TREASURY—GENERAL

(a)

DIVISION OF STATE LOTTERY

Definitions and Disclosure

Adopted Amendment: N.J.A.C. 17:20-2.1

Adopted Repeal and New Rule: N.J.A.C. 17:20-7.7

Proposed: December 4, 2023, at 55 N.J.R. 2397(a).
Adopted: July 15, 2024, by James A. Carey, Executive Director.
Filed: July 17, 2024, as R.2024 d.075, **without change**.

Authority: N.J.S.A. 5:9-7.b.

Effective Date: August 19, 2024.
Expiration Date: November 21, 2029.

Summary of Public Comment and Agency Response:

An anonymous comment was submitted as follows:

1. COMMENT: An anonymous email was received by the Division of State Lottery (Division) that voiced full support of the anonymity rules proposed.

RESPONSE: The Division appreciates the public support of this rulemaking.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendment and repeal and new rule are not subject to any Federal standards or requirements.

Full text of the adopted amendment and new rule follows:

SUBCHAPTER 2. DEFINITIONS

17:20-2.1 Definitions

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

. . .

"Second chance drawing" means a feature whereby winning and/or non-winning tickets provide an additional opportunity to win prizes other than those in the specific game presented on the ticket.

. . .

SUBCHAPTER 7. PAYMENT OF PRIZES

17:20-7.7 Disclosure of winner's information

(a) Pursuant to N.J.S.A. 5:9-7.b, holders of winning tickets or shares may remain anonymous indefinitely. The identity of a prize winner choosing to remain anonymous shall be confidential and proprietary for all purposes, including the New Jersey Open Public Records Act (OPRA), N.J.S.A. 47:1A-1 et seq.

(b) In accordance with (a) above, winner information will be restricted as follows:

1. Winners are anonymous, but may expressly consent to waive their anonymity to allow the following information to be published by the Division or its marketing and sales contractors and subcontractors:

i. Name;

ii. Town and state of residence;

iii. Game name and drawing date;

iv. Amount won; and

v. Photographic and video-graphic likeness in any medium for purposes of publicity or promotion; and

2. In the event that a winner remains anonymous, the Division or its marketing and sales contractors and subcontractors may publish the following:

i. Name of the county and state where winner resides;

ii. Name of retailer who sold the winning ticket, including the retailer's town and county;

iii. Game name and drawing date; and

iv. Amount won.

(c) Anonymity does not apply to those who win a second chance drawing, as defined at N.J.A.C. 17:20-2.1, or things such as a contest or giveaway where the player has not purchased a ticket. In such instances, house number, street name, Social Security numbers, taxpayer ID numbers, driver's license numbers, passport numbers, and any other identifying information, other than individual's name and town of residence, shall remain confidential for all purposes, including the Open Public Records Act, N.J.S.A. 47:1A-1 et seq.

(d) For winners that waive anonymity, information including their house numbers, street name, Social Security numbers, taxpayer ID numbers, driver's license numbers, passport numbers, and any other identifying information other than the information set forth at (b)1 above, shall not be disclosed for any purposes, including the Open Public Records Act, N.J.S.A. 47:1A-1 et seq.

(e) For winners that do not waive anonymity, retailers and courier services may choose to advertise or publish winner information, but shall release the following information only:

1. Name of the county where winner resides;

2. Game name and drawing date; and

3. Amount won.

(f) A winner who procured their ticket through a lottery courier service may, in writing, expressly waive anonymity. Such waiver shall permit the courier and the Division of Lottery to publish winner information. Pursuant to such circumstances, a courier service and the Division shall release only the identifying information set forth at (b)1 above. Additionally, a courier service must continue to follow the provisions at N.J.A.C. 17:20-12.23. Waiver of anonymity cannot be required by a courier service as a condition of service.

(b)

NEW JERSEY CANNABIS REGULATORY COMMISSION

Medical Cannabis Rules

Adopted Amendments: N.J.A.C. 17:30A-1.2 and 7.1

Adopted New Rules: N.J.A.C. 17:30A-7.12 and 7A

Proposed: August 7, 2023, at 55 N.J.R. 1670(a).
Adopted: July 22, 2024, by the New Jersey Cannabis Regulatory Commission, Dianna Houenou, Chair.
Filed: July 22, 2024, as R.2024 d.076, **with non-substantial changes** not requiring additional notice or public comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 24:6I-1 et seq.

Effective Date: August 19, 2024.
Expiration Date: April 26, 2026.

Summary of Public Comments and Agency Responses:

The New Jersey Cannabis Regulatory Commission (Commission) received timely comments from the following commenters during the 60-day public comment period, which ended on October 6, 2023. The numbers in parenthesis after each comment correspond to the commenter(s) listed below.

1. Bill
2. Cannabis Advisory Group
3. Chris Roebuck
4. Dominique Graham
5. Gaetano Lardieri
6. Jacqueline Ferraro
7. Jeffrey Jones
8. Jonathan LaRocca
9. Mw
10. Peter Szlasa
11. Sheri Adriano
12. Steven DeCredico
13. Sylvie
14. Tom
15. Van Brown

General

1. COMMENT: Several commenters stated they were in support of the rules surrounding clinical registrants and support the research of cannabis and clinical trials. (2, 3, 4, 7, 9, 11, 12, 13, and 15)

RESPONSE: The Commission acknowledges the commenters' support for the laws and rules.

2. COMMENT: Several commenters offered non-responsive statements and provided no requests to the Commission or provided statements beyond the scope of this rulemaking. Requests that fall beyond the scope of the rulemaking include licensing issues because of the alleged lack of municipal approval, high prices, and a request for home grow. (1, 8, 10, and 14)

RESPONSE: This rulemaking pertains solely to the Commission's proposed rules on clinical registrants at N.J.A.C. 17:30A. Thus, the Commission acknowledges the commenters' statements, and no further response is necessary.

3. COMMENT: One commenter states that "medical centers should be headquartered or have a satellite equipped with all relevant personnel to conduct clinical trials." The commenter suggests that this "will help practitioners and patients alike." (5)

RESPONSE: N.J.S.A. 24:6I-7.3.e allows clinical registrants to operate more than one physical location, provided that the Commission approves the satellite locations. The Commission has determined that there will be no mandate that clinical registrants operate a satellite location through rulemaking. A clinical registrant that chooses to operate a satellite location will be required to submit the requisite application in accordance with the Commission's notice of application acceptance for clinical registrants. Thus, no changes will be made upon adoption.

N.J.A.C. 17:30A-1.2 Definitions

4. COMMENT: Two commenters request that the Commission allow clinical registrants and academic medical centers to conduct research in both the medical and adult-use markets. The commenters argue that the "definition of Clinical Registrant limits the research to the use of medical cannabis" and states that the "data shows that the number of cannabis patients has declined since the inauguration of New Jersey's adult-use cannabis program." The commenters argue that this "decline will likely continue if New Jersey follows the trends of other regulated states. Many former medical cannabis patients will transition to the adult use program to obtain their medicine." The commenters state that there "is not enough of a medical cannabis market to support a Clinical Registrant's research, let alone business." Additionally, the commenters state that "many adult-use consumers consume cannabis for its perceived wellness benefits" and reasons that by "only limiting research to medical cannabis, the definition leaves out thousands of adult-use consumers who utilize cannabis for medical purposes." The commenters argue that this "limitation needlessly reduces the efficacy of clinical research by curtailing the scope of research" and "inhibits the study of the public health consequences of the widespread regulated use of adult-use cannabis in New Jersey." The commenters suggest that this "section should be revised to expand the scope of research conducted by Clinical Registrants and their academic partner to the broader use of cannabis by medical patients and adult consumers" and further suggests that "the regulations should be revised to allow Clinical Registrants to hold personal-use cannabis licenses in the same manner as ATCs that become expanded ATCs." (2 and 6)

RESPONSE: The Commission has interpreted the enabling statute to mean that clinical registrants are permitted to conduct research on medical cannabis only. For example, N.J.S.A. 24:6I-7.3.d states, "[a] clinical registrant issued a permit pursuant to this section shall be authorized to engage in all conduct involving the cultivation, manufacturing, and dispensing of medical cannabis as is authorized for an entity holding medical cannabis cultivator, medical cannabis manufacturer, and medical cannabis dispensary permits pursuant to P.L.2009, c.307 (C.24:6I-1 et al.), including dispensing medical cannabis and medical cannabis products to qualifying patients and designated and institutional caregivers." Thus, no changes will be made upon adoption.

5. COMMENT: Two commenters request that the Commission amend the definition of "academic medical center" to include human clinical trials and clarify that Investigational New Drug (IND) applications are not required. The commenters state that this change would allow for more rigorous academic research, specifically the public health impacts of medical and adult-use cannabis. Academic medical centers do not have to hold an IND application. (2 and 6)

RESPONSE: The definition of "academic medical center" pursuant to the New Jersey Cannabis Regulatory, Enforcement, Assistance, and Marketplace Modernization (CREAMM) Act does not give the Commission the authority to allow academic medical centers, even if in partnership with clinical registrants, to conduct research on adult-use cannabis. The definition at N.J.S.A. 24:6I-3 states that the academic medical center has the ability to conduct research "related to medical cannabis" or "has an institutional review board that has, on the effective date of P.L.2021, c.16 (C.24:6I-31 et al.), previously approved a clinical research study in this State involving medical cannabis." The Commission has interpreted this definition to mean that the New Jersey Legislature intended to limit research related to medical cannabis only. However, the Commission has also interpreted this definition to mean that the New Jersey Legislature did not limit research to non-human clinical trials only. Regarding the IND, the statutory definition of academic medical center does not explicitly require an IND application. Thus, while the Commission is not requiring an IND, a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for State purposes, clinical registrants and affiliated entities are advised to review any applicable Federal requirements or regulations regarding the marketing or labeling of products that may fall within the purview of the U.S. Food and Drug Administration or the Federal Food, Drug, and Cosmetic Act.

The Commission is changing the definition of academic medical center at N.J.A.C. 17:30A-1.2 upon adoption in response to the comment to clarify human trials are permissible, but animal testing is not.

6. COMMENT: Two commenters request that the Commission amend the definition of "Institutional Review Board" or "IRB." The commenter states that "IRB's membership and authority are governed by regulations administered by the Office for Human Research Protections (OHRP) Department of Human Services" and further states that the "referenced IRB, if created solely for this purpose, should still be governed by federal law." The commenters suggest that "an academic medical center will have an IRB or a contracted IRB that reviews all institutional research, and the process for reviewing cannabis studies should not follow a different standard." Further, the commenters suggest that an IRB should review the proposed scope of the study and further suggests "any modifications [to the study scope] must be submitted and reviewed by the IRB." The commenters suggest the following changes to the definition: "Institutional Review Board" or "IRB" means, in accordance with 45 CFR Part 46 and 21 CFR part 56, a board, committee, research approval committee, or group created or designated by an academic medical center, as applicable, that reviews and approves the proposed scope and research protocols of a clinical registrant's proposed research study. (2 and 6)

RESPONSE: Although a statutory definition of "institutional review board" (or IRB) pursuant to the CREAMM Act does not exist, the Commission's definition of IRB is derived from the Legislature's reference of the term pursuant to the statutory definition of "academic medical center" at N.J.S.A. 24:6I-3. The Commission interpreted the Legislature's reference of the term to mean that the Commission had the authority to provide its own definition to assist both permittees and the public. Further, N.J.A.C. 17:30A-7A.2(c)1i provides that "an IRB shall review the anticipated scope and research protocol of the proposed research study involving human subjects pursuant to the criteria at 45 CFR 46.111 (relating to criteria for IRB approval of research) and 21 CFR 56.111 (relating to criteria for IRB approval of research). Additionally, the Commission's intention was always to allow IRBs to review both expected and proposed research. Thus, the Commission is modifying the definition of "Institutional Review Board" upon adoption in response to the comment to change "anticipated" to "proposed."

N.J.A.C. 17:30A-7A.1 Clinical Registrants and Academic Medical Centers

7. COMMENT: One commenter referenced the Commission's proposed definition of "academic medical center" at N.J.A.C. 17:30A-7A.1, and cited a portion of the definition, which states, "... Has an addiction medicine faculty practice or is in the same health care system as another facility located in New Jersey that offers outpatient medical

detoxification services or inpatient treatment services for substance use disorder." The commenter states that he agrees with this definition but suggests that treatments should include "all entheogens" as well. (5)

RESPONSE: The Commission is modifying N.J.A.C. 17:30A-7A.1 upon adoption to clarify that treatment for substance use disorders includes entheogens.

8. COMMENT: One commenter referenced the Commission's proposed definition of "academic medical center" at N.J.A.C. 17:30A-7A.1, and cited a portion of the definition, which states that an academic medical center is an accredited school of osteopathic medicine that: "Has an agreement to establish and maintain an apprenticeship program in this State to train workers in the cannabis industry, which training would earn college credit with the partner state college or university." The commenter states that he agrees with this definition but suggests that "it should also be aligned with 501(c)(3)'s that are cannabis advocated." Although the commenter was unclear, the commenter appears to suggest that the Commission amend the definition to require that academic medical centers are all non-profit groups (that is, 501(c)(3)s pursuant to the Internal Review Code). (5)

RESPONSE: The Commission's proposed definition of "academic medical center" is aligned with the statutory definition of academic medical center at N.J.S.A. 24:6I-3, and the Commission has determined that the commenter's suggested additions will deviate too far from the statutory definition. Thus, no changes will be made upon adoption.

9. COMMENT: One commenter referenced the Commission's proposed definition of "academic medical center" at N.J.A.C. 17:30A-7A.1, and cited a portion of the definition, which states that an academic medical center is an accredited school of osteopathic medicine that: "Has an institutional review board that has approved a clinical research study in this State involving medical cannabis." The commenter suggests amending the definition to state "has approved a study [within] the last [three] years." The commenter further suggests "extra points for a cannabis study outside of the state." (5)

RESPONSE: The Commission's proposed definition of "academic medical center" is aligned with the statutory definition of academic medical center at N.J.S.A. 24:6I-3, and the Commission has determined that the commenter's suggested amendments will deviate too far from the statutory definition. Thus, no changes will be made upon adoption.

10. COMMENT: One commenter referenced the Commission's proposed definition of "academic medical center" at N.J.A.C. 17:30A-7A.1, and cited a portion of the definition, which states that an academic medical center is an accredited school of osteopathic medicine that: "Has the ability to, and will, conduct all research and development in the county in which the partner state college or university is located." The commenter suggests that the word "will" be changed to "shall." Additionally, the commenter states that the word "ability" needs clarification and suggests that "dedicated staff should have principal investigator and site coordinator." The commenter further suggests that language should be added that states the academic medical center "will conduct research in the community as well as communities determined by the [State of New Jersey] or University as being harmed by the war on drugs." (5)

RESPONSE: The Commission's definition of academic medical center mirrors the statutory definition at N.J.S.A. 24:6I-3, which states an academic medical center "has the ability and will conduct all research and development in the county in which the partner State college or university is located." The Commission has determined that the commenter's other suggested changes will deviate too far from the statutory definition. Thus, no changes will be made upon adoption.

11. COMMENT: One commenter referenced the Commission's proposed definition of "clinical registrant" at N.J.A.C. 17:30A-7A.1, and cited a portion of the definition, which states "The academic medical center or its affiliate will provide advice to the ATC regarding patient health and safety, medical applications, and dispensing and managing controlled dangerous substances, among other areas." The commenter suggests that "among other areas should be defined more." The commenter suggests several examples such as "compliance, drug storage and destruction guidelines, inspections, data collection" and Health Insurance Portability and Accountability Act (HIPAA) compliance. (5)

RESPONSE: The Commission proposed the language "among other areas" to broadly give the clinical registrant the authority to research other areas it chooses to research. The Commission is modifying the Commission's proposed definition of "clinical registrant" at N.J.A.C. 17:30A-7A.1 to provide further clarification to include other optional categories of advice.

N.J.A.C. 17:30A-7A.2 Clinical Registrant Conduct; Prohibitions; Reporting; Revocation

12. COMMENT: Two commenters request that the Commission clarify that vertical integration for clinical registrants is authorized, and that more than one dispensary is permissible. The commenters state that N.J.A.C. 17:30A-7A.2(a) provides that "A clinical registrant issued a permit pursuant to this chapter shall be authorized to engage in the cultivation, manufacturing, or dispensing of medical cannabis as is authorized for a non-clinical ATC holding a medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit pursuant to the Act." However, the commenters state that "the list of authorizations is presented as disjunctive in that the Clinical Registrant is authorized to engage in cultivation, manufacturing, 'or' dispensing of medical cannabis." The commenters state that "pursuant to the Act and state law, it appears that the disjunctive 'or' should be changed to the conjunctive 'and' because under the Act, Clinical Registrants will be vertically integrated and authorized to engage in all the authorized activities." The commenters request that the Commission amend the section to remove any ambiguity on this point. Moreover, the commenters state that N.J.A.C. 17:30A-7A.2(a) and the regulations generally appear to limit the clinical registrant to a single dispensary. The commenters argue that such "a limitation would (1) disincentivize applications for clinical registrant permits and (2) reduce the efficacy of observational research." The commenters state that "A restriction to a single dispensary would render a Clinical Registrant a vertically integrated ATC in the pattern of the vertically integrated ATC Permits awarded pursuant to the 2019 request for application and, but for the medical limitation, no different than what could be obtained through the current personal use licensing program." However, the commenters argue that "the Clinical Registrant would bear significantly greater costs, resources, and regulatory burdens than either a vertically integrated non-clinical ATC or personal use operator that achieved vertical integration." In this case, the commenters argue that "there isn't an economic incentive to undertake these additional burdens, and otherwise, qualified applicants may forgo the pursuit of a clinical registrant permit." Also, the commenters state that "by limiting a Clinical Registrant to a single dispensary, the scope of research will be curtailed because the available study cohorts will be constrained to the single, localized dispensary." To provide a range of study subjects that reflect a substantial cross-section of the State's population, the commenter requests that "the regulation should be revised to provide a Clinical Registrant with more than a single dispensary." The commenters suggest N.J.A.C. 17:30A-7A.2(a) read as follows: "A clinical registrant issued a permit pursuant to this chapter shall be authorized to engage in the cultivation, manufacturing, and dispensing of cannabis as is authorized for a non-clinical ATC holding a cannabis cultivator, cannabis manufacturer, or cannabis dispensary permit pursuant to the Act, including dispensing cannabis items to adult consumers aged twenty-one years or older, registered patients and designated caregivers.1. A clinical registrant may buy, sell, and transfer cannabis items to and from another ATC or other New Jersey licensed cannabis business that possesses a valid permit. 2. A clinical registrant may dispense usable cannabis, cannabis items, and medical cannabis products to an adult consumer, patient, caregiver with a registry identification card, regardless of whether the individual is a participant in a research study. 3. A clinical registrant may operate more than one dispensary." (2 and 6)

RESPONSE: Regarding the operation of more than one dispensary, the enabling statute, at N.J.S.A. 24:6I-7.3.e(3), states that "[t]he commission may authorize a clinical registrant to dispense medical cannabis and medical cannabis products from more than one physical location if the [C]ommission determines that authorizing additional dispensing locations is necessary for the clinical registrant to best serve and treat qualifying patients and clinical trial participants." The Commission has determined that clinical registrants need to be operational prior to determining whether authorizing additional dispensing locations is necessary for the clinical registrant to best serve and treat qualifying patients and clinical

trial participants. Regarding the request to operate in the adult-use market and the request for clarification regarding vertical integration, the Commission will modify the rule. The changes will allow a clinical registrant to apply for conversion into the personal use cannabis market.

13. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(a), and cited "A clinical registrant issued a permit pursuant to this chapter shall be authorized to engage in the cultivation, manufacturing, or dispensing of medical cannabis as is authorized for a non-clinical ATC holding a medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit pursuant to the Act, including dispensing medical cannabis items to registered patients and designated caregivers." The commenter suggests that it be amended to read "and/or designated caregivers." The commenter believes this would give the "flexibility to alter in case of some medical situations or hospitalizations." Additionally, the commenter requests the Commission to provide examples of designated caregivers. The commenter asks whether this includes a "school setting" or "underaged children." (5)

RESPONSE: N.J.A.C. 17:30A-7A.2(a) authorizes the clinical registrant to dispense medical cannabis items to both registered patients and primary caregivers. Thus, the commenter's suggested change to "and/or designated caregivers" is unnecessary. Additionally, the Commission has defined "primary caregiver" or "caregiver" at N.J.A.C. 17:30A-1.2. Thus, no changes will be made upon adoption.

14. COMMENT: Two commenters request that the commission clarify that all cannabis activity related to clinical registrants and academic medical centers occurs within the State of New Jersey. The commenters state that N.J.A.C. 17:30A-7A.2(b)1 could leave the door open to interstate commerce due to the definition of an "accredited school of osteopathic medicine." The commenters state that pursuant to this section, a clinical registrant could have an academic medical center partner, which is a school of osteopathic medicine that is located outside of New Jersey. As such, the commenters suggest clarifying the regulations to avoid any potential violations of engaging in interstate commerce of cannabis. To avoid such a circumstance, the commenters state that this section should be revised to require medical cannabis that is dispensed to such an academic medical center only be dispensed to a facility in New Jersey that is subject to the control and supervision of the academic medical center. The commenters acknowledge that facilitating interstate commerce through the clinical registrant program is not the Commission's intent. Therefore, the commenters recommend explicitly stating that all cannabis activity shall occur within the boundaries of New Jersey. (2 and 6)

RESPONSE: Regarding the request to clarify that interstate commerce of cannabis remains prohibited, including for an academic medical center located in another state, the Commission is modifying N.J.A.C. 17:30A-7A.2(b) upon adoption.

15. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(b)1 and cited "A clinical registrant may dispense usable medical cannabis and medical cannabis products, in any form authorized by an institutional review board (IRB), directly to an academic medical center as part of a research study." The commenter appears to suggest that it "needs to be assured" that obtained research data (for example, form and dose) must "be captured on all 'dispensed' cannabis medicine." (5)

RESPONSE: The Commission has determined that the proposed language at N.J.A.C. 17:30A-7A.2(b)1 is sufficient to ensure that research data will be collected from medical cannabis products dispensed to an academic medical center. Thus, no changes will be made upon adoption.

16. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(b)1 and cited "An academic medical center that handles medical cannabis items shall do so in a manner consistent with the academic medical center's standards used for the handling, storage, and disposal of other patient medications." The commenter suggests that these "should be standards that are established by experts and are uniform among academic institutions." (5)

RESPONSE: An "academic medical center" is not issued a medical cannabis permit. Thus, the Commission has determined that its regulatory authority surrounding academic medical centers is limited to its activities relating to clinical registrant applicants and clinical registrant permittees. As such, the Commission has determined that it does not have the authority to require changes to an academic medical center's current standards for the handling, storage, and disposal of other patient medications. Instead, an academic medical center is required to handle medical cannabis consistent with its current standards. Thus, the commenter's suggested additions will not be made upon adoption.

17. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(b)2 and cited "A clinical registrant applicant shall provide written documentation of an existing research contract with an academic medical center, which shall include a commitment by the academic medical center, or its affiliate, to engage in or oversee clinical research related to the use or adverse effects of cannabis in order to advise the clinical registrant concerning patient health and safety; medical applications; dispensing and management of controlled substances; and ways to mitigate adverse health or societal effects of adult, personal-use legalization, among other areas." The commenter suggests that a hotline should be established for public, private, and professional reporting. Additionally, the commenter suggests that all adverse effects should be reported to the Commission within 24 to 48 hours of being known by the institution. (5)

RESPONSE: A clinical registrant or member of the public may contact the Commission for public, private, and professional reporting. Thus, the Commission has determined that promulgating a hotline number by regulation is unnecessary. Additionally, mandating a timeline of reporting adverse effects to the Commission within 24 to 48 hours may disrupt the clinical research process and may not be reasonably practical. Thus, no changes will be made upon adoption.

18. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(b)4 and cited "A research contract shall contain the responsibilities and duties of each party with respect to the research study." The commenter suggests that the language should be amended to read "roles, responsibilities duties." Additionally, the commenter suggests that an organizational chart should be established with titles and pictures. Finally, the commenter states the following: "Reporting numbers of at least the institution, PI, Sub-PI, Research Assist., RN, MA's, Site Coordinator." (5)

RESPONSE: The Commission has determined that a research contract that contains the responsibilities and duties of each party with respect to the research study is sufficient. Additionally, as mentioned above, the Commission does not issue medical permits to an academic medical center, and the Commission's regulatory authority surrounding academic medical centers is limited to activities relating to clinical registrant applicants and clinical registrant permittees. Thus, the Commission does not have the authority to mandate that an academic medical center publish an organizational chart with titles and pictures. Finally, it is unclear what the commenter is requesting regarding the reporting of numbers. Thus, no changes will be made upon adoption.

19. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(b)5ii(6), which states "A research contract shall include a description of the research study the clinical registrant and the academic medical center intend to conduct. The description of the research study shall include the research protocol, and a written procedure for conducting the research program, which shall include the following information: The locations of the clinical registrant dispensaries that will be participating in the research study." The commenter suggests that "business hour phone numbers should be included," including the "full address" and "principal owner." Additionally, the commenter states that a "copy of the Consent Form and all current and future Amendments to the consent form should be available." The commenter states that "guaranteeing that informed consent will be obtained from each prospective participant or the participant's legally authorized representative and is properly documented." The commenter appears to suggest adding language that guarantees "that any updates [or] new information on the product or study" and "updates that effect the study participant" will be made available to that participant. The commenter also appears to suggest adding language that a consent form be re-signed "so that HIPAA compliance will be maintained throughout." (5)

RESPONSE: Each clinical registrant is required to ensure compliance with all Federal, State and local laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Further, N.J.A.C. 17:30A-7A.2(c)2iv requires that: "A clinical registrant shall demonstrate to the Commission that an IRB has taken the following actions to review the research study and that the clinical registrant has met the requirements of this subsection: Both an IRB and the clinical registrant shall ensure that the clinical registrant's research study addresses all of the following: Guaranteeing that informed consent will be obtained from each prospective participant or the participant's legally authorized representative and is properly documented." Thus, it is up to the clinical registrant permittee and its IRB to ensure HIPPA compliance and that informed consent is obtained from each participant before they participate in the study. No changes will be made upon adoption.

20. COMMENT: Two commenters request that the Commission expand the scope of authorized research at N.J.A.C. 17:30A-7A.2(b) and (c). The commenters state that this "section requires that the description of the research study shall include the research protocol and a written procedure for conducting the research program, which shall consist of, among other things, the types and amounts of medical cannabis items and the dosage and method of administration used in the research study." The commenters state that while "these requirements are doubtless beneficial for certain types of studies, they will limit other types of valuable studies." The commenters state, "For example, observational studies that seek to understand the broader consequences of cannabis use would not be able to control for the prescribed requirements." In general, the commenters argue that "the scope of studies should be dictated by the experts at the academic medical center and should not be curtailed ex-ante by regulation." The commenters state that "this section should be revised to remove these requirements, thus allowing the scientists and medical research experts to define the scope and methods to develop the most impactful studies possible." The commenters suggest amendments to proposed N.J.A.C. 17:30A-7A.2(b)1 and suggests removing reference to "medical" cannabis to allow both research in medical and adult-use cannabis. The commenters suggest removing proposed N.J.A.C. 17:30A-7A.2(b)5ii(1) through (6). Finally, the commenters suggest amendments at proposed N.J.A.C. 17:30A-7A.2(c)2, by changing the word "patients" to "participants" and removing proposed N.J.A.C. 17:30A-7A.2(c)2iii. (2 and 6).

RESPONSE: The statutory definition of academic medical center at N.J.S.A. 24:6I-3 states that the academic medical center has the ability to conduct research "related to medical cannabis" or "has an institutional review board that has, on the effective date of P.L.2021, c.16 (C.24:6I-31 et al.), previously approved a clinical research study in this State involving medical cannabis." The Commission has interpreted this definition to mean that the New Jersey Legislature intended to limit research related to medical cannabis only. Thus, the Commission does not have the authority to amend N.J.A.C. 17:30A-7A.2(b)1 to allow research in both medical and adult-use cannabis. In accordance with N.J.S.A. 24:6I-7.3, participants in the research study must be registered patients. Thus, the recommended change of the word "patients" to "participants" will not be made. The Commission proposed N.J.A.C. 17:30A-7A.2(b)5ii(1) through (6) to set forth background information clinical registrants must submit to the Commission at a minimum, but a clinical registrant may submit more information on the description of the research study, if desired. Additionally, the purpose behind proposed N.J.A.C. 17:30A-7A.2(c)2iii is to ensure that clinical registrants provide cost-benefit analyses for their research programs. Thus, no changes will be made upon adoption.

21. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(d), which states "An academic medical center may not solicit or accept anything of value from an approved clinical registrant or its owner, passive investor, principal, MSC, financial source, or employee of an approved clinical registrant except for reasonable remuneration, specifically in a research contract for the services to be performed or costs to be incurred by the academic medical center." The commenter appears to suggest that the regulation does not prescribe "rules on 'advertising' to recruit patients into clinical trials." The commenter suggests that "there should be some rules around what academic institutions ... can say and how to advertise for clinical trial." The commenter states that "this will be necessary to obtain study participants." (5)

RESPONSE: The Commission has determined that it is not necessary to promulgate its own rules on the recruitment of patients into clinical trials. For recruiting study subjects, clinical registrants should follow any applicable guidelines and laws to ensure IRB review of the proposed method of recruitment. Please be advised that advertising for recruitment into a study must not violate New Jersey law. Thus, no changes will be made upon adoption.

22. COMMENT: Two commenters request that the Commission allow clinical registrants to research the public health impacts of a regulated adult-use market. The commenters state that the "prohibition on Clinical Registrants holding a personal-use cannabis business license will have insurmountable problems that will render the clinical registrant permit unviable, thereby thwarting the legislative intent in creating this permit class." Additionally, the commenters argue that "the medical market is shrinking, and other than some of the long-established ATCs, there have not been enough medical cannabis transactions for new ATCs to maintain a viable business." Further, the commenters state that "these newer ATCs have seen little medical cannabis transactions and consequently have needed to add personal-use licenses to remain viable businesses." The commenters conclude that for "a vertically integrated medical-only company, such as is being proposed for Clinical Registrants, this problem would be significantly exacerbated due to the high costs associated with opening and operating a vertically integrated business." The commenters suggest removing N.J.A.C. 17:30A-7A.2(e) in its entirety. (2 and 6).

RESPONSE: Proposed N.J.A.C. 17:30A-7A.2(e) is derived from the enabling statute at N.J.S.A. 24:6I-7.a(2)(d), which states, "No entity issued a medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit may concurrently hold a clinical registrant permit issued pursuant to section 13 of P.L.2019, c.153 (C.24:6I-7.3), and no entity issued a clinical registrant permit pursuant to section 13 of P.L.2019, c.153 (C.24:6I-7.3) may concurrently hold a medical cannabis cultivator permit, a medical cannabis manufacturer permit, or a medical cannabis dispensary permit." Thus, the Commission cannot remove proposed N.J.A.C. 17:30A-7A.2(e) in its entirety, as requested by the commenters. However, regarding the commenters' request that a clinical registrant be permitted to apply for and hold a personal-use cannabis business license, the Commission agrees that although clinical registrants may only conduct research in medical cannabis, it may apply for a license to operate a personal-use cannabis business.

23. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(i), which states, "Each clinical registrant shall submit a written report of the results and findings of its clinical research study to the Commission no later than one year following the conclusion of the research study or no later than 30 days following the publication of the research study in a peer-reviewed medical, whichever is first." The commenter appears to suggest that the time-period to submit the results of the clinical research study to the Commission should be amended to "within 6 months." Further, the commenter appears to suggest that the regulations should be amended to require clinical registrants to submit a "preliminary top line report 'draft' with preliminary results" to be sent within three (3) months. Additionally, the commenter appears to suggest that "following the publication of the research study" should be amended to "following the acceptance to be published." The commenter reasons that there are "months between acceptance and actual publishing of the research, as this is determined by several factors of the publisher." (5)

RESPONSE: The Commission has determined that the timeframes set forth at N.J.A.C. 17:30A-7A.2(i) to submit research findings to the Commission are reasonable and the changes the commenter suggests would be overly burdensome. Regarding the request regarding the acceptance to be published, the Commission will make that change.

24. COMMENT: Two commenters request that the Commission allow clinical registrants to partner with several academic medical centers. The commenters state that N.J.A.C. 17:30A-7A.2(f) and (g) are confusing and should be clarified. Moreover, the commenters state that "limiting written contracts to one partner hinders the research that could be conducted by Clinical Registrants and unnecessarily restricts their research partnerships." The commenters suggest removing N.J.A.C. 17:30A-7A.2(f) and (g) in their entirety. (2 and 6).

RESPONSE: Proposed N.J.A.C. 17:30A-7A.2(f) is derived directly from the enabling statute, at N.J.S.A. 24:6I-7.3(b), which states, "[i]n no

case shall the commission accept, process, or approve an application submitted by an applicant that has contracted with an academic medical center that is part of a health care system that includes another academic medical center that has contracted with an applicant for, or a holder of, a clinical registrant permit." Additionally, proposed N.J.A.C. 17:30A-7A.2(g) is derived from N.J.S.A. 24:6I-7.3(c), which states, "[a] clinical registrant issued a permit pursuant to this section shall have a written contractual relationship with no more than one academic medical center." Thus, no changes will be made upon adoption.

25. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(i)1, which states, "The Commission may post such results and findings on its publicly accessible website and share them with other clinical registrant permit holders, academic medical centers, or any other person it determines would benefit from the findings." The commenter states that the "Commission or Chair needs to be advised on how to properly report preliminary data." The commenter further states that this "should be the responsibility of a Chair level medical person." (5)

RESPONSE: The Commission's proposed regulations require that each clinical registrant is required to partner with an academic medical center, which designates an institutional review board to review and approve the anticipated scope and research protocols of a clinical registrant's proposed research study. The Commission's proposed regulations ensure that all research protocols are scientifically sound, and the Commission would merely be posting the results of the clinical registrant's study. Thus, the Commission has determined that the commenter's suggested additions are unnecessary, and no changes will be made upon adoption.

26. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.2(j), which states, "The Commission may suspend or revoke the permit of a clinical registrant where: 1) The academic medical center no longer meets the requirements to be an academic medical center pursuant to this chapter; or 2) The research contract between the clinical registrant and the academic medical center expires without being renewed or is terminated by either party." The commenter states that the "suspension terms need to be clarified as to what the violation is." The commenter asks whether the suspension time-period is 30 days or 60 days. Additionally, the commenter suggests that if a suspension is the result of "administrative items," that the Commission ensure that research is not interrupted. Further, the commenter requests that the regulation be amended to add the following: "3) Has not been compliant with patient safety 4) Has not maintained patient anonymity 5) Has been accused of any sexual misconduct towards a patient while in study." (5)

RESPONSE: The Commission has determined that suspension terms are fact-dependent. Thus, the commenter's suggested change regarding suspension terms will not be made upon adoption. Additionally, the Commission has determined that it cannot add additional violations upon adoption, but will consider to do so in a future rulemaking, if the Commission finds it necessary.

27. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.3(a), which states, "The Commission shall issue a sufficient number of clinical registrant permits, pursuant to need, as it deems necessary to meet the needs of qualifying patients in the State, and may accept new clinical registrant permit applications for such permits as it deems necessary to meet those needs." The commenter suggests that this regulation needs "more clarity around what this may look like" and appears to suggest that the Commission define a minimum and maximum number. The commenter suggests that the Commission refer to Pennsylvania regarding the number of clinical registrants it currently has for research. (5)

RESPONSE: N.J.A.C. 17:30A-7A.3(a) is derived from the statutory requirement at N.J.S.A. 24:6I-7.3.b, which states that the Commission shall "begin accepting and processing applications for five clinical registrant permits. Thereafter, the Commission shall accept applications for and issue such additional clinical registrant permits as it determines to be necessary and consistent with the provisions of P.L.2009, c.307 (C.24:6I-1 et al.)." The Commission cannot make a determination regarding the sufficient number of clinical registrants, until it has accepted and processed applications for five clinical registrant permits, and the Commission has ascertained the need for additional clinical research. Thus, no changes will be made upon adoption.

28. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.3(c)1, which states, "Such determination may include a determination that the Commission requires more time to adequately review the application." The commenter also references N.J.A.C. 17:30A-7A.3(d), which states, "Applications shall be reviewed for completeness and then scored in accordance with the criteria included in the notice of application acceptance pursuant to (b) above." The commenter appears to suggest that for the notice of application acceptance that the Commission "take a look at [Pennsylvania's] application requirements" and its "comprehensive scoring system." (5)

RESPONSE: The Commission has reviewed other states' laws and regulations prior to proposing its own rules on clinical registrants, and the proposed rules reflect the culmination of that research. It should be noted that the Commission has yet to release its notice of application acceptance for clinical registrants but will do so in the future. Thus, no changes will be made upon adoption.

29. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.3(g), which states, "The Commission shall approve a clinical registrant permit applicant for an annual permit where the applicant has: 1. Submitted a complete clinical registrant permit application in accordance with N.J.A.C 17:30A-7A.4; 2. Scored sufficiently high to be issued a permit in accordance with the criteria included in the notice of application acceptance pursuant to (b) above." The commenter appears to suggest that for the notice of application acceptance that the Commission take a look at Pennsylvania's "comprehensive scoring system." (5)

RESPONSE: As mentioned in the Response to Comment 28, the Commission has yet to release its notice of application acceptance for clinical registrants but will do so in the future. Thus, no changes will be made upon adoption.

N.J.A.C. 17:30A-7A.4 Clinical Registrant Permit Application

30. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)8, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application process, the following materials for the Commission's evaluation: Proof of local support, which shall be demonstrated by a resolution adopted by the municipality's legislative body, or by a written letter of support from the municipality's executive." The commenter asked why the above is needed. The commenter reasons that "these are medical clinical trials" which is "under medical supervision." Thus, the commenter states, "local support is not required to conduct a cancer clinical trial" and asked "why should cannabis clinical trials be under harsher scrutiny than other clinical trials?" (5)

RESPONSE: Proposed N.J.A.C. 17:30A-7A.2(a) authorizes a clinical registrant to engage in the cultivation, manufacturing, or dispensing of medical cannabis as is authorized for a non-clinical ATC holding a medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit. Thus, because a clinical registrant may cultivate, manufacturer, and dispense medical cannabis to patients, proof of municipal approval is necessary and consistent with other medical cannabis entities. Thus, no changes will be made upon adoption.

31. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)14, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application process, the following materials for the Commission's evaluation: An environmental impact plan, which shall, at a minimum, include consideration of sustainable alternatives to single-use plastic packaging, efforts to minimize water usage, and any other factor required by the Commission in its notice of application acceptance." The commenter suggests that clinical registrants "should also have a section to demonstrate which UN ESG17 [United Nations Sustainable Development] guidelines they comply with." (5)

RESPONSE: The Commission has determined that the submission of an environmental impact plan by the clinical registrant is sufficient to demonstrate its efforts for sustainable packaging, water, and energy usage. Thus, no changes will be made upon adoption.

32. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)16, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application process, the following materials for the Commission's evaluation: A community impact or social responsibility plan." The commenter states that the "research center, if not in an area deemed as an area harmed by the war-on-drugs," should "make sure they include a community that is." (5)

RESPONSE: A community impact or social responsibility plan details the clinical registrant applicant's commitment to a local community and commitment to social responsibility. This submitted document includes how the applicant plans to support the local community. However, because each municipality has the authority to approve a clinical registrant applicant, it cannot be guaranteed that the research center is located directly in an area impacted by the "war-on-drugs," as requested by the commenter. The Commission will provide more details regarding the requirements of a community impact or social responsibility plan in its notice of application acceptance pursuant to N.J.A.C. 17:30A-7A.3(b).

33. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)18, which states: "A clinical registrant permit applicant shall disclose and submit, as part of the, permit application process, the following materials for the Commission's evaluation: Standard operating procedures for: i. Adverse event reporting; ii. Quality assurance and quality control; iii. Recall of medical cannabis items, as needed, or directed." Regarding recall of medical cannabis items, the commenter appears to suggest that the Commission should require a "policy on proper return/destruction of study drug." (5)

RESPONSE: The requested standard operating procedure at N.J.A.C. 17:30A-7A.4(b)18iii, recall of medical cannabis items, combined with the standard operating procedure at N.J.A.C. 17:30A-7A.4(b)18vii, waste disposal/sanitation, will provide the Commission the clinical registrant's policy regarding the proper recall or destruction of the study drug. Thus, no changes will be made upon adoption.

34. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)22, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application process, the following materials for the Commission's evaluation: If a permit applicant intends to enter into, or has entered into, a partnership with a re-entry program for the purpose of identifying and promoting employment opportunities for currently or formerly incarcerated people at the alternative treatment center, the details of such partnership, including: i. The name of the re-entry program; ii. The employment or training opportunities at the permit applicant's alternative treatment center that will be made available to the re-entry population." The commenter suggests "it be clarified which state the re-entry program should come from." (5)

RESPONSE: The Commission intends to promote economic opportunities in the cannabis market to all people who are currently or formerly incarcerated, regardless of the state in which the re-entry organization is located. Thus, no changes will be made upon adoption.

35. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)28, which states, "For a clinical registrant, in its initial and renewal application: A list of the approved research programs or research studies that are continuing or, if any of them are concluded, the dates they were concluded." The commenter states that the "CRC or CRC Medical Chair should review all programs and research studies to assure no duplication of studies among institutions." (5)

RESPONSE: As mentioned in the response to prior comments, the Commission's proposed regulations require that each clinical registrant is required to partner with an academic medical center, which designates an institutional review board or IRB. The IRB is in charge of reviewing and approving the anticipated scope and research protocols of a clinical registrant's proposed research study, which includes the determination on whether a study is unnecessary. The Commission defers to the IRB whether a duplication of a study would have benefit. Thus, no changes upon adoption will be made in response to the comment.

36. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(b)29, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the, permit application process, the following materials for the Commission's evaluation: Any other information the Commission deems relevant in determining whether to grant a permit to the applicant." The commenter states that there "should be a team of inspectors from the CRC that can do a walk-through inspection of facilities." (5)

RESPONSE: Proposed N.J.A.C. 17:30A-7A.7 details the onsite inspection process, which includes a walk-through inspection of facilities by Commission compliance officers. Thus, no changes will be made upon adoption in response to the comment.

37. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(d)3, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application, the following submissions relating to its qualification for a permit, pursuant to N.J.A.C. 17:30A-7A.5: For all persons who are owners or principals of the permit applicant, a copy of their unexpired driver's license or other photo identification issued by the State, another state, or the Federal government, which shall be proof that the person is at least 21 years of age." The commenter appears to suggest that the Commission amend the regulation to include submission of "copies of their medical/professional licenses." (5)

RESPONSE: The Commission is modifying N.J.A.C. 17:30A-7A.4(d)3 in response to the comment to include a copy of professional and/or medical licenses, as appropriate.

38. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(d)9, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application, the following submissions relating to its qualification for a permit, pursuant to N.J.A.C. 17:30A-7A.5: For the permit applicant and each of its owners, principals, or managers, a list of any pending or adjudicated criminal charges or convictions." The commenter asks, "What about expungements?" (5)

RESPONSE: The purpose behind N.J.A.C. 17:30A-7A.4(d)9, is to determine whether any of the clinical registrant applicant's persons of interest have a pending disqualifying conviction pursuant to N.J.S.A. 24:6I-7.c. If a criminal conviction has been expunged, it is no longer applicable to the Commission's analysis. Thus, no changes will be made upon adoption in response to the comment.

39. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(d)19, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application, the following submissions relating to its qualification for a permit, pursuant to N.J.A.C. 17:30A-7A.5: For the permit applicant and each of its parent companies, subsidiaries, affiliates, predecessors, or successors: i. A list of any previous violation of, or judgment, order, consent decree, consent order, sanction, or penalty pertaining to any state or Federal statute, rule, regulation, or code; and ii. A list of all pending litigation or past litigation that concluded in the last five years, whether in the State of New Jersey or in another jurisdiction, in which the entity was involved." The commenter asks whether the Commission checks the above submissions to assure compliance. The commenter asks, "are state records/databases being checked?" (5)

RESPONSE: Each clinical registrant permit applicant is required to undergo a criminal history background investigation and probity review from assigned Commission investigators and compliance officers, pursuant to N.J.A.C. 17:30A-7A.6. This includes checking state databases to ensure that the applicant is truthful in their submissions. Thus, no changes will be made upon adoption.

40. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(d)27, which states, "A clinical registrant permit applicant shall disclose and submit, as part of the permit application, the following submissions relating to its qualification for a permit, pursuant to N.J.A.C. 17:30A-7A.5: Documentation that the clinical registrant applicant has a minimum of $15 million in capital." The commenter suggests this "should be raised to $25-$50 million." (5)

RESPONSE: The enabling statute at N.J.S.A 24:6I-7.3.a(4), states that a clinical registrant permit applicant "submit to the commission documentation that the applicant has a minimum of $15 million in capital." Thus, the Commission is not statutorily authorized to raise the amount of capital and no changes will be made upon adoption.

41. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.4(e)1, which states, "The permit applicant or permit holder shall not attempt to conceal or disguise ownership or other control over its operations in its submissions." The commenter asks, "what is the CRC's responsibility and due diligence here to assure compliance?" (5)

RESPONSE: As mentioned in the response to prior comments, each clinical registrant permit applicant is required to undergo a background investigation from assigned Commission investigators and compliance officers, pursuant to N.J.A.C. 17:30A-7A.6. This includes vetting of all owners and persons of interest and verifying of the application information. Additionally, the Commission requires ongoing compliance with its rules, as well as a yearly renewal application, pursuant to N.J.A.C. 17:30A-7A.8. Thus, no changes will be made upon adoption.

N.J.A.C. 17:30A-7A.5 Qualification for a Clinical Registrant Permit

42. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.5(a)1, which states, " A permit applicant or permit holder is qualified to hold a permit where: Each owner, principal, employee, or volunteer of a permit applicant or permit holder, as well as each staff member of a permit applicant's or permit holder's management services contractor that participates in the obtaining, possession, securing, cultivating, manufacturing, transporting, selling, delivering, or destroying of medical cannabis items has submitted to a criminal history background check pursuant to N.J.A.C. 17:30A-7A.6." The commenter asks whether there are guidelines established for the proper destruction of the study drug. (5)

RESPONSE: As mentioned in the response to prior comments, the requested standard operating procedure at N.J.A.C. 17:30A-7A.4(b)18iii, pertaining to recall of medical cannabis items, combined with the standard operating procedure at N.J.A.C. 17:30A-7A.4(b)18vii, waste disposal/sanitation, will provide the Commission the clinical registrant's policy regarding the proper recall or destruction of the study drug. The Commission acknowledges that each clinical registrant may have expertise in clinical trials and has its own unique policies regarding the proper destruction of the study drug and requires that the clinical registrant abides by its own policies. Thus, no changes will be made upon adoption.

43. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.5(c)2, which states, "[t]he Commission may determine a permit applicant or permit holder is unsuitable pursuant to [N.J.A.C. 17:30A-7A.5(b)5], where the permit applicant or permit holder has demonstrated, or is determined to: Have a history of: i. Distributing marijuana to minors; ii. Involvement with organized crime; iii. Diverting marijuana from personal-use or medical cannabis states to other states." The commenter appears to suggest this regulation "needs to be further defined." (5)

RESPONSE: N.J.A.C. 17:30A-7A.5 details the qualifications necessary for a clinical registrant permit. N.J.A.C. 17:30A-7A.5(c)2 discusses factors by which a clinical registrant permit applicant is unsuitable to hold a permit, which includes having a history of distributing marijuana to minors, involvement with organized crime and diverting marijuana from personal-use or medical cannabis states to other states, as well as other factors. These actions are evidenced by corroborating evidence discovered by the Commission's investigations team for one or more of these offenses. It is unclear what needs to be further defined, and thus, no changes will be made upon adoption.

N.J.A.C. 17:30A-7A.6 Criminal History Background Check

44. COMMENT: One commenter referenced the Commission's proposed regulation at N.J.A.C. 17:30A-7A.6(a), which states, "Each owner, principal, employee, or volunteer of a clinical registrant permit applicant or holder or staff member of a permit applicant's or permit holder's management services contractor shall provide written consent to submit to a criminal history background check pursuant to the Act and shall comply with the procedures established by the Division of State Police pursuant to N.J.A.C. 13:59 for obtaining readable fingerprint impressions." The commenter asks, "for above who performs and who pays?" (5).

RESPONSE: The New Jersey Division of State Police conducts a background check pursuant to N.J.A.C. 13:59 and the clinical registrant applicants must submit background investigation fees pursuant to N.J.A.C. 17:30A-7A.9(a)5. No changes will be made upon adoption.

N.J.A.C. 17:30A-7A.7 Clinical Registrant Permit Acceptance; Inspection; Issuance; Commencement of Operations

45. COMMENT: One commenter referenced the Commission's proposed rule at N.J.A.C. 17:30A-7A.7(e), which states, "A permit applicant shall have 365 days from the date of the notice of approval to request a final onsite assessment pursuant to (g) below before commencing medical cannabis operations." The commenter agrees with the above but suggests the regulation must be written "in greater detail of what an on-line inspection looks like." The commenter suggests that it "should be on the same level as any other big-pharma inspection conducting a clinical trial," and should require "all the same elements, storage, interviews, [and] document review." (5)

RESPONSE: Pursuant to N.J.A.C. 17:30A-7A.7(h), during the onsite assessment, the Commission compliance officer determines whether the "clinical registrant premises, operations, plans, procedures, protocols, and actions are consistent with the entity's permit application and compliant with [P.L.2019, c.153], [the Commission's regulations,] the requirements in the entity's written notice of approval, and any additional requirements provided by the Commission." The Commission requires standard operating procedures related to inventory control, storage, diversion prevention and recordkeeping, and during the final onsite inspection, the Commission's compliance officer ensures that the clinical registrant is complying with its own protocols.

Regarding the 365-day deadline to become operational, the Commission is deleting N.J.A.C. 17:30A-7A.7(e) upon adoption. On April 11, 2024, the Commission issued Resolutions 2024-220 and 2024-211, which removed all operational deadlines for 2019 Request for Application awardees and adult-use entities.

N.J.A.C. 17:30A-7A.9 Clinical Registrant Fees

46. COMMENT: Two commenters request that the Commission reduce the licensing fees and authorize permits for more than one year. The commenters state that "the proposed fees in § 17:30A-7A.9 are unreasonably expensive." The commenters reason that data "from other medical and adult-use markets demonstrate that higher fees are a disincentive and discourage participation." Now that New Jersey has legalized medical and adult use, the commenters state that "the State cannot afford to prevent research into cannabis because that research will likely directly impact the State's public health." Moreover, the commenters argue that "if the State licenses more Clinical Registrants, it could make up for the shortfall in reduced fees by increasing the volume of licensees." The commenters state that the "same logic applies to extending the license renewal requirements." The commenters conclude that "renewing annually places an undue burden on the applicant, who should be incentivized and encouraged to participate." (2 and 6).

RESPONSE: N.J.S.A. 24:6I-7.3.a(2) gives the Commission the authority to charge clinical registrants any "required application and permit fees." Pursuant to N.J.S.A. 24:6I-11.b "[a]ll fees collected pursuant to P.L.2009, c.307 (C.24:6I-1 et al.), including those from qualifying patients, designated and institutional caregivers, and initial, modification and renewal applications for alternative treatment centers, including medical cannabis cultivators, medical cannabis manufacturers, medical cannabis dispensaries, and clinical registrants, shall be used to offset the cost of the commission's administration of the provisions of P.L.2009, c.307 (C.24:6I-1 et al.)." The application, initial, and renewal permitting fees for clinical registrants mirror the fees pursuant to the Commission's personal-use regulations, which were reasonably calculated to offset the cost of implementing the provisions at P.L. 2021, c. 16. Like its personal-use rules, the proposed initial or renewal permitting fees for clinical registrants are tiered by size. Larger entities generally have more persons of interest, which consumes more investigative time spent by the Commission. Regarding renewal, N.J.S.A. 24:6I-7.e. states, "... A permit to operate a medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary issued on or after the effective date of P.L.2019, c.153 (C.24:6I-5.1 et al.) shall be valid for one year and shall be renewable annually." A clinical registrant is authorized to operate as a

medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary. Thus, no changes will be made upon adoption.

Federal Standards Statement

The Jake Honig Compassionate Use Medical Cannabis Act (the Act), N.J.S.A. 24:6I-1 et seq., obliges the Commission to promulgate rules necessary or proper to enable it to carry out the Commission's duties, functions, and powers with respect to overseeing the development, regulation, and enforcement of activities associated with the medical use of cannabis. These duties include the regulation of the purchase, sale, cultivation, production, manufacturing, transportation, and delivery of medical cannabis or medical cannabis items in accordance with the provisions of the Act. Therefore, the Act requires the Commission to promulgate rules governing the regulated community's cultivation, possession, manufacture, sale, distribution, and use of medical cannabis. The Controlled Substances Act, 21 U.S.C. §§ 801 et seq., prohibits the cultivation, distribution, and possession of marijuana or cannabis, for any reason, regardless of state law. 21 U.S.C. §§ 841 et seq. The adopted new rules on clinical registrants anticipate that members of the regulated community would possess cannabis and may engage in certain financial activities that are ancillary to cultivation, distribution, and possession of cannabis. These ancillary financial activities may constitute prohibited conduct pursuant to other Federal criminal and civil laws, such as the money laundering statutes, the unlicensed money transmitter statute, and the Bank Secrecy Act (BSA). 18 U.S.C. §§ 1956 through 1957, and 1960; and 31 U.S.C. § 5318.

Therefore, the new rules on clinical registrants will conflict with Federal law. Members of the regulated community who engage in activities contemplated by the Act might incur Federal civil and criminal liability. N.J.S.A. 24:6I-2(d) notes that "States are not required to enforce [Federal] law or prosecute people for engaging in activities prohibited by [Federal] law; therefore, compliance with [the Act] does not put the State of New Jersey in violation of [Federal] law," and N.J.S.A. 24:6I-54 further directs law enforcement in New Jersey to not cooperate with Federal agencies enforcing the Controlled Substances Act for activities solely authorized by the Act. Between October 2009 and late October 2014, the United States Department of Justice (Justice Department) issued a series of formal memoranda to United States Attorneys to guide their exercise of investigative and prosecutorial discretion in states enacting laws authorizing the cultivation, distribution, and possession of marijuana, for medicinal or personal-use purposes. *See e.g.,* David W. Ogden, Deputy Attorney Gen., Memorandum for Selected United States Attorneys: Investigations and Prosecutions in 9 States Authorizing the Medical Use of Marijuana (October 19, 2009); James M. Cole, Deputy Attorney Gen., Memorandum for United States Attorneys: Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use (June 29, 2011); James M. Cole, Deputy Attorney Gen., Memorandum for All United States Attorneys: Guidance Regarding Marijuana Enforcement (August 29, 2013); James M. Cole, Deputy Attorney Gen., Memorandum for All United States Attorneys: Guidance Regarding 32 Marijuana Related Financial Crimes (February 14, 2014); and Monty Wilkinson, Director of the Executive Office for United States Attorneys, Policy Statement Regarding Marijuana Issues in Indian Country (Oct. 28, 2014). While noting the Justice Department's commitment to enforcing the Controlled Substances Act, these guidance memoranda instructed United States Attorneys to focus on the following eight enforcement interests in prioritizing the prosecution of Federal laws criminalizing marijuana-related activity in states that have enacted laws authorizing marijuana-related conduct:

1. Preventing the distribution of marijuana to minors;

2. Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;

3. Preventing the diversion of marijuana from states where it is legal in some form under state law to other states;

4. Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

5. Preventing violence and the use of firearms in the cultivation and distribution of marijuana;

6. Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;

7. Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and

8. Preventing marijuana possession or use on Federal property. Cole (August 29, 2013), *Id.*, at 1-2.

The memoranda encouraged United States Attorneys to continue to rely on states that have enacted laws authorizing marijuana-related conduct to address marijuana related activity through enforcement of state controlled substances laws, if those states "provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine", the eight Federal enforcement priorities, *Id.*, at 2-3, and "implement clear, strong and effective regulatory and enforcement systems in order to minimize the threat posed" to the eight Federal enforcement priorities. Cole (February 14, 2014), *Id.*, at 3. The memoranda noted that persons and entities engaged in marijuana-related activities "are more likely to risk entanglement with conduct that implicates the eight [Federal] enforcement priorities" in states that lack "clear and robust" regulatory schemes and enforcement systems. *Ibid*.

In guidance issued concurrently with Deputy United States Attorney General Cole's February 14, 2014, memorandum on marijuana-related financial crime enforcement priorities, *Ibid.*, the Financial Crimes Enforcement Network (FinCEN) of the United States Department of the Treasury (Treasury Department) issued a companion guidance document that "clarifies how financial institutions can provide services to marijuana-related businesses consistent with their Bank Secrecy Act (BSA) obligations, and aligns the information provided by financial institutions in BSA reports with [Federal] and state law enforcement priorities. This FinCEN guidance should enhance the availability of financial services for, and the financial transparency of, marijuana-related businesses." FinCEN, United States Department of the Treasury, Guidance FIN-2014- G001: BSA 34 Expectations Regarding Marijuana-Related Businesses (February 14, 2014) (FinCEN Guidance).

The FinCEN Guidance emphasizes that financial institutions' exercise of thorough due diligence is critical to their assessment of the risk of providing services to marijuana-arelated businesses, and specifies tasks financial institutions should perform as part of their due diligence, noting that as "part of its customer due diligence, a financial institution should consider whether a marijuana-related business implicates one of the [eight Federal enforcement] priorities or violates state law." *Id.*, at 2-3. The FinCEN Guidance identifies the types of required "Suspicious Activity Report" and "Currency Transaction Report" filings that financial institutions are to make attendant to their engagement with marijuana-related businesses, and provides a non-exhaustive list of "red flags" or indicia that could give rise to a financial institution's suspicion, or actual or constructive knowledge, "that a marijuana-related business may be engaged in activity that implicates one of the [eight Federal enforcement] priorities or violates state law," thereby triggering the financial institution's obligations to perform additional due diligence investigation or file a "Marijuana Priority" Suspicious Activity Report. *Id.*, at 3-7.

On January 4, 2018, the Justice Department issued a memorandum to all United States Attorneys, instructing them that, in "deciding which marijuana activities to prosecute under [applicable Federal] laws with the [Justice] Department's finite resources, to follow the well-established principles that govern all [Federal] prosecutions as reflected in the United States Attorneys' Manual. These principles require [Federal] prosecutors deciding which cases to prosecute to weigh all relevant considerations, including [Federal] law enforcement priorities set by the Attorney General, the seriousness of the crime, the deterrent effect of criminal prosecution, and the cumulative impact of particular crimes on the community. Given the Department's well-established general principles, previous nationwide guidance specific to marijuana enforcement is unnecessary and is rescinded, effective immediately." Jefferson B. Sessions, III, Attorney Gen., Memorandum for All United States Attorneys: Marijuana Enforcement (January 4, 2018) (Sessions Memorandum) (specifically listing, at n.1, the 2009 through 2014 Justice Department Memoranda, discussed above, as rescinded). The Sessions Memorandum neither identified the "law enforcement priorities set by the

Attorney General" that United States Attorneys were to consider instead of the eight Federal enforcement priorities announced in the rescinded Justice Department Memoranda, nor did it explain whether and how those sets of priorities might differ. However, the press release accompanying its issuance characterized the Sessions Memorandum as "announcing a return to the rule of law," and quoted Attorney General Sessions as saying that the Sessions Memorandum "simply directs all [United States] Attorneys to use previously established prosecutorial principles that provide them all the necessary tools to disrupt criminal organizations, tackle the growing drug crisis, and thwart violent crime across our country." Office of Public Affairs, Justice Department, Press Release No. 18-8: Justice Department Issues Memo on Marijuana Enforcement (January 4, 2018). The Treasury Department did not issue guidance, concurrent with the issuance of the Sessions Memoranda or thereafter, rescinding its FinCEN Guidance. Therefore, the FinCEN Guidance appears to remain extant.

While there has been no new guidance released from the Justice Department since the Sessions Memorandum, Attorney General Merrick Garland twice provided testimony to Congress in 2021, where he reiterated the spirit of the Cole Memorandum and its commitment to deprioritizing Federal enforcement against persons and entities complying with state law in a state with a well-regulated cannabis program. He stated: "I do not think it the best use of the [Justice] Department's limited resources to pursue prosecutions of those who are complying with the laws in states that have legalized and are effectively regulating marijuana." Senate Committee on the Judiciary, Responses to Questions for the Record to Judge Merrick Garland, Nominee to be United States Attorney General (February 28, 2021); Senate Committee on the Judiciary, Hearing on the Nomination of the Honorable Merrick Brian garland to be Attorney General of the United States (February 22, 2021); House Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies, Hearing on the Fiscal Year 2022 Budget Request for the Department of Justice (May 4, 2021).

Additionally, existing Federal budget laws protect and safeguard state administered legal medicinal marijuana programs. The Blumenauer amendment (previously known as the Rohrabacher-Farr amendment), most recently sponsored by United States Representative Earl Blumenauer (D-OR), prevents the Justice Department from using Federal funds to prosecute state-compliant medical marijuana operators in states that have legal cannabis programs. It was first approved in 2014, and has been approved or renewed by Congress more than 29 times since.

The new rules on clinical registrants adhere to the standards outlined in the Cole Memorandum. The rules require stringent security standards for those who apply for and are issued a clinical registrant permit and further enforce the Act's prohibition on the sale of cannabis to anyone under the age of 21.

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

SUBCHAPTER 1. GENERAL PROVISIONS

17:30A-1.2 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise, or another subchapter defines one of the following words or terms differently for the purposes of that subchapter:

"Academic medical center" means a health care practice, accredited medical training program, medical school, or school of osteopathic medicine, that has the ability to conduct research***, which may include human clinical trials but in no case shall include animal testing,*** related to medical cannabis in partnership with clinical registrants as fully defined at N.J.A.C. 17:30A-7A.1.

. . .

"Aggregate ownership interest" means the total ownership interest held by an owner, including a passive investor, that is a person and by the spouse, domestic partner, civil union partner, child, sibling, or parent of the person.

"Alternative treatment center" or "ATC" means an entity that has been issued one or more permits to cultivate, manufacture, or dispense medicinal marijuana and related paraphernalia to registered qualifying patients in accordance with the provisions of the Act and this chapter. This term includes the ATC's officers, directors, board members, and employees and any clinical registrant. "Alternative treatment center" includes a "vertically integrated alternative treatment center" and both clinical registrant ATCs and non-clinical ATCs.

. . .

"Clinical registrant" means a clinical research-focused alternative treatment center issued one or more ATC permits pursuant to N.J.S.A. 24:6I-7.3, as fully defined at N.J.A.C. 17:30A-7A.1.

. . .

"Financial source" means a person or entity that lends any amount of capital to an ATC permit applicant or permit holder pursuant to a secured or unsecured financing agreement and who is not an owner, passive investor, or principal of such ATC permit applicant or permit holder.

"Financial source agreement" means any agreement, contract, arrangement, or other type of formal understanding between a financial source and an ATC permit applicant or permit holder where the financial source lends capital to the ATC permit applicant or permit holder pursuant to a secured or unsecured financing agreement and does not receive ownership interest.

"Institutional Review Board" or "IRB" means a board, committee, research approval committee, or group created or designated by an academic medical center, as applicable, that reviews and approves the *[anticipated]* ***proposed*** scope and research protocols of a clinical registrant's proposed research study.

. . .

"Management services agreement" means any agreement, contract, arrangement, or other type of formal understanding between a management services contractor and an ATC permit applicant or permit holder where the management services contractor provides professional staffing, administrative, operational, advisory, or management services to the ATC permit applicant or permit holder in exchange for remuneration, but not an ownership interest.

"Management services contractor" or "MSC" means a third-party vendor-contractor person or entity supervised by the principals and owners of the ATC permit applicant or permit holder, that provides professional staffing, administrative, operational, advisory, or management services to the ATC permit applicant or permit holder in exchange for remuneration pursuant to a management services agreement.

. . .

"Owner" means:

1. Any person or entity that holds at least a five percent aggregate ownership interest in an ATC permit applicant or permit holder;

2. Where an entity, including a parent company, holds at least a five percent ownership interest in an ATC permit applicant or permit holder, any person or entity that holds at least a 10 percent aggregate ownership interest in or is a member of the executive team of such entity, except that, where such entity holding at least a five percent ownership interest in an ATC permit applicant or permit holder:

i. Is a nonprofit entity, any person or entity that is an officer of that nonprofit entity in accordance with the articles of incorporation, or the bylaws, or is a member of the governing board of such entity;

ii. Is a qualified institutional investor, any person or entity that holds at least a 30 percent aggregate ownership interest in or is a member of the executive team of such entity; or

iii. Is a trust, any trustee of such entity; or

3. A significantly involved person of a cannabis business license applicant or license holder, as that term is defined pursuant to N.J.S.A. 24:6I-3.

. . .

"Passive investor" means a person or entity that:

1. Holds an aggregate ownership interest that is greater than zero percent but less than five percent in an ATC permit applicant or permit holder; and

2. Does not have control or decision-making authority over the management, operations, or policies of such permit applicant's or permit holder's ATC.

. . .

"Permit applicant" means a person or entity that is applying for, or has a pending application for, an alternative treatment center permit.

"Permit holder" or "permittee" means a person or entity registered to do business in New Jersey that holds an alternative treatment center permit.

. . .

SUBCHAPTER 7. GENERAL PROCEDURES AND STANDARDS APPLICABLE TO ALTERNATIVE TREATMENT CENTERS

17:30A-7.1 Permit application procedures and requirements for non-clinical alternative treatment centers

(a) An applicant for a non-clinical ATC permit shall submit an application form and the fees required at N.J.A.C. 17:30A-6.5, as well as all other required documentation on forms obtained from the permitting authority or on the Commission's website at http://www.nj.gov/cannabis.

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

17:30A-7.12 Probity review

(a) After the receipt of an application from a permit applicant, as part of the verification and probity review, the Commission, at its discretion, may require additional information and the submission, by the permit applicant, of supporting documents and other evidence before making a final decision on the application or issuing a permit.

(b) At the discretion of the Commission, an owner, passive investor, management services contractor, or financial source may be required to submit documentation verifying the source of the funds provided to the permit applicant, including, but not limited to, a promissory note, credit facility, debt instrument, guarantor agreement, or loan agreement, as well as closing documents.

(c) The following persons or entities shall be required to submit to a financial probity review:

1. Owners;

2. Principals;

3. Members of a governing body that governs an owner or a principal of a permit applicant or holder that is an entity;

4. Management services contractors contracting with a permit applicant;

5. Any person or entity that holds at least 10 percent aggregate ownership interest in or who is a member of the executive team of a management services contractor contracting with a permit applicant or permit holder;

6. Financial sources that are not a qualified institutional investor;

7. Any person or entity that holds at least a 10 percent aggregate ownership interest in or who is a member of the executive team of a financial source entity that is not a qualified institutional investor; and

8. Vendor-contractors.

(d) Financial probity review for a person for the purposes of verification of a permit application and qualification for a permit may include submission of:

1. A state driver's license, or other photo identification issued by the State of New Jersey, another state, or the Federal government;

2. A passport;

3. Any college diploma, transcript, or letter from a registrar providing confirmation of a person's status at an academic or educational institution;

4. Ownership documents for any vehicles, aircraft, or boats owned by the person or the person's business;

5. Any professional licenses held, and any documents related to sanctions imposed, or known investigations in connection with those licenses;

6. Any criminal record history and any information regarding rehabilitation pursuant to N.J.A.C. 17:30A-7.2(f) and 7A.6(e);

7. Documentation for any business, aside from the permit applicant, in which the person currently holds at least a 25 percent ownership interest, including, but not limited to, partnership papers, operating agreements, and stock registry-stock certificates;

8. Summary of any pending litigation or past litigation that concluded during the previous five years, other than divorce or child custody matters, in which the person was involved, including docket number, venue, cause of action, named litigants, a copy of the complaint, and disposition or current status;

9. Any employment contract or offer letter between the permit applicant and the person;

10. Most recently filed individual State, Federal, and foreign tax returns including Schedule K1, and, if applicable, the most recently filed letter requesting an extension;

11. Most recently filed business State, Federal, and foreign tax returns for any business, aside from the permit applicant, in which the person holds more than a 50 percent ownership interest;

12. Any W-2 and 1099 forms for the prior three tax years;

13. Account statements for any personal bank account, including a money market account, for which the person has signatory authority;

14. An original deed and purchase settlement statement, for any real estate property in which the person has an ownership interest;

15. The declaration page of any cash value life insurance policy held by the person and the names of all beneficiaries, including the name, trustee, and beneficiaries of any trust;

16. Account statements for any pension or retirement account held by the person, including any 401k;

17. Account statements for any account held by the person that holds securities, including a brokerage or investment account;

18. Any notes or loans receivable in the person's name;

19. Any notes or loans payable in the person's name;

20. Any documents relative to any contingent liabilities in which the person serves as a guarantor;

21. Any liens, judgments, or taxes payable levied against the person; and

22. Additional identifying information about the person's immediate family, including, but not limited to, marriage, death, and birth certificates.

(e) Financial probity review for an entity for the purposes of verification of permit application submissions and qualification may include submission of:

1. Entity organizational chart;

2. Entity business formation documents;

3. List and summary of all fines or sanctions imposed by any agency regulating cannabis on the entity in any jurisdiction and the circumstances surrounding such fines or sanctions;

4. Summary of any pending litigation or past litigation that concluded during the previous five years in which the entity or its subsidiaries was involved, including docket number, court name, cause of action, named litigants, a copy of the complaint, and disposition or current status;

5. Documentation for any company, aside from the permit applicant, in which the entity currently holds at least 25 percent ownership interest, including, but not limited to, partnership papers, operating agreements, and stock registry-stock certificates;

6. Most recently filed individual state, Federal, and foreign tax returns, including Schedule K1, and, if applicable, most recently filed letter requesting an extension;

7. Most recently filed business state, Federal, and foreign tax returns for any business, aside from the permit applicant, in which the entity holds more than a 50 percent ownership interest;

8. Minutes of the meetings of and resolutions passed by the entity's governing board for the previous two calendar years;

9. Any filed annual financial reports of the entity that are required to be filed with a national securities exchange or over-the-counter market;

10. Unaudited balance sheet and income statement or audited financial statement of the entity for the 24 months previous to the application;

11. Monthly bank statements for the previous year for all entity bank accounts related to the permit applicant;

12. Any notes or loans receivable in the entity's name;

13. Any notes or loans payable in the entity's name;

14. Any liens, judgments, or taxes payable levied against the entity;

15. Where the entity is a publicly traded corporation or a private capital fund, a complete list of persons and entities with any ownership interest in the entity; and

16. Any other information the Commission deems relevant in determining whether to grant a permit to the applicant.

(f) Probity review materials submitted to the Commission pursuant to this section shall not be considered public records pursuant to N.J.S.A. 47:1A-1 et seq., or the common law concerning access to government records.

SUBCHAPTER 7A. CLINICAL REGISTRANTS AND ACADEMIC MEDICAL CENTERS

17:30A-7A.1 Clinical registrants and academic medical centers

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

"Academic medical center" means:

1. An entity located in New Jersey that has the ability to conduct research related to medical cannabis (if the entity is part of a system of health care facilities, the entity shall not qualify as an academic medical center unless the health care system is principally located within the State) and that:

i. Has an addiction medicine faculty practice or is in the same health care system as another facility located in New Jersey that offers outpatient medical detoxification services or inpatient treatment services***, including entheogens,*** for substance use disorder;

ii. Has a pain management faculty practice or a facility-based pain management service located in New Jersey;

iii. Has graduate medical training programs accredited, or pending accreditation, by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association in primary care and medical specialties; or

iv. Is the principal teaching affiliate of a medical school based in the State; or

2. An accredited school of osteopathic medicine that:

i. Is located in a state that shares a common border with this State;

ii. Has an articulation agreement or similar memorandum of understanding with any state college or university located in a county of the first class with a college of nursing or nursing degree program accredited by the Commission on Collegiate Nursing Education;

iii. Has an agreement to establish and maintain an apprenticeship program in this State to train workers in the cannabis industry, which training would earn college credit with the partner state college or university;

iv. Has an institutional review board that has approved a clinical research study in this State involving medical cannabis; and

v. Has the ability to, and will, conduct all research and development in the county in which the partner state college or university is located.

"Clinical registrant" means a clinical research focused alternative treatment center issued an ATC permit pursuant to N.J.S.A. 24:6I-7.3 and this chapter that has a written contractual relationship with an academic medical center in the region in which it has its principal place of business, and such research contract includes provisions whereby:

1. The parties will engage in clinical research related to the use of medical cannabis; and

2. The academic medical center or its affiliate will provide advice to the ATC regarding patient health and safety, medical applications, and dispensing and managing controlled dangerous substances, among other areas. ***Other optional categories of advice may include compliance, drug storage, and destruction guidelines, inspections, data collection, and Health Insurance Portability and Accountability Act compliance.***

17:30A-7A.2 Clinical registrant conduct; prohibitions; reporting; revocation

(a) A clinical registrant issued a permit pursuant to this chapter shall be authorized to engage in the cultivation, manufacturing, *[or]* ***and*** dispensing of medical ***or personal use*** cannabis as is authorized for a non-clinical ATC holding a medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit ***or an expanded ATC holding a cannabis cultivator, cannabis manufacturer, or cannabis dispensary license*** pursuant to the Act***, this chapter, and N.J.A.C. 17:30***, including dispensing medical cannabis ***or cannabis*** items to ***consumers 21 years of age or older,*** registered patients***,*** and *[designated]* ***primary*** caregivers.

1. A clinical registrant may buy, sell, and transfer medical cannabis ***or cannabis*** items to and from another ATC ***or other New Jersey cannabis business*** that possesses a valid permit ***or license***.

2. A clinical registrant may dispense usable cannabis***,*** *[and]* medical cannabis products***, and cannabis products*** to a patient or caregiver with a registry identification card ***or a consumer 21 years of age or older,*** regardless of whether the *[patient]* ***individual*** is a participant in a research study.

(b) The clinical registrant shall additionally be authorized to engage in clinical research involving medical cannabis with the participation of registered patients who consent to being part of such research, subject to any restrictions established by the Commission.

1. A clinical registrant may dispense usable medical cannabis and medical cannabis products, in any form authorized by an institutional review board (IRB), directly to an academic medical center as part of a research study. An academic medical center that handles medical cannabis items shall do so in a manner consistent with the academic medical center's standards used for the handling, storage, and disposal of other patient medications.

i. Where an academic medical center is located outside of New Jersey, such dispensing shall be received by the academic medical center's partner state college or university and all cannabis items and medical cannabis items shall remain in New Jersey.

2. A clinical registrant applicant shall provide written documentation of an existing research contract with an academic medical center, which shall include a commitment by the academic medical center, or its affiliate, to engage in or oversee clinical research related to the use or adverse effects of cannabis in order to advise the clinical registrant concerning patient health and safety; medical applications; dispensing and management of controlled substances; and ways to mitigate adverse health or societal effects of adult, personal-use legalization, among other areas.

3. A clinical registrant shall have a written contractual relationship with no more than one academic medical center.

4. A research contract shall contain the responsibilities and duties of each party with respect to the research study.

5. A research contract shall include a description of the research study the clinical registrant and the academic medical center intend to conduct.

i. Research study topics may include, but are not limited to, the therapeutic or palliative efficacy of medical cannabis on the qualifying medical conditions established pursuant to the Act or on any other medical or psychological condition.

ii. The description of the research study shall include the research protocol, and a written procedure for conducting the research program, which shall include the following information:

(1) Each investigator's name, address, institutional affiliation, and qualifications, including a curriculum vitae and list of publications, if any;

(2) The title of the research study;

(3) The research study statement of the purpose;

(4) The types and amounts of medical cannabis items and the dosage and method of administration used in the research study;

(5) The duration of the research study; and

(6) The locations of the clinical registrant dispensaries that will be participating in the research study.

(c) A clinical registrant shall demonstrate to the Commission that an IRB has taken the following actions to review the research study and that the clinical registrant has met the requirements of this subsection:

1. An IRB shall review and approve each proposed research study in accordance with its established practices and procedures.

i. An IRB shall review the anticipated scope and research protocol of the proposed research study involving human subjects pursuant to the criteria at 45 CFR 46.111 (relating to criteria for IRB approval of research) and 21 CFR 56.111 (relating to criteria for IRB approval of research); and

2. Both an IRB and the clinical registrant shall ensure that the clinical registrant's research study addresses all of the following:

i. Protecting the rights and welfare of patients involved in research studies conducted pursuant to this section.

ii. Minimizing the risk of adverse outcomes for patients by using procedures that are consistent with sound research design and that do not expose patients to undue risk as a result of participating in the research study.

iii. Determining that the risks to patients involved in research programs are reasonable in relation to the anticipated benefits (if any) to the patients, and the importance of the knowledge that may be expected to result from the research program.

iv. Guaranteeing that informed consent will be obtained from each prospective participant or the participant's legally authorized representative and is properly documented.

v. Protecting the privacy of every patient and maintaining the confidentiality of patient data.

(d) An academic medical center may not solicit or accept anything of value from an approved clinical registrant or its owner, passive investor, principal, MSC, financial source, or employee of an approved clinical registrant except for reasonable remuneration, specifically in a research contract for the services to be performed or costs to be incurred by the academic medical center.

(e) No permit holder issued a non-clinical medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit may concurrently hold a clinical registrant permit, and no permit holder issued a clinical registrant permit may concurrently hold a non-clinical medical cannabis cultivator, medical cannabis manufacturer, or medical cannabis dispensary permit *[or a personal-use cannabis business license]*.

(f) No clinical registrant shall contract with an academic medical center that is part of a health care system that includes another academic medical center that has contracted with another clinical registrant permit applicant or permit holder.

(g) A clinical registrant shall have a written contractual relationship with no more than one academic medical center. An academic medical center may enter into a letter of intent with more than one clinical registrant ATC permit applicant but may only execute a research contract with one clinical registrant permit holder.

(h) A clinical registrant may not operate or be located on land that is valued, assessed, or taxed as an agricultural or horticultural use pursuant to the Farmland Assessment Act of 1964, P.L. 1964, c. 48 (N.J.S.A. 54:4-23.1 et seq.).

(i) Each clinical registrant shall submit a written report of the results and findings of its clinical research study to the Commission no later than one year following the conclusion of the research study or no later than 30 days following the *[publication]* ***acceptance*** of the research study ***to be published*** in a peer-reviewed medical journal, whichever is first.

1. The Commission may post such results and findings on its publicly accessible website and share them with other clinical registrant permit holders, academic medical centers, or any other person it determines would benefit from the findings.

2. Nothing in this subsection shall be deemed to require the disclosure of any clinical research that would infringe on the intellectual property of the clinical registrant or on the confidentiality of patient information.

(j) The Commission may suspend or revoke the permit of a clinical registrant where:

1. The academic medical center no longer meets the requirements to be an academic medical center pursuant to this chapter; or

2. The research contract between the clinical registrant and the academic medical center expires without being renewed or is terminated by either party.

(k) The Commission shall not revoke the permit on the grounds at (j) above, if, in the 90 days following receipt of the Commission's written notice of its intent to revoke the permit, the clinical registrant provides the Commission with documentation that:

1. It has established a contractual relationship with a qualifying academic medical center that is not already a party to a research contract with another clinical registrant permit holder; or

2. The clinical registrant's existing partner academic medical center meets the requirements to be an academic medical center established in this subchapter.

(l) If a permit is suspended or revoked, the Commission shall provide notice of the suspension or revocation to the applicant, in writing, which shall include:

1. The specific reason for the suspension or revocation; and

2. The opportunity to request an administrative hearing within 45 days after the date of the suspension or revocation.

(m) An administrative hearing pursuant to this section shall take place in the Office of Administrative Law in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(n) The final decision of a suspension or revocation after an administrative hearing shall be considered a final agency decision, subject to judicial review by, and of which jurisdiction and venue for such review are vested in, the Appellate Division of the Superior Court.

17:30A-7A.3 Clinical registrant permit application submission; approval; denial

(a) The Commission shall issue a sufficient number of clinical registrant permits, pursuant to need, as it deems necessary to meet the needs of qualifying patients in the State, and may accept new clinical registrant permit applications for such permits as it deems necessary to meet those needs.

(b) The Commission shall provide notice of the acceptance of clinical registrant permit applications on the Commission website, to the Commission email list, and at a Commission public meeting.

1. Such notice shall be compliant with N.J.A.C. 17:30A-7A.4, and shall include:

i. Measures by which the permit applicant will be scored;

ii. Maximum scores for each individual measure; and

iii. The total score required for a permit applicant to be approved for a permit.

(c) Not more than 90 days after the receipt of a complete permit application, the Commission shall make a determination on the application.

1. Such determination may include a determination that the Commission requires more time to adequately review the application.

(d) Applications shall be reviewed for completeness and then scored in accordance with the criteria included in the notice of application acceptance pursuant to (b) above.

(e) The Commission shall verify the information contained in a clinical registrant permit application by any means authorized pursuant to N.J.A.C. 17:30A-6.3 or 7.3.

(f) The Commission shall investigate and conduct a probity review of the permit applicant, its owners, principals, and related entities and their finances, ownership, and control structure as it deems necessary.

1. The permit applicant shall cooperate with the Commission's investigation and verification process and shall provide all information requested by the Commission.

(g) The Commission shall approve a clinical registrant permit applicant for an annual permit where the applicant has:

1. Submitted a complete clinical registrant permit application in accordance with N.J.A.C 17:30A-7A.4;

2. Scored sufficiently high to be issued a permit in accordance with the criteria included in the notice of application acceptance pursuant to (b) above;

3. Been deemed qualified to hold a clinical registrant permit pursuant to N.J.A.C. 17:30A-7A.5; and

4. Submitted its permit application submission fee, pursuant to N.J.A.C. 17:30A-7A.9.

(h) A clinical registrant permit application the Commission deems incomplete because of failure to address all applicable criteria and measures or to provide requested information shall be returned to the permit applicant with the opportunity to cure the deficiencies in the permit application and resubmit it.

(i) The Commission may deny a clinical registrant permit to an applicant that:

1. Is not qualified to hold a clinical registrant permit pursuant to N.J.A.C. 17:30A-7A.5;

2. Has not scored sufficiently high enough to be issued a clinical registrant permit in accordance with the criteria included in the notice of application acceptance pursuant to (b) above;

3. Fails to reveal any material fact pertaining to qualification pursuant to N.J.A.C. 17:30A-7A.5 or fails to cooperate in the Commission's investigation into the applicant;

4. Has been determined by the Commission, by clear and convincing evidence, to be unsuitable to hold a clinical registrant permit pursuant to N.J.A.C. 17:30A-7A.5;

5. Presents false or intentionally misleading information in the application process; or

6. Has a history of violating the requirements established in the chapter, the Act, or the entity's written notice of approval, or a history of violating regulatory requirements in other jurisdictions.

(j) If an application is denied, the Commission shall provide notice of the denial to the applicant, in writing, which shall include:

1. The specific reason for the denial; and

2. The opportunity to request an administrative hearing within 45 days after the date of the denial.

(k) An administrative hearing pursuant to (j) above shall take place in the Office of Administrative Law in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(l) The final decision on an application after an administrative hearing shall be considered a final agency decision, subject to judicial review by, and of which jurisdiction and venue for such review are vested in, the Appellate Division of the Superior Court.

(m) A clinical registrant permit shall be valid for one year and may be renewed in accordance with N.J.A.C. 17:30A-7A.8.

17:30A-7A.4 Clinical registrant permit application

(a) An applicant for a clinical registrant permit shall submit a complete, separate application, on forms prescribed by the Commission, for each physical address and premises at which a permit applicant seeks to operate.

(b) A clinical registrant permit applicant shall disclose and submit, as part of the permit application process, the following materials for the Commission's evaluation:

1. The Federal and State tax identification numbers for the permit applicant;

2. Documentation of a valid Business Registration Certificate on file with the Division of Revenue and Enterprise Services in the Department of the Treasury;

3. Information about the permit applicant, including its legal name, and any registered alternate name;

4. A copy of the documents reflecting the formation of the permit applicant entity, including, but not limited to, articles of incorporation or organization, charter, bylaws, stock issuance records, operating agreements, partnership agreements, other formation documents filed with the Secretary of State, and any other documents that govern the legal and ownership structure of the entity;

5. If applicable, documents from the Federal or State government recognizing the permit applicant entity's nonprofit status;

6. A description of the proposed location and its surrounding area, including the following:

i. The mailing and physical address of the permit applicant's proposed location;

ii. A description of the suitability or advantages of the proposed location; and

iii. A site plan of the proposed location, including a floor plan, which may optionally include renderings, architectural plans, or engineering plans;

7. Evidence of compliance with local codes and ordinances.

i. Zoning approval, which shall consist of a letter or affidavit from appropriate officials of the municipality stating that the location will conform to municipal zoning requirements allowing for activities related to the operations of the proposed clinical registrant permit, and any variances granted concerning the operation of the clinical registrant;

8. Proof of local support, which shall be demonstrated by a resolution adopted by the municipality's legislative body, or by a written letter of support from the municipality's executive;

9. Documentation demonstrating that the permit applicant will have final control of the premises upon approval of the application. Documentation includes, but is not limited to, a lease agreement, contract for sale, title, deed, or similar documentation. Where a permit applicant will lease the premises, the lease shall include a provision acknowledging that the tenant's use of the premises will involve medical cannabis-related activities associated with operations as a clinical registrant;

10. The plan by which the permit applicant intends to obtain appropriate liability insurance coverage for the proposed alternative treatment center;

11. Evidence supporting any of the following bonus point categories, as applicable:

i. Permit applicants that are party to a collective bargaining agreement with a *bona fide* labor organization that currently represents, or is actively seeking to represent, cannabis workers in New Jersey;

ii. Permit applicants that are party to a collective bargaining agreement with a *bona fide* labor organization that currently represents cannabis workers in another state;

iii. Permit applicants that submit a signed project labor agreement with a *bona fide* building trades labor organization for the construction or retrofit of the facilities associated with the permit applicant;

iv. Permit applicants that submit a signed project labor agreement with a *bona fide* labor organization for any other applicable project associated with the permit applicant; or

v. Permit applicants that include at least one owner lawfully residing in New Jersey for at least two years as of the date of the application;

12. A clinical registrant operating plan, including a cultivation, manufacturing, or dispensing operating plan pursuant to N.J.S.A. 24:6I-7.2.c(1), (2), and (3);

13. A business and financial plan;

14. An environmental impact plan, which shall, at a minimum, include consideration of sustainable alternatives to single-use plastic packaging, efforts to minimize water usage, and any other factor required by the Commission in its notice of application acceptance;

15. A safety and security plan that conforms with N.J.A.C. 17:30A-9.7;

16. A community impact or social responsibility plan;

17. A workforce development, job creation, and diversity plan;

18. Standard operating procedures for:

i. Adverse event reporting;

ii. Quality assurance and quality control;

iii. Recall of medical cannabis items, as needed, or directed;

iv. Packaging and labeling;

v. Inventory control, storage, and diversion prevention;

vi. Recordkeeping;

vii. Waste disposal/sanitation;

viii. Cultivation, manufacturing, dispensing, delivery, and secure transport, as applicable;

ix. Accounting and tax compliance; and

x. The reporting of test results, as applicable;

19. An attestation signed by a bona fide labor organization stating that the permit applicant has entered into a labor peace agreement with a *bona fide* labor organization;

20. If the permit applicant opts to include in its governance structure the involvement of a school of medicine or osteopathic medicine licensed and accredited in the United States, or a general acute care hospital, ambulatory care facility, adult day care services program, or pharmacy licensed in New Jersey, the permit applicant shall demonstrate that involvement, provided that:

i. The school, hospital, facility, or pharmacy has conducted or participated in research approved by an institutional review board related to cannabis involving the use of human subjects, except in the case of an accredited school of medicine or osteopathic medicine that is located and licensed in New Jersey;

ii. The school, hospital, facility, or pharmacy holds at least a 10 percent profit share or ownership interest in the permit applicant, except in the case of an accredited school of medicine or osteopathic medicine that is located and licensed in New Jersey; and

iii. The school, hospital, facility, or pharmacy participates in major decision-making activities within the permit applicant, which may be demonstrated by representation on the board of directors of the permit applicant;

21. If the permit applicant optionally has a medical board, the by-laws, and a list of names of the members of the permit applicant's medical board;

22. If a permit applicant intends to enter into, or has entered into, a partnership with a re-entry program for the purpose of identifying and promoting employment opportunities for currently or formerly incarcerated people at the alternative treatment center, the details of such partnership, including:

i. The name of the re-entry program;

ii. The employment or training opportunities at the permit applicant's alternative treatment center that will be made available to the re-entry population;

iii. Any other initiatives the permit applicant will undertake to provide support and assistance to the re-entry population; and

iv. The training and support offered or provided for the advancement of the re-entry population;

23. An affidavit that the statements included in the application are true and correct, sworn by the permit applicant's representative;

24. An authorization to release all information pertaining to the permit applicant, as requested by the Commission, signed by the permit applicant's representative;

25. A waiver of liability for any damages to the permit holder as a result of any disclosure or publication in any manner, other than a willfully unlawful disclosure or publication, of any information acquired during the permitting process, signed by the permit applicant's representative;

26. A copy of a written research contract between the clinical registrant and an academic medical center that meets the requirements at N.J.A.C. 17:30A-7A.2.

i. A clinical registrant permit applicant may only contract with one academic medical center;

27. Written documentation from the academic medical center that it meets the requirements at N.J.A.C. 17:30A-7A.1(a), including:

i. A demonstration of current accreditations, as applicable;

ii. A declaration stating that the academic medical center has the ability to conduct medical cannabis research;

iii. The State and Federal tax identification numbers of the academic medical center; and

iv. For a school of osteopathic medicine, an articulation agreement or similar memorandum of understanding, an apprenticeship program agreement with a partner State college or university, and institutional review board approval information;

28. For a clinical registrant, in its initial and renewal application:

i. A list of the approved research programs or research studies that are continuing or, if any of them are concluded, the dates they were concluded;

ii. A report of the current status of active research programs or research studies being conducted under the research contract, including preliminary findings, if applicable; and

iii. A description of proposed research programs or research studies covered by the research contract that the clinical registrant intends to conduct within the next year following submission of the renewal application, including any institutional review board approval for the proposed research program or research study; and

29. Any other information the Commission deems relevant in determining whether to grant a permit to the applicant.

(c) The medical cannabis permit application shall additionally include a certification that the proposed medical cannabis dispensary location is not in or upon any premises that operates a grocery store, delicatessen, indoor food market, or other store engaging in retail sales of food; or any premises that operates a store that engages in licensed retail sales of alcoholic beverages, as defined at N.J.S.A. 33:1-1.b.

(d) A clinical registrant permit applicant shall disclose and submit, as part of the permit application, the following submissions relating to its qualification for a permit, pursuant to N.J.A.C. 17:30A-7A.5:

1. Organizational charts of the applicant identifying ownership, control, and operational structure, including owners, principals, management services contractors, managers, as well as all parent companies, subsidiaries, affiliates, predecessors, and successors of the permit applicant;

2. A list of all persons who are owners, passive investors, principals, and managers of the permit applicant, including their names, addresses, dates of birth, and each owner's and passive investor's percentage of ownership interest;

3. For all persons who are owners or principals of the permit applicant, a copy of their unexpired driver's license or other photo identification issued by the State, another state, or the Federal government, which shall be proof that the person is at least 21 years of age***. For any person(s) directing or implementing the research study, a copy of their professional license, and/or medical license***;

4. For all persons who are owners and principals of the permit applicant, a completed Personal History Disclosure Form, including a resume;

5. A list of the persons who are owners of the permit applicant who have resided in this State for at least two years as of the date of the application and documentation of such residency;

6. For each owner, principal, or employee of a permit applicant, as well as for each staff member of a permit applicant's management services contractor that participates in the obtaining, possession, securing, cultivating, manufacturing, transporting, selling, delivering, or destroying of medical cannabis items, proof that the person has been fingerprinted and written consent to undergo a criminal history record background check pursuant to N.J.A.C. 17:30A-7A.6;

7. For any person seeking to become an owner, principal, or employee of a permit applicant who has a disqualifying conviction pursuant to N.J.A.C. 17:30A-7A.6(d), evidence of rehabilitation pursuant to N.J.A.C. 17:30A-7A.6(e), if any;

8. For any person seeking to become a staff member of a permit applicant's management services contractor that participates in the obtaining, possession, securing, cultivating, manufacturing, transporting, selling, delivering, or destroying of medical cannabis items who has a disqualifying conviction pursuant to N.J.A.C. 17:30A-7A.6(d), evidence of rehabilitation pursuant to N.J.A.C. 17:30A-7A.6(e), if any;

9. For the permit applicant and each of its owners, principals, or managers, a list of any pending or adjudicated criminal charges or convictions;

10. A list of entities that are owners, passive investors, principals, and management services contractors of the permit applicant, including their names, addresses, and each owner's and passive investor's percentage of ownership interest;

11. For each entity that is an owner, principal, or management services contractor of a permit applicant, a completed Entity Disclosure Form;

12. For all persons or entities that hold at least 10 percent aggregate ownership interest in, or are a member of the executive team of, a management services contractor of a permit applicant, their names, addresses, dates of birth, positions held, percentage of ownership interest in the management services contractor entity, and a completed Personal History Disclosure Form for each person.

i. Except that for a person or entity holding ownership interest in or control over a management services contractor that is a qualified institutional investor, a completed Personal History Disclosure Form for each person is not required;

13. Any management services agreement;

14. A list that describes, beginning with the formation of the permit applicant entity, any and all sales, mergers, business combinations, and consolidations involving the entity, including any such events that occurred under a former name of the entity;

15. A list of all financial sources, including qualified institutional investors, holding debt of the permit applicant.

i. The nature, type, terms, covenants, and priorities of all outstanding debts of the permit applicant, including, but not limited to, bonds, loans, mortgages, trust deeds, debentures, lines of credit, notes issued or executed, or to be issued or executed, or other forms of indebtedness of the permit applicant or on its behalf;

ii. A completed Entity Disclosure Form for each financial source, except a qualified institutional investor; and

iii. A completed Personal History Disclosure Form for each financial source that is a person;

16. Any proposed or executed contract, term sheet, agreement, or side letter between an owner, principal, or financial source and another party that relates to the ownership and control structure, assets, liabilities, real or intellectual property, revenue, funding or capitalization, royalties, or profit, or future profit, of the permit applicant or comparable documents

that change the legal structure of the permit applicant, including any financial source agreement;

17. A list of all vendor-contractors with whom the permit applicant has contracts or agreements;

18. For the permit applicant and each of its owners, principals, managers, management services companies, parent companies, subsidiaries, affiliates, predecessors, or successors:

i. A list of any currently held or previously held authorizations to participate in the cultivation, manufacturing, sale, or distribution of medical cannabis or personal-use cannabis in any jurisdiction, including a foreign jurisdiction, where the person or entity serves or served as an owner, principal, or employee for six or more months;

19. For the permit applicant and each of its parent companies, subsidiaries, affiliates, predecessors, or successors:

i. A list of any previous violation of, or judgment, order, consent decree, consent order, sanction, or penalty pertaining to any state or Federal statute, rule, regulation, or code; and

ii. A list of all pending litigation or past litigation that concluded in the last five years, whether in the State of New Jersey or in another jurisdiction, in which the entity was involved;

20. A list of every financial institution at which the permit applicant has had an account in the last five years;

21. A list of bankruptcy or insolvency proceedings by the permit applicant, and each of its parent companies, subsidiaries, affiliates, predecessors, or successors, and a copy of any bankruptcy decree as a result of the same;

22. A list of any charitable contributions made by the permit applicant in the last five years;

23. A list of stocks held by the permit applicant;

24. For each owner, principal, management services contractor, and employee of the permit applicant, certification confirming the person's or entity's submission to the jurisdiction of the courts of the State of New Jersey and agreeing to comply with all laws and rules of the State of New Jersey pertaining to medical cannabis;

25. An affirmation that the permit applicant exercised reasonable care to confirm its submission information and the ability of each person or entity in its submission to serve as an owner or principal;

26. Any other application requirement established by the Commission in a notice of application acceptance issued pursuant to N.J.A.C. 17:30A-7A.3(b);

27. Documentation that the clinical registrant applicant has a minimum of $15 million in capital; and

28. An affidavit from the clinical registrant disclosing any payments to its partner academic medical center made by the clinical registrant or any of its owners, passive investors, principals, management services contractors, financial sources, or employees, up to and including the date of the submission of the application, including the amount and purpose of each payment made.

(e) A clinical registrant permit applicant shall provide the Commission with a complete disclosure pursuant to (d) above that includes all true parties of interest.

1. The permit applicant or permit holder shall not attempt to conceal or disguise ownership or other control over its operations in its submissions.

(f) Application materials submitted to the Commission pursuant to N.J.S.A. 24:6I-7.3 or this section shall not be considered public record pursuant to N.J.S.A. 47:1A-1 et seq., or the common law concerning access to government records.

1. This includes a clinical registrant's or an academic medical center's research contract and research study description, patient information, and intellectual property.

17:30A-7A.5 Qualification for a clinical registrant permit

(a) A permit applicant or permit holder is qualified to hold a permit where:

1. Each owner, principal, employee, or volunteer of a permit applicant or permit holder, as well as each staff member of a permit applicant's or permit holder's management services contractor that participates in the obtaining, possession, securing, cultivating, manufacturing, transporting, selling, delivering, or destroying of medical cannabis items has submitted to a criminal history background check pursuant to N.J.A.C. 17:30A-7A.6;

2. No owner, principal, employee, or volunteer of a permit applicant or permit holder has a disqualifying conviction pursuant to N.J.A.C. 17:30A-7A.6(d) without evidence of rehabilitation pursuant to N.J.A.C. 17:30A-7A.6(e);

3. No staff member of a permit applicant's or permit holder's management services contractor that participates in the obtaining, possession, securing, cultivating, manufacturing, transporting, selling, delivering, or destroying of any medical cannabis items of the permit applicant or permit holder has a disqualifying conviction pursuant to N.J.A.C. 17:30A-7A.6(d) without evidence of rehabilitation pursuant to N.J.A.C. 17:30A-7A.6(e);

4. Each owner and principal of the permit applicant or permit holder is eligible to be an owner or principal, respectively, of the permit applicant or permit holder;

5. No employee or other government official of any State, county, or local government entity involved in the process of reviewing, processing, or making determinations with regard to clinical registrant permit applications has any direct or indirect financial interest in the permit applicant or permit holder; and

6. The permit applicant or permit holder has not provided anything of value to an employee of any State, county, or local government entity involved in the process of reviewing, processing, or making determinations with regard to permit applications in exchange for reviewing, processing, or making any recommendations with respect to a permit application.

(b) A permit applicant or permit holder is not qualified to hold a permit where the permit applicant or permit holder:

1. Does not meet the requirements at (a) above;

2. Fails to provide information, documentation, and assurances as required pursuant to this subchapter or as requested by the Commission, including failure to provide a required criminal history record background check or to cooperate with the Commission in its investigation of the permit applicant or permit holder;

3. Fails to reveal any material fact pertaining to qualification;

4. Supplies information that is untrue or misleading as to a material fact pertaining to the qualification criteria for a permit; or

5. Has been determined by the Commission to be unsuitable to hold a clinical registrant permit pursuant to (c) below.

(c) The Commission may determine a permit applicant or permit holder is unsuitable pursuant to (b)5 above, where the permit applicant or permit holder has demonstrated, or is determined to:

1. Be a danger to the public health, safety, or general welfare of the State; or

2. Have a history of:

i. Distributing marijuana to minors;

ii. Involvement with organized crime;

iii. Diverting marijuana from personal-use or medical cannabis states to other states;

iv. Engaging in trafficking of controlled substances not authorized by the Act or this chapter, or other illegal activity;

v. Engaging in violence or the use of firearms as part of alternative treatment center operations; or

vi. Violating the requirements established in this subchapter, the Act, or the entity's written notice of approval.

(d) If the person is determined to be not qualified to hold a permit, such disqualification shall be considered a final agency action subject to judicial review, and the Commission shall provide notice of the determination to the person, in writing, which shall include:

1. The specific reason for the disqualification, including any conviction that constitutes the basis for the disqualification; and

2. Information about appeal rights.

17:30A-7A.6 Criminal history background check

(a) Each owner, principal, employee, or volunteer of a clinical registrant permit applicant or holder or staff member of a permit applicant's or permit holder's management services contractor shall provide written consent to submit to a criminal history background check pursuant to the Act and shall comply with the procedures established by

the Division of State Police pursuant to N.J.A.C. 13:59 for obtaining readable fingerprint impressions.

1. The permit applicant or holder, as applicable, shall bear the cost for the criminal history background check, including all costs of fingerprinting and administering and processing the background check.

2. For a management services contractor, only staff members that participate in obtaining, possessing, securing, cultivating, manufacturing, transporting, selling, delivering, or destroying medical cannabis items on behalf of a permit applicant or permit holder shall be required to consent and comply with a criminal history record background check.

(b) A person who is required to undergo a criminal history background check pursuant to this section who refuses to consent to, or cooperate in, the securing of a check of criminal history and background information shall be deemed unqualified as a permit applicant or holder.

(c) Where the criminal history background information demonstrates that a person has been convicted of a disqualifying conviction pursuant to (d) below, the Commission shall find the person disqualified from holding a permit and shall not approve the person for participation in a clinical registrant permit applicant or holder.

(d) A disqualifying conviction for an individual to participate in a clinical registrant permit applicant or holder is a conviction of an:

1. Indictable offense of the first, second, or third degree pursuant to this State's law;

2. Indictable offense or disorderly persons offense involving any controlled dangerous substance or controlled substance analog as set forth at N.J.S.A. 2C:35-1 et seq., except:

i. Paragraph (11) or (12) of subsection b. at N.J.S.A. 2C:35-5;

ii. Paragraph (3) or (4) of subsection a. at N.J.S.A. 2C:35-10;

iii. A conviction that occurred after January 18, 2010, for a violation of Federal law relating to possession or sale of cannabis for conduct that is authorized under the Act; or

3. Equivalent offense pursuant to Federal law or any other state's law.

(e) Notwithstanding the provisions at (c) above to the contrary, a person required to consent to a criminal history background check pursuant to (a) above shall not be disqualified on the basis of any disqualifying conviction disclosed by a criminal history record background check if the person has affirmatively demonstrated to the Commission, clear and convincing evidence of rehabilitation. In determining whether clear and convincing evidence of rehabilitation exists, the Commission shall consider, at a minimum, the following factors:

1. With respect to the permit applicant or holder, the nature and responsibility of the position that the person with a conviction would hold, has held, or currently holds;

2. The nature and seriousness of the crime or offense;

3. The circumstances under which the crime or offense occurred;

4. The date of the crime or offense;

5. The age of the person when the crime or offense was committed;

6. Whether the crime or offense was an isolated or repeated incident;

7. Any social conditions that may have contributed to the commission of the crime or offense; and

8. Any evidence of rehabilitation, including good conduct while incarcerated or in the community, counseling or psychiatric treatment received, acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs, or the recommendation of those who have had the person under their supervision.

(f) Notwithstanding the provisions at (c) above to the contrary, the Commission may, in its discretion, offer provisional authority for a person to be an owner, principal, or employee of a clinical registrant permit applicant or holder for a period not to exceed three months if the person submits to the Commission a sworn statement attesting that the person has not been convicted of any disqualifying conviction.

1. Such person's provisional status does not guarantee a person's qualification.

2. Submission of a false attestation shall result in a determination of the person's disqualification, the revocation of the person's provisional status and any Cannabis Business Identification Card and may result in permanent ineligibility for the person to participate in regulated medicinal or personal-use cannabis activities.

3. If a permit applicant or holder demonstrates a pattern of submission of such false attestations, the Commission may sanction the permit applicant or holder pursuant to N.J.A.C. 17:30A-20, including civil monetary penalties.

(g) In accordance with the provisions of the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedures Rules, N.J.A.C. 1:1, any individual disqualified from owning, operating, or being employed by a clinical registrant permit applicant or holder shall be given an opportunity to challenge the accuracy of the disqualifying criminal history record prior to being permanently disqualified from participation.

1. Such challenges shall be made within 20 days of the disqualification.

17:30A-7A.7 Clinical registrant permit acceptance; inspection; issuance; commencement of operations

(a) After the Commission approves an application for a clinical registrant permit pursuant to N.J.A.C. 17:30A-7A.3, the Commission shall give written notice of approval to the applicant.

(b) Within five business days after receiving notice of approval, a permit applicant shall notify the Commission as to whether it will:

1. Accept the permit; or

2. Abandon the permit, which is required if accepting the permit would violate this subchapter or make the permit applicant otherwise ineligible or if the circumstances of the permit applicant have changed.

(c) Failure of the applicant to notify the Commission of its decision pursuant to (b) above, to accept or abandon the permit, shall result in the permit being deemed abandoned.

(d) If the permit applicant accepts the permit, it shall submit the annual permit application approval fee, pursuant to N.J.A.C. 17:30A-7A.9.

(e) *[A permit applicant shall have 365 days from the date of the notice of approval to request a final onsite assessment pursuant to (g) below before commencing medical cannabis operations.]* ***(Reserved)***

(f) The permit applicant has a continuing duty to seek approval for or report changes in the information submitted as part of the permit application.

1. If a material change occurs to an application that is otherwise complete, the Commission may deem the application incomplete pending further review.

(g) After the permit applicant has completed construction and preparation of its clinical registrant premises, the permit applicant shall request, in writing, that the Commission conduct a final onsite assessment.

(h) The Commission shall conduct a final onsite assessment of the clinical registrant and shall determine whether the clinical registrant premises, operations, plans, procedures, protocols, and actions are consistent with the entity's permit application and compliant with the Act, this chapter, the requirements in the entity's written notice of approval, and any additional requirements provided by the Commission.

(i) No later than 30 days after a clinical registrant successfully passes such onsite assessment, unless the Commission finds the applicant is not in compliance with this subchapter or the Commission is notified by the relevant municipality that the applicant is not in compliance with its ordinances or regulations, the Commission shall issue the clinical registrant permit to the permit applicant.

1. A clinical registrant annual permit shall be valid for one year from its date of issuance and may be renewed annually.

(j) If the Commission determines that the clinical registrant permit applicant is not compliant with this chapter, or the permit applicant does not undergo a successful final onsite assessment yielding a determination of compliance pursuant to (h) above, the Commission shall decline to issue the clinical registrant permit and the permit shall be returned to the Commission.

(k) Within 14 days of the issuance of a clinical registrant permit, the permit holder shall notify the Commission, in writing, of a proposed opening date for the clinical registrant.

17:30A-7A.8 Clinical registrant permit renewals

(a) A clinical registrant permit shall be valid for one year.

(b) The Commission may renew a clinical registrant permit subject to the conditions set forth in this subchapter.

(c) A clinical registrant permit holder shall submit a renewal application and the annual permitting fee pursuant to N.J.A.C. 17:30A-

7A.9 no later than 90 days prior to the expiration of the current clinical registrant permit. Submission within 90 days of expiration of the current clinical registrant permit may result in a lapse in the clinical registrant's permitting and subject the clinical registrant to enforcement action.

(d) The following may be grounds for denial of a clinical registrant permit renewal application:

1. Failure to provide truthful, correct, and current information;

2. Failure to maintain compliance with the Act or this chapter;

3. The inclusion of a person or entity not deemed qualified to hold a permit pursuant to N.J.A.C. 17:30A-7A.5; or

4. The commission of three or more violations within the preceding 12 months.

(e) Renewal materials submitted to the Commission pursuant to N.J.S.A. 24:6I-7.3 or this section shall not be considered a public record pursuant to N.J.S.A. 47:1A-1 et seq., or the common law concerning access to government records.

1. The information in this subsection shall include a clinical registrant's or an academic medical center's research contract and research study description, patient information, and intellectual property.

(f) If a permit renewal application is denied, the Commission shall provide notice of the renewal denial to the applicant, in writing, which shall include:

1. The specific reason for the renewal denial; and

2. The opportunity to request an administrative hearing within 45 days after the date of the renewal denial.

(g) An administrative hearing pursuant to (f) above shall take place in the Office of Administrative Law in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(h) The decision to affirm the denial after an administrative hearing shall be considered a final agency decision, subject to judicial review by, and of which jurisdiction and venue for such review are vested in, the Appellate Division of the Superior Court.

17:30A-7A.9 Clinical registrant fees

(a) The following permitting fees shall be paid by clinical registrant permit applicants or holders, as applicable:

1.	Annual clinical registrant permit application fee	$2,000
2.	Annual medical cannabis cultivator initial or renewal permitting fee:	
i.	Tier I (up to 10,000 sq. ft.)	$5,000
ii.	Tier II (10,001-25,000 sq ft.)	$10,000
iii.	Tier III (25,001-50,000 sq ft.)	$20,000
iv.	Tier IV (50,001-75,000 sq ft.)	$30,000
v.	Tier V (75,001-100,000 sq ft.)	$40,000
vi.	Tier VI (100,001-150,000 sq ft.)	$50,000
3.	Annual medical cannabis manufacturer initial or renewal permitting fee:	
i.	With premises up to 10,000 square feet	$20,000
ii.	With premises greater than 10,000 square feet	$30,000
4.	Annual medical cannabis dispensary initial or renewal permitting fee	$10,000
5.	Background investigation fee:	
i.	Financial source	$1,000
ii.	Management services contractor	$1,000
iii.	Each owner or principal of clinical registrant	$250.00
6.	ATC Identification Card issuance fee	$25.00

(b) The total application fee, which is non-refundable, includes fees for submission and approval payable by all clinical registrant permit applicants.

(c) For the first year of operation for a clinical registrant following the initial issuance of the clinical registrant's permit(s), the amount due in annual permitting fee shall be calculated by subtracting the amount of application fees submitted pursuant to this subchapter from the total amount of permitting fees due for the clinical registrant.

1. Background investigation fees shall not be considered application fees pursuant to this subsection.

(d) The following material change fees shall be paid by annual permit holders, as applicable:

1. The fee to apply for a change of location of a clinical registrant premises is $10,000;

2. The fee to apply for a change or modification of the clinical registrant's capacity or physical plant is $2,000; and

3. The fee to apply for the transfer of any ownership interest that results in a change in who owns more than 50 percent in a permit holder is $20,000.

i. Any owner or principal may be required to pay background investigation fees as part of an ownership interest transfer.

(e) Fees shall be paid by certified check, money order, or any other form of payment approved by the Commission, and made payable to "Treasurer, State of New Jersey."

(f) Fees shall be deposited in the Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Fund established pursuant to N.J.S.A. 24:6I-50.

TREASURY—TAXATION

(a)

DIVISION OF TAXATION

Gross Income Tax

Adopted Amendments: N.J.A.C. 18:35-1.3, 4.1, and 11.3

Adopted New Rule: N.J.A.C. 18:35-5.3

Proposed: May 6, 2024, at 56 N.J.R. 759(a).
Adopted: July 23, 2024, by Marita Sciarrotta, Acting Director, Division of Taxation.
Filed: July 23, 2024, as R.2024 d.077, **without change**.

Authority: N.J.S.A. 54A:4-10, 54A:9-8.2, 54A:9-17(a), and 54:50-1.

Effective Date: August 19, 2024.
Expiration Date: December 13, 2029.

Summary of Public Comment and Agency Response:
No comments were received.

Federal Standards Statement

A Federal standards analysis is not required because the rulemaking authority is granted by the operative provisions of the New Jersey Gross Income Tax Act, N.J.S.A. 54A:1-1 et seq., and is not subject to any Federal requirements or standards.

Full text of the adoption follows:

SUBCHAPTER 1. GROSS INCOME—CATEGORIES AND CALCULATION

18:35-1.3 Partnerships and partners

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

(f) Partnership filing requirements are as follows:

1. Partnerships having a New Jersey resident partner or having any income or loss derived from New Jersey sources shall file the following with the Division:

i. Form NJ-1065; including the statement of income and expenses, balance sheet per books, any and all referenced supporting schedules, and partner directory;

ii. Form NJ-CBT-1065 if the partnership is subject to the tax on nonresident partners;

Recodify existing ii.-iii. as iii.-iv. (No change in text.)

v. Pages 1 through 5 of Federal Form 1065 and any Federal extension request forms filed;

vi. Schedule NJ-NR-A, if required pursuant to (d)4 above; and

vii. Any partnership that requests an extension of time to file must file Form PART-200-T if the partnership is subject to the per partner filing fee or Form CBT-206 to apply for an extension of time to file an NJ-CBT-1065 that has tax due.

2. Information filings shall be made on or before the date of expiration of the permitted filing period for the partnership's Federal Form 1065,