharmacist-in-charge of a pharmacy, both the outgoing and incoming pharmacist-in-charge and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(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.-3. (No change.)

4. Security of the prescription area and its contents are maintained at all times consistent with the requirements set forth in N.J.A.C. 13:39-4.15;

5.-10. (No change.)

[page=3772] (g) The pharmacist-in-charge is responsible for the accuracy and completeness of the biennial inventory of all controlled dangerous substances required under N.J.A.C. 13:45H-5.5, and shall sign and date the biennial inventory upon its completion. This requirement applies whether the inventory is conducted by the pharmacist-in-charge or another licensed pharmacist.

13:39-6.3 Identification tag

All personnel working at any pharmacy practice site, except personnel engaging in the compounding of sterile preparations consistent with the requirements of N.J.A.C. 13:39-11, shall wear an identification tag, which shall include at least the person's first name, first initial of their last name, and job title. The identification tag of any employee in training shall reflect the status of the employee as a trainee.

13:39-6.5 Prescription handling by pharmacy externs, pharmacy interns, pharmacy technicians, pharmacy technician applicants, or unlicensed or unregistered personnel

(a) A pharmacy intern, pharmacy extern, pharmacy technician, or pharmacy technician applicant in any pharmacy may perform the component functions of prescription handling described in N.J.A.C. 13:39-4.19, consistent with the requirements of this chapter. All steps performed by a pharmacy technician, pharmacy technician applicant, pharmacy intern, or pharmacy extern shall be documented in the pharmacy audit trail consistent with the requirements of N.J.A.C. 13:39-7.6.

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

13:39-6.6 Pharmacy technician registration and pharmacy technician applicants

(a) (No change.)

(b) A pharmacy shall only employ a person registered with the Board as a pharmacy technician pursuant to (a) above, or a pharmacy technician applicant, consistent with (c) below, to perform pharmacy technician functions.

(c) Any person who is hired as a pharmacy technician who is not registered with the Board shall be designated a pharmacy technician applicant. A person may only be considered a pharmacy technician applicant one time and only for a maximum of 180 consecutive days. During the first 10 days of employment, the pharmacy technician applicant shall file an application with the Board to begin the pharmacy technician registration process. The applicant shall retain proof of filing the application until he or she receives his or her registration. If at the conclusion of the

180-day period, the pharmacy technician applicant has not completed the pharmacy technician registration process, consistent with (a) above, the applicant shall cease performing pharmacy technician functions in the pharmacy.

Recodify existing (e)-(f) as (d)-(e) (No change in text.)

13:39-6.7 Authorization to practice as a pharmacy technician; display of registration

(a) (No change.)

(b) Upon issuance, the current biennial renewal registration shall be conspicuously displayed in view of the public in the registered pharmacy technician's principal place of employment.

(c) (No change.)

13:39-6.13 Pharmacy technician registration renewal

(a) The Board shall send a notice of renewal to each pharmacy technician registrant, at least 60 days prior to the expiration of the registration. The notice of renewal shall explain inactive renewal and advise the registrant of the option to renew as inactive. If the notice to renew is not sent 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew provided that the registration is renewed within 60 days from the date the notice is sent or within 30 days following the date of registration expiration, whichever is later.

(b) A pharmacy technician shall renew his or her registration for a period of two years from the last expiration date. The pharmacy technician shall submit a renewal application to the Board, along with the renewal fee set forth in N.J.A.C. 13:39-1.3, prior to the date of registration expiration.

(c) A pharmacy technician may renew his or her registration by choosing inactive status. A pharmacy technician electing to renew his or her registration as inactive shall not perform the functions of a pharmacy technician, or hold himself or herself out as eligible to perform the functions of a pharmacy technician, in New Jersey until such time as the registration is returned to active status.

(d) If a pharmacy technician does not renew the registration prior to its expiration date, the pharmacy technician may renew the registration within 30 days of its expiration by submitting a renewal application, a renewal fee, and a late fee as set forth in N.J.A.C. 13:39-1.3. During this 30-day period, the registration shall be valid and the pharmacy technician shall not be deemed practicing without a registration.

(e) A pharmacy technician who fails to submit a renewal application within 30 days of registration expiration shall have his or her registration suspended without a hearing.

(f) A pharmacy technician who continues to perform the functions of a pharmacy technician with a suspended registration shall be deemed to be engaging in unauthorized practice and shall be subject to action consistent with N.J.S.A. 45:1-14 et seq., even if no notice of suspension has been provided to the individual.

13:39-6.14 Pharmacy technician registration reactivation

(a) A pharmacy technician who holds an inactive registration pursuant to N.J.A.C. 13:39-6.13(c) may apply to the Board for reactivation of the inactive registration. A pharmacy technician seeking reactivation of an inactive registration shall submit:

1. A renewal application;

2. A certification of employment listing each job held during the period the registration was inactive, which includes the name, address, and telephone number of each employer; and

3. The renewal fee for the biennial period for which reactivation is sought as set forth in N.J.A.C. 13:39-1.3.

i. If the renewal application is sent during the first year of the biennial period, the applicant shall submit the renewal fee as set forth in N.J.A.C. 13:39-1.3.

ii. If the renewal application is sent during the second year of the biennial period, the applicant shall submit one-half of the renewal fee as set forth in N.J.A.C. 13:39-1.3.

(b) If a Board review of an application establishes a basis for concluding that there may be practice deficiencies in need of remediation prior to reactivation, the Board may require the applicant to submit to and successfully pass an examination or an assessment of skills, a refresher course, or other requirements as determined by the Board prior to reactivation of the registration. If that examination or assessment identifies deficiencies or educational needs, the Board may require the applicant as a condition of reactivation of the registration to take and successfully complete any education or training or to submit to any supervision, monitoring, or limitations as the Board determines is necessary to assure that the applicant practices with reasonable skill and safety. The Board, in its discretion, may restore the registration subject to the applicant's completion of the training within a period of time prescribed by the Board following the restoration of the registration. In making its determination whether there are practice deficiencies requiring remediation, the Board shall consider the following non-exhaustive issues:

1. Length of time registration was inactive;

2. Employment history;

3. Professional history;

4. Disciplinary history and any action taken against the applicant's license or registration by any licensing board;

5. Actions affecting the applicant's privileges taken by any institution, organization, or employer related to the practice of a pharmacy technician or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction;

6. Pending proceedings against a professional or occupational license issued to the pharmacy technician by a professional board in New Jersey, any other state, the District of Columbia, or in any other jurisdiction; and

[page=3773] 7. Civil litigation related to the practice of a pharmacy technician or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction.

13:39-6.14A Pharmacy technician registration reinstatement from administrative and disciplinary suspensions

(a) A pharmacy technician who has had his or her registration administratively suspended pursuant to N.J.A.C. 13:39-6.13(e) may apply to the Board for reinstatement. A pharmacy technician applying for reinstatement shall submit:

1. A reinstatement application;

2. A certification of employment listing each job held during the period of suspended registration, which includes the names, addresses, and telephone number of each employer;

3. The renewal fee for the biennial period for which reinstatement is sought;

4. The past due renewal fee for the biennial period immediately preceding the renewal period for which reinstatement is sought; and

5. The reinstatement fee set forth in N.J.A.C. 13:39-1.3.

(b) If a Board review of an application establishes a basis for concluding that there may be practice deficiencies in need of remediation prior to reinstatement, the Board may require the applicant to submit to and successfully pass an examination or an assessment of skills, a refresher course, or other requirements as determined by the Board prior to reinstatement of the registration. If that examination or assessment identifies deficiencies or educational needs, the Board may require the applicant as a condition of reinstatement of the registration to take and successfully complete any education or training or to submit to any supervision, monitoring, or limitations as the Board determines is necessary to assure that the applicant practices with reasonable skill and safety. The Board, in its discretion, may restore the registration subject to the applicant's completion of the training within a period of time prescribed by the Board following the restoration of the registration. In making its determination whether there are practice deficiencies requiring remediation, the Board shall consider the following non-exhaustive issues:

1. Length of time registration was suspended;

2. Employment history;

3. Professional history;

4. Disciplinary history and any action taken against the applicant's license or registration by any licensing board;

5. Actions affecting the applicant's privileges taken by any institution, organization, or employer related to the practice of a pharmacy technician or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction;

6. Pending proceedings against a professional or occupational license, registration, or certificate issued to the pharmacy technician by a professional board in New Jersey, any other state, the District of Columbia, or in any other jurisdiction; and

7. Civil litigation related to the practice of a pharmacy technician or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or in any other jurisdiction.

(c) A pharmacy technician who has had his or her registration suspended pursuant to disciplinary action taken by the Board may apply to the Board for reinstatement of his or her registration at the conclusion of the suspension period. A pharmacy technician applying for reinstatement from a disciplinary suspension shall submit:

1. A reinstatement application, including an affidavit of employment listing each job held during the period of registration suspension, including the names, addresses, and telephone numbers of each employer;

2. A reinstatement fee set forth in N.J.A.C. 13:39-1.3;

3. The applicable renewal fee(s) set forth in N.J.A.C. 13:39-1.3; and

4. Evidence of having met all conditions imposed by the Board pursuant to the disciplinary and/or reinstatement order(s).

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.5 Approval of FDA necessary

(a) No drug or medicine other than a compounded prescription order, consistent with (c) below, shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Investigational New Drug Application (INDA) or other Federal Food and Drug Administration (FDA) approval, where required.

(b) The storage, labeling, and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of such drugs shall not be construed to be a violation of (a) above. A pharmacy participating in experimental research shall comply with Federal Department of Health and Human Services regulations set forth at 45 CFR Part 46, Protection of Human Subjects of Research, incorporated by reference herein, as amended and supplemented and with the Rowan University Guidance on Human Subjects Research, which is incorporated herein by reference, as amended and supplemented, and which is available at http://www.rowan.edu/som/hsp/guidance/index.html.

(c) No pharmacy or pharmacist shall compound products prohibited by the FDA or use ingredients that are restricted by the FDA.

13:39-7.6 Required records and documents

(a) A pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s), or extern(s) performing the component functions of intake, processing, fulfillment, and dispensing of prescriptions as defined in N.J.A.C. 13:39-4.19, which are required to be performed by a pharmacist, pharmacy technician, intern, or extern pursuant to the requirements of this chapter. The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)3 is not required to be, but may be, recorded in the audit trail.

(b) All entries to the audit trail made by a pharmacy technician, intern, or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, each pharmacist shall be responsible for the accuracy and appropriateness of each component function he or she performed or reviewed and approved, and his or her unique and secure user identifier(s) shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each component function(s) is performed.

Recodify existing (b)-(e) as (c)-(f) (No change in text.)

13:39-7.7 Copies of prescriptions and/or patient profile

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions and/or patient profile. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY--FOR INFORMATION ONLY." For purposes of this section, ***for requests for prescriptions that are one year or less from the original date of filling,*** "immediately" shall not exceed 24 hours. ***For all other prescriptions, "immediately" shall not exceed 72 hours.***

(b) (No change.)

13:39-7.8 Transfer of prescriptions between pharmacies

(a) When a patient, the patient's caregiver, or a pharmacy acting on behalf of a patient or caregiver requests the transfer of a valid prescription between pharmacies, a pharmacy, the registered pharmacist-in-charge, and the pharmacist who receives the request for transfer shall immediately comply with the patient's request. For purposes of this section, "immediately" shall not exceed four hours.

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

(d) A prescription for a Schedule III, IV, or V controlled substance may be transferred between pharmacies pursuant to N.J.A.C. 13:45H-7.18. A prescription for a Schedule III, IV, or V controlled substance that has been transferred shall not be transferred a second time. This prohibition shall not apply to the transfer of such prescriptions between [page=3774] pharmacies engaged in central prescription handling pursuant to N.J.A.C. 13:39-4.18(e) and to pharmacies that share a real-time, online database consistent with the requirements of 21 CFR 1306.25.

(e) (No change.)

13:39-7.11 Electronically transmitted prescriptions

(a)-(d) (No change.)

(e) An electronic prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-7.2(d), except that a handwritten original signature and an NJPB shall not be required for the prescription. An electronic prescription for a Schedule II controlled substance shall not be required to include words, in addition to numbers, to indicate the drug quantity authorized. Consistent with the requirements of N.J.A.C. 13:35-7.4A, the practitioner's electronic signature or other secure method of validation shall be provided with the electronic prescription unless the prescription is transmitted by the practitioner's authorized agent. If transmitted by an authorized agent, the full name and title of the agent shall be included on the transmission and the agent shall not sign the prescription.

(f)-(m) (No change.)

13:39-7.12 Labeling

(a) The dispensed container for any product shall bear a permanently affixed label with at least the following information:

1.-2. (No change.)

3. The brand name, or if a generic, the brand name, if still available in the marketplace, and the name of the generic in the following form, with the generic name and brand name inserted as appropriate:

"---------- Generic for ----------"

If the brand name is not still available in the marketplace, the generic name.

4.-10. (No change.)

11. Directions for use;

12. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging.

i. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container; and

13. For substituted biological products, the information required in N.J.A.C. 13:39-7.23(d).

(b)-(d) (No change.)

13:39-7.16 Return of prescription medication

(a)-(b) (No change.)

(c) For purposes of this subsection, a prescription medication shall be considered to be abandoned when a prescription is prepared and made available for dispensing by the pharmacy but is not dispensed to the patient for whom it was prepared within two weeks. Prescription medication that has been prepared for a patient and that is abandoned by a patient, or that has not been dispensed by a long-term care pharmacy to a patient in a long-term care facility, may be placed back in stock for reuse or resale provided that:

1. In the professional judgment of the pharmacist, the prescription medication is eligible for re-dispensing. Eligible medications are those medications that are able to be consumed by a patient within the original time frame established for the medication's stability and expiration, were maintained under proper storage conditions to ensure their integrity, and have remained under the exclusive control and custody of the pharmacy or the patient's long-term care facility, as applicable, at all times. Products that have a limited shelf life and/or that have not been stored consistent with manufacturers' storage requirements may not be re-dispensed;

2.-5. (No change.)

6. Medications held for re-dispensing shall be used as soon as possible. Such medications, lacking original lot numbers and expiration dates, shall not be dispensed to patients later than one year from the date the medications were originally prepared for dispensing. Re-dispensed medications shall be marked with the same use by date as the medication which was originally prepared for dispensing.

13:39-7.19 Patient profile record system

(a) An electronic patient profile system shall be maintained by all pharmacies for persons for whom prescriptions are dispensed. The Patient Profile Record System (PPRS) shall be devised, so as to enable the immediate retrieval of current clinical information necessary to enable the dispensing pharmacist to identify previously dispensed medication and patient specific information at the time a prescription is presented for dispensing.

(b)-(h) (No change.)

13:39-7.21 Patient counseling

(a)-(b) (No change.)

(c) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling.

(d) (No change.)

(e) At the time of dispensing, the pharmacist shall document by obtaining the signature of the patient or caregiver that counseling was provided or refused.

(f) (No change in text.)

13:39-7.22 Accurate processing and dispensing

A pharmacist shall be responsible for the processing, accuracy, appropriateness, and dispensing of the filled prescription.

13:39-7.23 Biological products

(a) A pharmacist may substitute a biological product for a prescribed biological product, provided that the following conditions are met:

1. The authorized prescriber has not indicated that there shall be no substitution as set forth in N.J.S.A. 24:6E-7; and

2. The biological product to be substituted has been determined by the Federal Food and Drug Administration (FDA) to be:

i. Interchangeable with the prescribed biological product; or

ii. Therapeutically equivalent to the prescribed biological product.

(b) If a pharmacist dispenses a biological product, the pharmacist or the pharmacist's designee shall, within five business days following the dispensing of the biological product, communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. No communication shall be required under this subsection when:

1. There is no biological product that has been determined by the FDA to be either:

i. Interchangeable with the product prescribed; or

ii. Therapeutically equivalent to the product prescribed; or

2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(c) The communication requirement under (b) above may be satisfied by making an entry in an interoperable electronic medical records system or an electronic pharmacy record that can be accessed electronically by the prescriber, or through the use of another electronic prescribing technology that can be accessed electronically by the prescriber. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, the communication may be conveyed using other electronic means, if available, or by facsimile.

(d) A pharmacist who substitutes a biological product in compliance with this section shall record, on the prescription label and record of dispensing, the product name and manufacturer of the biological product dispensed, followed by the words: "Substituted for" and the name of the biological product for which the prescription was written.

(e) The recordkeeping requirements of this subchapter and N.J.A.C. 13:39-9, as applicable, which apply to the dispensing of drugs shall apply to the dispensing of biological products.

(f) The Board shall maintain a link to the current list of all biological products determined by the FDA to be interchangeable pursuant to section 351 of the Public Health Service Act (42 U.S.C. § 262) on the Board's website.

[page=3775] SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

13:39-9.2 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

…

"Health care facility" means a facility or institution licensed by the Department of Health pursuant to N.J.S.A. 26:2H-1 et seq.

…

13:39-9.6 Pharmacy and Therapeutics Committee; applicability; policies and procedures

(a) In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established if required pursuant to Department of Health rules. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

(b) In all health care facilities providing pharmaceutical services to patients that are not required to maintain a Pharmacy and Therapeutics Committee pursuant to Department of Health rules, the pharmacist-in-charge of the provider pharmacy, in cooperation with the health care facility, shall create policies and procedures as needed to provide pharmaceutical services to the health care facility. Copies of the policies and procedures shall be made available to the Board upon request.

13:39-9.10 Pharmaceuticals; drug supply; investigational drugs; controlled dangerous substances

(a)-(b) (No change.)

(c) Written policies and procedures for the control, use, and accountability of Investigational New Drugs shall be developed by the pharmacist-in-charge and the Pharmacy and Therapeutics Committee. The storage, labeling, and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters, the dispensing of these drugs shall not be construed to be a violation of N.J.A.C. 13:39-7.5(a). A facility participating in experimental research involving residents shall comply with Federal Department of Health and Human Services regulations, set forth at 45 CFR Part 46, Protection of Human Subjects of Research, which is incorporated by reference herein, as amended and supplemented and with the Rowan University Guidance on Human Subjects Research, which is incorporated herein by reference, as amended and supplemented, and which is available at http://www.rowan.edu/som/hsp/guidance/index.html.

(d) (No change.)

13:39-9.11 Drug disbursement; written orders

(a)-(c) (No change.)

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use in accordance with health care facility policies and, where applicable, pursuant to regulations of the Department of Health and/or Centers for Medicare and Medicaid Services.

13:39-9.18 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the pharmacist-in-charge and shall comply with the following requirements:

1.-3. (No change.)

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and cosigned and witnessed by a licensed nurse, physician, or pharmacist, or where allowed by Department of Health rules an administrator of the health care facility, and disposed of by the health care facility according to its written protocol and consistent with all local, State, and Federal laws and regulations.

13:39-9.19 Records and reports

(a) Records of the pharmaceutical services of the provider pharmacy for the facility shall be the responsibility of the pharmacist-in-charge. A pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s), or extern(s) performing the component functions of intake, processing, fulfillment, and dispensing of prescriptions as defined in N.J.A.C. 13:39-4.19, which are required to be performed by a pharmacist, pharmacy technician, intern, or extern pursuant to the requirements of this chapter. The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)2i is not required to be, but may be, recorded in the audit trail. All entries to the audit trail made by a pharmacy technician, intern, or extern shall be reviewed and approved by the pharmacist. The pharmacist shall be responsible for the accuracy and appropriateness of the filled prescription. When more than one pharmacist is involved in the component functions of prescription handling, each pharmacist shall be responsible for the accuracy and appropriateness of each component function he or she performed or reviewed and approved, and his or her unique and secure user identifier(s) shall be recorded in an audit trail. Audit trail documentation shall be generated at the time the component function(s) is performed. All audit trail and medication order information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used

to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b)-(f) (No change.)

13:39-9.22 Pharmacy facilities; space

(a) (No change.)

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39-5.4 through 5.8 and 5.11.

13:39-9.23 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1.-2. (No change.)

3. The pharmacist-in-charge or, where provided for in Department of Health rules, the director of pharmaceutical services shall be responsible for all the medications in the facility.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by N.J.A.C. 13:39-5.7(b).

(b) The pharmacist-in-charge or, where provided for in Department of Health rules, the director of pharmaceutical services shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service area of the facility at least once every two months to check for expiration or use by dates, proper storage, misbranding, physical integrity, security, and accountability of all drugs. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by the pharmacy technician, intern, or extern and co-signed by his or her supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, pharmacy technicians, interns, and externs are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the health care facility.

(c) (No change.)

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

13:39-10.2 "Automated medication system" definition

As used in this subchapter, "automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, [page=3776] dispensing, and distribution of medications, and which collects,

controls, and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39-5.9 or a drug dispensing device operated pursuant to N.J.A.C. 13:39-9.17.

13:39-10.3 Authority to use automated medication system

(a) Prior to use for the first time of an automated medication system, the pharmacy shall conduct and submit to the Board a self-inspection of the automated medication system documented on a form provided by the Board. After receipt of the self-inspection, the Board shall conduct an inspection of the automated medication system. The pharmacy shall not use the system until it receives Board approval.

(b) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that the pharmacy:

1. Conducts an annual self-inspection of the automated medication system documented on a form provided by the Board. The pharmacy shall make the self-inspection available to the Board upon request;

2. Tests the automated medication system consistent with N.J.A.C. 13:39-10.6. The pharmacy shall make the results of such testing available to the Board upon request; and

3. Makes the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the self-inspection and/or of the system.

(c) The pharmacist-in-charge shall be responsible for the following:

1. Supervision of the operation of the system, or in the case of an automated medication system utilized at a location with no on-site pharmacy, the pharmacist-in-charge of the provider pharmacy shall be responsible for the supervision of the operation of the system;

2. Ensuring that there are written policies and procedures, which are reviewed and approved by the pharmacist-in-charge for system operation, safety, security, accuracy, and access, patient confidentiality and prevention of unauthorized access and malfunction, and ensuring compliance with such policies and procedures;

3. Ensuring that the pharmacy conducts an annual self-inspection of the automated medication system documented on a form provided by the Board. Such inspection shall verify that the automated medication system has been tested by the pharmacy and found to dispense accurately;

Recodify existing 2.-5. as 4.-7. (No change in text.)

SUBCHAPTER 11. COMPOUNDING STERILE PREPARATIONS IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39-11.3 Application and pre-approval requirements for compounding sterile preparations

(a) An applicant for a new pharmacy who wishes to compound sterile preparations shall satisfy all pharmacy permit application requirements set forth in N.J.A.C. 13:39-4.1. As part of the

permit application, the applicant shall submit plans detailing the physical arrangements necessary to ensure compliance with the requirements in this subchapter. An applicant for a pharmacy permit shall not compound sterile preparations at the site until receiving written approval from the Board to engage in such activities. Prior to issuing the written approval, the Board shall conduct an inspection of the pharmacy to ensure compliance with the requirements in this subchapter.

(b) The holder of an existing pharmacy permit who wishes to compound sterile preparations shall submit an amended pharmacy permit application to the Board. The amended permit application shall contain plans detailing the physical arrangements necessary to ensure compliance with the requirements in this subchapter. The holder of an existing pharmacy permit shall not compound sterile preparations at the site until receiving written approval from the Board to engage in such activities. Prior to issuing the written approval, the Board shall conduct an inspection of the pharmacy to ensure compliance with the requirements in this subchapter.

(c)-(e) (No change.)

(f) Notwithstanding the requirements of (a) through (e) above, a pharmacy permit holder or pharmacy applicant may compound sterile preparations for the sole purposes of process, equipment, ***personnel,*** and environmental testing. Any sterile preparations compounded for these purposes shall be destroyed.

(g) Approval by the Board to dispense compounded sterile preparations shall be contingent upon demonstration that, as is related to maintaining a sterile compounding environment, all environmental control and processes have been tested and validated, and all equipment has been certified, tested, and validated.

13:39-11.4 Cleanroom: use, access, location; temperature; air pressure

(a)-(c) (No change.)

(d) A pressure indicator or air velocity meter shall be installed that can be readily monitored for correct room pressurization or air velocity, respectively, consistent with the following:

1. (No change.)

2. For compounding of antineoplastic agents and other hazardous substances, the standards set forth in N.J.A.C. 13:39-11B.

(e) (No change.)

13:39-11.5 Cleanroom requirements

(a)-(f) (No change.)

(g) There shall be no dust-collection overhangs (such as ceiling utility pipes) and ledges (such as window sills) shall be avoided. All sprinkler heads shall be flush with the ceiling.

(h)-(j) (No change.)

13:39-11.6 Ante area requirements

(a) The ante area shall have appropriate environmental control devices capable of maintaining ISO class 8 air quality conditions for non-hazardous drug compounding activities.

(b) (No change.)

(c) The ante room shall continuously maintain ISO Class 8 air quality under dynamic conditions.

13:39-11.7 Buffer area requirements

(a) (No change.)

(b) The buffer area shall contain only the following:

1. (No change.)

2. Items that are nonpermeable, nonshedding, cleanable, and resistant to damage from disinfectants; and

3. (No change.)

(c)-(f) (No change.)

(g) The buffer area shall be a minimum of 100 square feet in size and shall continuously maintain ISO Class 7 air quality under dynamic conditions.

(h) (No change.)

13:39-11.8 Use of compounding aseptic isolators and compounding aseptic containment isolators located outside of a cleanroom

A pharmacy may utilize compounding aseptic isolators and compounding aseptic containment isolators not located in a cleanroom to prepare compounded sterile preparations, provided the compounding aseptic isolators and compounding aseptic containment isolators can provide isolation from the room and maintain ISO class 5 air quality during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations. Particle counts sampled approximately six to 12 inches upstream of the critical exposure site must maintain ISO class 5 air quality levels during compounding operations. Compounding personnel shall obtain documentation from the manufacturer that the compounding aseptic isolator or compounding aseptic containment isolator will meet this standard when located in worse than ISO class 7 environments. A compounding aseptic isolator and compounding aseptic containment isolator not located in a buffer area shall be located in an area that is maintained under sanitary conditions and such area shall only be traveled by persons engaging in the compounding of sterile preparations.

13:39-11.12 Pharmacist-in-charge responsibilities

(a) (No change.)

(b) The pharmacist-in-charge shall be responsible for, at a minimum, the following:

[page=3777] 1.-11. (No change.)

12. Ensuring that the pharmacy contains, in addition to the minimum reference library mandated in N.J.A.C. 13:39-5.8(a)1, the most recent edition of references pertinent to compounding sterile preparations;

13. Ensuring that records are maintained that document, at least twice daily, that appropriate controlled cold (refrigerator), controlled freezer, if applicable, and controlled room temperatures, as these terms are defined in United States Pharmacopeia 797, are maintained. Such records shall be maintained for no less than five years and shall be made available to the Board for inspection upon request;

14.-15. (No change.)

16. Maintaining a policy and procedures manual detailing the pharmacy's standard operating procedures with regard to compounded sterile preparations, consistent with the requirements of N.J.A.C. 13:39-11.23, ensuring compliance with such policies and procedures, and maintaining a written quality assurance program, consistent with the requirements of N.J.A.C. 13:39-11.24.

13:39-11.16 Training and evaluation requirements

(a)-(c) (No change.)

(d) All pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs engaging in the compounding of sterile preparations shall successfully complete an initial gloved fingertip/thumb sampling procedure prior to compounding sterile preparations. Gloved fingertip/thumb sampling shall be conducted annually for all personnel engaged in compounding low- and medium-risk level preparations and semi-annually for all personnel engaged in compounding high-risk level preparations. All initial and subsequent gloved fingertip/thumb sampling procedures shall be consistent with the standards established in USP 797, which is incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org.

(e)-(f) (No change.)

13:39-11.17 Batch preparation

(a) (No change.)

(b) Pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs shall not batch prepare compounded sterile preparations for human use without a prescription for a licensed prescriber to use in his or her practice, except to the extent permitted by Federal law. Anyone batch preparing compounds for non-human use without a prescription pursuant to this section shall comply with all requirements of N.J.A.C. 13:39-11.18 and the documentation requirements of N.J.A.C. 13:39-11.20(c).

13:39-11.18 Compounded sterile preparations for prescriber practice use

In the absence of a valid patient-specific prescription or medication order, pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs shall not prepare compounded sterile preparations for human use for a licensed prescriber to use in his or her practice, except to the extent permitted by Federal law. A pharmacy may prepare compounded sterile preparations for a licensed prescriber for non-human use in the prescriber's practice without a prescription consistent with State and Federal laws pertinent to the prescriber's health care practice.

13:39-11.19 Stability and sterility criteria and beyond-use dating

(a)-(h) (No change.)

13:39-11.24 Quality assurance program

(a) The pharmacy's quality assurance program shall require, at a minimum, that:

1.-5. (No change.)

6. Air and surface sampling for microbial organisms in ISO class 5 primary engineering controls, such as laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets, and in all other ISO classified areas shall be certified by an independent certification company once every six months and at any time when microbial contamination is suspected;

7.-9. (No change.)

10. Whenever test results indicate that the cleanroom or any primary engineering controls do not meet the standards established in this section, the pharmacy shall immediately cease using the cleanroom or primary engineering control that is out of compliance until such time that the cleanroom and/or the primary engineering control meets the requisite standards. The pharmacy shall notify the Board in writing within 48 hours of any *[environmental,]* air and/or surface sampling test results that are out of compliance. Test results indicating non-compliance with the requisite standards shall require re-evaluation of all procedures associated with the production of compounded sterile preparations in the impacted cleanroom or primary engineering control and documentation with respect to the period of time that the cleanroom and/or primary engineering control was out of compliance.

13:39-11.25 Prohibited compounding

(a) A pharmacist shall not compound preparations that contain drug products that appear on the Federal Food and Drug Administration's List of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, codified at 21 CFR 216.24.

(b) A pharmacist shall not compound any commercially available drug products unless:

1. The commercially available product is modified to produce a significant difference, in the professional judgment of the prescriber, between the compounded product for the patient and the comparable commercially available product; or

2. The commercially available product is not available from normal distribution channels in a timely manner to meet the patient's needs, and the dispensing of the compounded product has been approved by the prescriber and the patient.

(c) A pharmacist who compounds a commercially available product consistent with the requirements of (b) above shall maintain documentation of the reason for such compounding.

SUBCHAPTER 11A. COMPOUNDING NON-STERILE PREPARATIONS IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39-11A.6 Compounded non-sterile preparations for prescriber practice use

In the absence of a valid patient-specific prescription or medication order, pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs shall not prepare compounded non-sterile preparations for human use for a licensed prescriber to use in his or her practice, except to the extent permitted by Federal law. A pharmacy may prepare compounded non-sterile preparations for a licensed prescriber for non-human use in the prescriber's practice without a prescription consistent with State and Federal laws pertinent to the prescriber's health care practice.

13:39-11A.9 Equipment and supplies

(a)-(f) (No change.)

13:39-11A.10 Responsibilities of the compounding pharmacist; reporting requirement

(a) A compounding pharmacist shall be responsible for the ensuring that:

1.-4. (No change.)

5. Compounded preparations are of acceptable strength, quality, and purity, with appropriate packaging and labeling, and are prepared in accordance with good compounding practices, official standards, and relevant scientific data and information as set forth in USP 795, which is incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org;

6.-11. (No change.)

(b) (No change.)

13:39-11A.13 Information required to appear on prescription label

(a) The dispensed container for any compounded non-sterile preparation shall bear a permanently affixed label with at least the following information:

1. In a retail pharmacy only, the name of the prescriber.

[page=3778] i. An institutional pharmacy compounding non-sterile preparations for out-patient use shall include the name of the prescriber on the label, consistent with the labeling requirements for a retail pharmacy;

2.-8. (No change.)

SUBCHAPTER 11B. COMPOUNDING ANTINEOPLASTIC AGENTS AND OTHER HAZARDOUS SUBSTANCES: STERILE AND NON-STERILE PREPARATIONS

13:39-11B.1 Purpose and scope

(a) The rules in this subchapter regulate the practice of compounding antineoplastic agents and other hazardous substances for both sterile and non-sterile preparations and shall apply to all retail and institutional pharmacies that compound and dispense antineoplastic agents and other hazardous substances. The rules in this subchapter supplement those of N.J.A.C. 13:39-11 and 11A. To the extent the requirements for compounding antineoplastic agents and other hazardous substances are not specifically addressed in this subchapter, the requirements of N.J.A.C. 13:39-11 and 11A, as applicable, shall be followed.

(b) Effective July 1, 2018, the compounding of antineoplastic agents and other hazardous substances shall be consistent with the standards established in USP 800, which is incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org.

13:39-11B.2 Definitions

(a) The following words and terms, when used in this subchapter, shall have the following meanings:

"Hazardous substances" shall mean those substances identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings, Appendix A (2012 Edition). The sample list of drugs that shall be handled as hazardous (Appendix A) is incorporated herein by reference, as amended and supplemented, and can be found at the Centers for Disease Control and Prevention website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/.

(b) Any term not defined in this section shall have the definition set forth in N.J.A.C. 13:39-11.2.

13:39-11B.3 Compounding antineoplastic agents and other hazardous products: sterile preparations

(a) Pharmacies shall not prepare antineoplastic agents and other hazardous substances as immediate use compounded sterile preparations.

(b) A pressure indicator or air velocity meter shall be installed that can be readily monitored for correct room pressurization or air velocity, respectively, consistent with the following:

1. Until June 30, 2018, for compounding of antineoplastic agents and other hazardous substances in a cleanroom pursuant to N.J.A.C. 13:39-11.9, the primary engineering control shall be placed in an ISO class 7 buffer room that is physically separated from other preparation areas and has not less than 0.01 inch water column negative pressure to adjacent positive pressure ISO class 7 or better ante room, thus providing inward airflow to contain any airborne

drug. Effective July 1, 2018, for compounding of antineoplastic agents and other hazardous substances in a cleanroom pursuant to N.J.A.C. 13:39-11.9, the primary engineering control shall be placed consistent with the standards set forth in USP 800.

2. Until June 30, 2018, for compounding of antineoplastic agents and other hazardous substances outside of a cleanroom pursuant to N.J.A.C. 13:39-11.8, if a compounding aseptic containment isolator is used outside of a buffer area, the compounding area shall be physically separated from other areas and shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of 12 air exchanges per hour. Effective July 1, 2018, for compounding of antineoplastic agents and other hazardous substances outside of a cleanroom pursuant to N.J.A.C. 13:39-11.8, if a compounding aseptic containment isolator is used outside of a buffer area, the compounding area shall meet the standards set forth in USP 800.

(c) The ante area shall have appropriate environmental control devices capable of maintaining ISO class 7 air quality conditions for hazardous drug compounding activities as provided in (b)1 above.

(d) A pharmacy utilizing a compounding aseptic containment isolator not located in a cleanroom to compound antineoplastic agents and other hazardous substances shall comply with the requirements of (b)2 above.

(e) Until June 30, 2018, pharmacies shall compound antineoplastic agents and other hazardous substances only in:

1. A compounding aseptic containment isolator or a Class II or Class III biological safety cabinet in a negative pressure cleanroom. When handling volatile hazardous drugs, such devices shall be vented to the outside air; or

2. A compounding aseptic containment isolator located outside of a negative pressure cleanroom, consistent with N.J.A.C. 13:39-11.8. When handling volatile hazardous drugs, such devices shall be vented to the outside air.

(f) Effective July 1, 2018, pharmacies shall compound antineoplastic agents and other hazardous substances consistent with the standards set forth in USP 800.

(g) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to standards established by the Occupational Health and Safety Administration (OSHA) set forth in Section VI, Chapter 2 of OSHA's Technical Manual on Controlling Occupational Exposure to Hazardous Drugs (effective date January 20, 1999). OSHA's Technical Manual is incorporated herein by reference, as amended and supplemented, and can be found at the OSHA website, www.osha.gov, specifically, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. Personnel shall also comply with the standards established by NIOSH in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. The NIOSH Publication No. 2004-165 (2012 Edition) is incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/. Effective July 1, 2018, personnel shall also comply with the standards set forth in USP 800.

(h) Antineoplastic agents and other hazardous substances used to compound sterile preparations shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Such storage is preferable within a containment area, such as a negative pressure room. The storage area shall have sufficient general exhaust, at least 12 air exchanges per hour to dilute and remove any airborne contaminants. Antineoplastic agents and hazardous substances used to compound sterile preparations shall be handled with caution using appropriate chemotherapy gloves during distribution, receiving, stocking, inventorying, preparing for administration, and disposal.

(i) Effective July 1, 2018, antineoplastic agents and other hazardous substances used to compound sterile preparations shall be stored and handled consistent with the standards set forth in USP 800.

13:39-11B.4 Compounding antineoplastic agents and other hazardous products: non-sterile preparations

When antineoplastic agents and hazardous substances are utilized in the compounding of non-sterile preparations, a pharmacy shall adhere to standards established by the Occupational Health and Safety Administration (OSHA) set forth in Section VI, Chapter 2 of OSHA's Technical Manual on Controlling Occupational Exposure to Hazardous Drugs (effective date January 20, 1999). OSHA's Technical Manual is incorporated herein by reference, as amended and supplemented, and can be found at the OSHA website, www.osha.gov, specifically, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. Personnel shall also comply with the standards established by National Institute for Occupational Safety and Health (NIOSH) in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. The NIOSH standard is incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/. Effective July 1, 2018, personnel shall also comply with the standards set forth in USP 800.

[page=3779] SUBCHAPTER 12. NUCLEAR PHARMACIES

13:39-12.2 General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a specialized retail permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a site employing a qualified nuclear pharmacist. All personnel performing tasks in the preparing and distribution of drugs shall be under the immediate personal supervision of the nuclear pharmacist who shall be responsible for all nuclear operations of the licensed area and shall be in personal attendance at all times when the nuclear pharmacy is open for business. Nuclear pharmacies shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s), or extern(s) performing the radiopharmaceutical services, which are required to be performed by a pharmacist, pharmacy technician, intern, or extern pursuant to the requirements of this chapter. The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)2i is not required to be, but may be, recorded in the audit trail. All entries to the audit trail made by a pharmacy technician, intern, or extern shall be reviewed and approved by the pharmacist. The pharmacist shall be responsible

for the accuracy and appropriateness of the radiopharmaceutical services performed. When more than one pharmacist is involved in performing radiopharmaceutical services pursuant to this subchapter, each pharmacist shall be responsible for the accuracy and appropriateness of the radiopharmaceutical services he or she performed or reviewed and approved, and his or her unique and secure user identifier(s) shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each service is performed. Such documentation shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) (No change.)

(c) The process used for handling radioactive materials by any license holder must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution, and disposal of radioactive materials. In order to ensure the public health, safety, and welfare, a nuclear pharmacy shall first meet the following general requirements:

1. (No change.)

2. The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas;

3. The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to insure proper operation of the corresponding assay equipment; and

4. Those engaged in the compounding of radiopharmaceuticals for injection shall comply with N.J.A.C. 13:39-11, 11A, and 11B, as applicable.

(d)-(l) (No change.)

SUBCHAPTER 13. COLLABORATIVE PRACTICE

13:39-13.7 Scope of collaborative drug therapy management

(a)-(b) (No change.)

(c) A pharmacist may perform laboratory tests that are granted waived status in accordance with the provisions of the "New Jersey Clinical Laboratory Improvement Act," P.L. 1975, c. 166 (N.J.S.A. 45:9-42.26 et seq.), Department of Health's rules set forth at N.J.A.C. 8:44, and Department of Health CLIA Program requirements, available at http://www.state.nj.us/health/phel/instruct116.shtml, provided the tests are consistent with the pharmacy practice area or disease state covered by the collaborative practice agreement.

(d)-(e) (No change.)

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