

Part 113 – Medical Cannabis APC

COMMENT: A few commenters inquired about the registered organization (RO) and dispensary expansion permitted by the Cannabis Law. One commenter suggested patient access to medical cannabis would improve by quickly identifying the underserved and unserved geographic regions in New York State (NYS) and opening applications for new registered organization licenses and prioritizing Minority & Women Business Development (MWBE) entities. Another commenter encouraged the Office of Cannabis Management (the Office) to provide a definition of “unserved and underserved geographic areas.” Additionally, another commenter stated that the Office should provide clarity on its plan to issue additional medical cannabis licenses as well as timing. The commenter added that they believe the existing medical cannabis program lacks diversity in ownership and is inhibited in the ability to serve and benefit a significant increase in potential patients based on the regulatory restrictions and limitations (i.e., the number of fully operational testing labs) of the program.

RESPONSE: The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

COMMENT: The Office received a few comments suggesting that the Office should encourage more social-equity applicant participation in the medical cannabis industry. One commenter suggested including provisions to allow equity applicants to enter the medical market without the full “seed-to-sale” vertically integrated structure, and instead permit equity participation in the same organizational categories as adult-use licensees. Another commenter also claimed the current medical cannabis operators have not delivered appropriate cannabis solutions designed to address patients' and community needs. Comments contain recommendations concerning; requiring dispensaries to operate in communities impacted by the "War on Drugs", medical

cannabis product effectiveness, clarifying registration application criteria and requirements, and exempting social equity applicants from other registration application requirements.

RESPONSE: The Office acknowledges all these comments. Regarding the comment on social-equity, Section 35 of the Cannabis Law states that the Board shall register additional registered organizations to provide services to unserved and underserved areas of the state. The Cannabis Law also requires the additional registered organizations to be reflective of the demographics of the state, be representative of communities disproportionately impacted by cannabis prohibition, and be culturally, linguistically, and medically competent to serve unserved and underserved areas of the state. The proposed regulations do not require an applicant to be vertically integrated, however the Office may specify on application the type of activities (ex: manufacturer, dispensing, etc.) for which it seeks a registered organization. Some comments contain matters which are beyond the scope of the proposed regulation. To the extent such comments contain matters within scope, the Office may consider future guidance or rulemaking. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter stated that the Office should fully implement the whole flower provisions of the MRTA, including smokable products. The commenter believes the Office appears to contemplate smokable products with the amendments to section 113.19(a), yet the Office continues to reject, or is unresponsive, to smokable whole flower products submitted for approval.

RESPONSE: In accordance with the Cannabis law, whole flower is among the approved forms of medical cannabis. The cannabis law and the proposed regulations have removed the prohibition on smoking in the medical cannabis program. Imposing rules on where such products are permitted to be consumed through the proposed regulations is consistent with the cannabis industry and similar industry standards. The Office acknowledges this comment. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter recommended that the State address the large out-of-pocket costs of practitioner visits and medical cannabis, that remain barriers to equitable access to treatment. The commenter encouraged the State to take measures to level the playing field in the medical cannabis market to enable opportunities for new smaller, social equity business entrants. The commenter also encouraged the Office to promote the availability of low or no cost loans, fee waivers or reductions (current application fee is \$10,000 and registration costs \$200,000), and other special programs to include equitable opportunities for small “minority owned” businesses.

RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: One commenter stated that they believe most ownership of cannabis business licensees should be residents of the State as a requirement rather than merely an optional path for licensure. They believe a residency requirement, even if lowered to 25% of total ownership, would give more opportunities to those New Yorkers who understand the unique political, social, and cultural environments throughout the state.

RESPONSE: The proposed regulation is not intended to curtail commerce or to only allow individuals whose primary residence is in New York State to be eligible applicants. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter recommended that the Office add definitions in section 113.1 for “Aggregate Ownership”; “Control”; “Financial Interest”; and “Financier” to mirror the proposed definitions set forth in Part

116, the Conditional Adult-Use Retail Dispensary Regulations to provide additional clarity regarding the Office’s interpretation of ownership and control of a Registered Organization.

RESPONSE: Not all the suggested terms are in scope with the proposed regulations, however, the proposed regulations were amended to add definitions based on suggested terms that were within the scope as a result of this comment.

COMMENT: A few commenters suggested the definition of “brand” should be modified to provide patients with a variety of product choices under a common brand name. Another commenter suggested the definition should include terpenoid content along with the THC and CBD content.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: Some commenters requested that the term “synthetic terpenes” be defined for clarity in section 113.12(c)(2)(iii). They also requested that the term “medicinal compounds” in section 113.12(c)(2)(iii) along with the term “synthetic cannabis additives” in section 113.12(n) be defined with more specificity as well. The commenters stated without having these terms defined it could potentially lead to confusion among Registered Organizations and patients.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: One commenter recommended changing the word “abuse” to “misuse” in section 113.2(b) and section 113.13(h)(9).

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter recommended removing or flagging for further clinical review, section 113.3(a)(8), stating that the requirement might impose an unnecessary burden on practitioners because section 113.3(a)(7) lists all 18 conditions plus a catchall category of “any other condition certified by the practitioner.”

RESPONSE: The proposed regulations require practitioners to include a statement that they are qualified to treat any of the specific conditions for which the practitioner is certifying the patient, including any unenumerated condition. The list does not, however, mean that the practitioner must be qualified to treat all 18 of the listed conditions, specifically. No changes to the proposed regulations were made as a result of this comment.

COMMENT: One commenter suggested simplifying the process to register as a certified patient, and suggested that the Office should look to New Mexico, Illinois, Oregon, or many other states, for ways to make it easier and more accessible to become a certified patient and utilize the medical cannabis program.

RESPONSE: Article 3 of the Cannabis Law provides the Board with a degree of flexibility as to the registration process. The proposed regulations were amended as a result of this comment.

COMMENT: One commenter questioned when the designated caregiver program will evolve. The commenter stated that right now designated caregivers are delivery service providers and would like to be able to help patients convert their cannabis for consumption.

RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: Two commenters suggested adding a provision to section 113.6 to allow RO applicants the right to designate portions of their applications as “exempt from disclosure under the New York State Freedom of

Information Law.” The commenters stated that all license applicants, including RO applicants, should be allowed to pre-designate certain portions that they believe are exempt from disclosure under New York’s Freedom of Information Law (FOIL).

RESPONSE: The Office acknowledges these comments and intends to address those “exempt from disclosures” portion for purposes of the New York State Freedom of Information Law within the applications. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested the Office should revise the reference to setbacks in section 113.6(b)(2) to be consistent with the setback language in section 113.11(b). The commenter stated the Office indicated the new setback standard would be implemented consistently with existing medical regulations and the ABC law in that it would be measured in a straight line on the same avenue/street and not turn corners.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: Two commenters suggested amending section 113.6(b)(5) by deleting the requirement that procedures comply with “all applicable federal rules, regulations, and laws as amended,” or alternatively, define “applicable: as excluding the Federal Controlled Substance Act. The commenters stated that cultivating cannabis and manufacturing cannabis products remain illegal under the Federal Controlled Substances Act, 21 U.S.C. §801 et. seq.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: One commenter recommended amending section 113.6(b)(7) to add a requirement to notify the Poison Control Center within 24 hours of any adverse events that the registered organization is made aware of.

RESPONSE: Notifying the Poison Control Center may not be appropriate in all instances of an adverse event. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Two commenters suggested adding “if any” after “a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant’s employees” or alternatively requiring applicants to certify that if a bona-fide labor organization actively engages in representing or attempting to represent the applicant’s employees, then the applicant or registered organization (“RO”) will enter into a labor peace agreement.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: One commenter suggested that there needs to be a lower registration fee rather than the current fee of \$200,000, and efforts like that of adult-use to encourage research, innovation, and entrepreneurship in the medical space.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested modifying sections 113.6 and 113.7 to authorize the Office to approve five additional Registered Organizations (for a total of fifteen) with an initial licensing fee set by an auction, paid in cash within 60 calendar days of award.

RESPONSE: Cannabis Law Section 35(3)(c) of the statute requires the registration fee to be an amount set by the Board in regulations. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested the following language be added to section 113.7(b) “including but not limited to consideration of any enforcement action or investigation against any of these individuals or related entities in another jurisdiction.” The commenter explained that the purpose of this would be to clarify that the actions of the people and entities with ownership and/or control of the New York licensees in other jurisdictions should be considered in the Office’s character and competency reviews as it is well established that most of the Registered Organizations are multi-state-operators, and such companies should be held to the highest standards throughout the entire cannabis industry, not just within fractionalized state markets. Enforcement actions and investigations by other regulators deserve to be disclosed to the Office for further review.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter requested to modify section 113.9 so that the Office can levy a special Cannabis License Transfer (CLT) fee along with providing a 60-day public comment period when the sale in the ownership of an entity holding a controlling interest in the Registered Organization exceeds \$10 million and requires prior regulatory approval. The commenter stated that the CLT fee would be a percentage-based fee levied on the transaction amount and would help recapture a portion of the value that the state created by issuing a limited number of licenses. They also stated a public comment period will provide a clear forum for stakeholders to weigh in without clouding the approval process the Office will be establishing.

RESPONSE: Pursuant to the Cannabis Law, no license, registration, or permit issued by the Board is transferable. The Office acknowledges these comments, however, no changes to the proposed regulations were made.

COMMENT: One commenter suggested modifying section 113.9 to ensure that the Office does not approve an application of a registered organization seeking to materially changes its composition if it requires the approval of shareholders and such approval has not yet been granted. The commenter stated that the Office should not grant approvals contingent on the approval of shareholders, as this action could be viewed by shareholders as a fait accompli and discourage them from exercising their rights to oppose a sale that may not be in their best interest.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested adding the following language to section 113.9(b) “registered Organizations shall not have any direct or indirect common interest or Financial Interest, including by beneficial stock ownership, interlocking directors, mortgage or lien, personal or real property, management agreement, share parent companies, or affiliated organization, or by any other means in any other Registered Organizations.” The commenter suggested that the existing language in section 113.9(b) refers only to the actual transfer of a registration from one entity to another and does not address at all the transfer of an entity that already owns a registration.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested that the Office consider amending the regulations to reflect that other than operating plans, which are required to be onsite and readily accessible at each facility, registered organizations only need to be prepared to produce other materials listed in section 113.11(a)(1) with 48 hours of any request from the Office or its authorized representative.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter proposed section 113.11(b)(5) be revised to state “remodel, expand, or reduce the interior space of a registered facility, or change the location of a registered facility, without receipt of prior written approval of the Office” in order to clarify what changes to the interior space of a facility must be approved by the Office.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance or regulations. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter proposed that the Office reduce the amount of time registered organizations must maintain records in the event that a registered organization elects to cease operation pursuant to section 113.11(c)(2)(iii). The commenter suggested the records should be maintained electronically and that three years would better balance the burden of maintaining records for a lengthy period of time with the Office’s need to ensure important records are kept for a reasonable period after operations cease.

RESPONSE: Registered organizations are required to make records “available to the office”, meaning a registered organization may supply such records electronically as determined by the Office. The Office acknowledges this comment and may consider it in future guidance or regulations. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Two commenters suggested the Office should allow registered organizations the ability to offer cannabis-related products or samples. One commenter stated it can be an important resource to businesses and consumers to understand opinions and preferences for new products and can assist patients, particularly those with limited means, by providing them with the tools necessary to consume their medicine, just as a pharmacy

might provide a pill-cutter. The commenter requested that the Office outline all scenarios where providing cannabis-related products or cannabis samples would be allowed and consider permitting the distribution of products associated with the consumption of medical cannabis. Another commenter stated that by allowing sampling for both quality and research and development purposes, the Office will give registered organizations the ability to build product lines based on new avenues of analysis, particularly as the state transitions to both a medical and adult use cannabis marketplace.

RESPONSE: The proposed regulations prohibit distribution of products or samples at no cost except as allowed by the Office. The proposed regulations do not prohibit a registered organization from offering discounts or a discount program to certified patients and designated caregivers for the purchase of medical cannabis products. Where necessary, the Office will issue guidance. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested clarification on whether section 113.11(b)(3) is referring to the exceptions as allowed in these rules, which would be for testing and research purposes if it means whenever the Office grants an exception. The commenter also recommended the language for registered organizations follow the language for registered practitioners in section 113.23 (a) and (d), Practitioner Prohibitions.

RESPONSE: In addition to exceptions for research and testing purposes, the Office may provide additional exceptions to section 113.11(b)(3). No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter recommended that the Office eliminates references to “adverse events” and “incidents” in subdivisions (a)(6)(i) and (iv), respectively, as those terms are undefined and vague. Alternatively, the commenter asks the Office to consider defining those terms so that operators understand the

types of events, other than those specified in the rule, that necessitate notification to the Office within 24 hours of occurrence.

RESPONSE: The proposed regulations were amended to provide a definition for adverse event as a result of this comment.

COMMENT: Many commenters suggested that RO's should be allowed to use additional extraction methods than what is stated in section 113.12(a). A few commenters requested adding solventless extraction to the list of permissible extraction methods in section 113.12(a). Another commenter suggested permitting butane (hydrocarbon) extraction. One commenter recommended the Office establish residual solvent testing limits for the suggested extraction methods. The commenter also stated that the limitations on other extraction methods makes it harder for medical patients to find out which extraction method works best for them.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: One commenter requested the inclusion of medium chain triglycerides (MCT oil) as an excipient in vaporized formulations in section 113.12(c)(2)(iii)(d). The commenter stated that their RO currently has a CBD dominant vaporization product that has an approved formulation by the state with MCT oil as an excipient and with this proposed regulation, would have to discontinue the product. The commenter also stated that they have years of safety data that shows that MCT oil does not cause harm to patients and not having this product would create issues for patients seeking the fast-acting CBD dominant formulation.

RESPONSE: Disallowing medium chain triglycerides (MCT oil) in vaporization forms aligns with Part 114, and other forms besides vaporization may provide fast onset, short duration relief. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested changing section 113.12(c)(2)(iii) and (iv) to allow for a full range of naturally occurring flavoring chemical beyond terpenes. The commenter further asked for clarification on the use of the term “medicinal compounds”, stating that it is vague and could include compounds that naturally exist in cannabis, such as ketones or alkaloids.

RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations.

COMMENT: Two commenters suggested amending section 113.12(c)(2)(i) by removing the term “disposable”, replacing it with the term “recyclable”, disallowing single-use devices and allowing re-fillable cartridges. Another commenter stated the Office should *not* refer to any electronic device as “disposable,” and opt to describe cartridges as “single use” instead. The commenters stated that the term “disposable” implies that patients should the throw the devices into the garbage instead of recycling them, contrary to the state’s Beyond Waste Plan. The commenters also suggested the Office reevaluate the provision in section 113.12(c)(2)(i) stating that single-use products “cannot be recharged.” They stated that that single-use products that cannot be recharged promote the proliferation of hazardous e-waste; having rechargeable devices and re-fillable cartridges would reduce that waste stream. One of the commenters also suggested allowing medical cannabis inhalers and flower vaporizers.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: One commenter proposed expanding the regulations requiring that medical vaporization devices be a closed system with pre-filled disposable cartridges to allow systems compatible with using unadulterated whole flower products.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: A few commenters requested guidance for minimum standards on recycling programs for medical cannabis products and how they should or must be structured and/or operated. Two commenters suggested removing the requirement for “prior written approval” in section 113.12 (i)(2). Another commenter requested more information on the steps needed for an operator to get prior written approval. The commenter also questioned if New York requires other types of businesses to get “prior written approval” for their recycling plans or if this is a special requirement for the cannabis industry.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: Two commenters questioned dosing for THC content in medical cannabis products. One commenter suggested increasing the THC content, stating that some patients have a higher tolerance and having to take multiple doses is not sufficient. Another commenter questioned if NYS is intentionally lowering dosages for THC.

RESPONSE: The THC content in medical cannabis products is not specified in the proposed regulations. The registered organization must properly label the product and validate concentration is within testing limits. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested that there be more medical cannabis that offers a low THC option. The commenter stated that some patients are very sensitive to THC and do not like having the psycho-active effects and would prefer a more micro-dosed product.

RESPONSE: Section 113.12(b)(3) of the proposed regulations requires registered organizations to offer and make available to patients at least one brand that has a low THC and a high CBD content and one brand that has equivalent amounts of THC and CBD. Other than that, the Office does not specify which medical cannabis

products a registered organization chooses to make available. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested having cannabis packaged for sale in clear plastic jar. The commenter stated that it currently comes in colored plastic jars, and they are not able to see the product until the container is opened, making it hard to see the quality. This often leads to being stuck with a costly purchase.

RESPONSE: There is no prohibition against packaging in clear packages unless such packaging degrades the medical cannabis product. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter expressed concern about having to make significant changes to their current labels without any added benefits to the patient. The commenter stated they understand the importance of including, THC, THCA, CBD and CBDA on labels for metered flower products to help inform patients, however, the THCA and CBDA on products such as their vape cartridges will not contain any THCA and CBDA due to the decarboxylation process use in the making of the cartridges.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter suggested including a QR code that would either link directly to the product CoA or an internal file showing the potency values for the products.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: A few commenters requested that the Board consider allowing other common forms of edibles such as infused-beverages, gummies, and chocolates, forms that are allowed for medical cannabis consumers in other jurisdictions and currently available on the unregulated market. The commenter suggested risks of

accidental or over consumption can be mitigated by strict packaging requirements, including those set forth in section 113.12(h). One commenter stated that not having these methods available leaves patients with limited options. Another commenter suggested allowing solid concentrates in the medical program and stated that without having it available, it will drive patients to adult-use markets.

RESPONSE: Solid and semisolid preparations, including capsules, chewables, effervescent tablets, and lozenges are approved forms of medical cannabis. Gelatin-based products, or gummies, and chocolates fall into this classification and are therefore approved forms. However, the term “gummy” is not used so as to not make the product attractive to minors. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter recommended replacing the language in section 113.12(k)(11) with “Store cannabis products securely, out of sight and reach of children. If a child accesses this product call the Poison Control Center at 1-800-222-1222.” The commenter stated providing more specificity is important.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: A few commenters recommended amending section 113.12(n) to remove the requirement that hemp and hemp extracts be New York grown or processed only. One commenter stated that New York does not discriminate against out-of-state hemp extract if the products satisfy the requirements set forth in the updated proposed cannabinoid hemp regulations. Other commenters stated the built-in flexibility to source hemp nationally ensures that New York’s program provides consumers with product diversity, competitive pricing and most importantly continuity in quality of inputs for operators and consumers. The commenters also stated that hemp and hemp extracts containing less than 0.3% of THC by dry weight are federally legal pursuant to the 2018 Farm Bill and may be sold freely within interstate commerce. By continuing to restrict compliant hemp

and hemp extract to that which is grown or processed in New York, the Board is vulnerable to challenges under federal dormant commerce clause.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested modifying consistency rules in section 113.12 to exclude whole flower so that different harvest of the same strain can be the same “product”.

RESPONSE: The manufacturing requirements in section 113.12 and the laboratory requirements in Part 130 ensure that registered organizations are able to demonstrate stability, consistency, and purity of the product. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested the Office should prioritize medical product reviews once the adult-use market is launched in an effort to protect patient access.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: The commenter suggested the solid and semi-solid preparations should also include various types of suppositories and that topical forms and transdermal patches should also include buccal, mucosal and/or sublingual films, patches, and strips, etc.

RESPONSE: Cannabis Law provides that the Board shall fix by rule and regulation the standards and requirements of the types, forms, and concentration of products which may be manufactured and/or processed, in order to ensure the health and safety of the public. A registered organization shall only produce such forms of medical cannabis as approved by the Office and according to the requirements set forth in section 113.12. The

examples noted in section 113.12 are not all-inclusive. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that dispensaries should be allowed to sell approved medical products from other RO's and from other medical cultivators throughout the state, to include Social Equity medical cultivators.

RESPONSE: The Office has issued guidance for wholesaling medical cannabis products and extract with prior written approval from the Office. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter encouraged the Office to consider eliminating sections 113.12(b)(1)(v) and 113.12(k)(4) which requires the reporting (and labeling) of the concentration of “any other marketed phytocannabinoid.” The commenter believes such language is ambiguous and likely to result in confusion for operators seeking to comply with the requirement and that such a reporting requirement is not necessary to safeguard the health and welfare of patients or in ensuring the quality and consistency of cannabis products produced by registered organizations.

RESPONSE: A marketed phytocannabinoid is the same as a phytocannabinoid, other than total THC and total CBD, except that phytocannabinoid is conspicuously promoted on the cannabis product label. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter advocated for the Office to remove section 113.12(b)(2)(iii) suggesting that it is not necessary to ensure product offerings are consistent and contain accurate labeling with respect to THC and CBD content. The commenter believes the language of section 113.12(b)(2) serves to ensure that THC and

CBD content of products will be within 10% of the labeled concentration, which is standard in the cannabis industry.

RESPONSE: Section 113.12(b)(2)(iii) provides for product homogeneity testing. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter encouraged the Office to eliminate the requirement that a product name be pre-approved by the Office and clarify that only individual products/SKUs need distinct names. The commenter expressed that requiring the prior approval of the Office would slow down the ability of operators to bring products to market and should not need approval as long as a brand name meets advertising, marketing, and labeling standards. The commenter stated that if the Office determines that brand names must still be approved before being made available to patients, the Office should at least allow individual products to be released, under a previously approved brand name, without further review of the Office.

RESPONSE: The Office acknowledges this comment. While medical cannabis products must comply with the requirements of this section, Section 113.12(b) has been modified to remove the requirement for registered organizations to obtain prior approval of the office before producing medical cannabis products.

COMMENT: One commenter suggested adding the phrase “to the extent feasible” to section 113.12(b)(6) in order to take into consideration, the possibility of market disruption beyond the control of operators such as global supply chain disruptions.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter urged the Office to clarify that botanically-derived terpenes and other ingredients that are Generally Recognized as Safe (GRAS) or otherwise approved by the United States Food and Drug Administration, including flavoring additives, are approved for use as ingredients in cannabis products. The commenter suggested the Office should consider allowing botanically-derived terpenes and other ingredients permitted by the United States Food and Drug Administration as an “inactive ingredient” for inhalation in such products. The commenter believes the Office should only prohibit the use of ingredients based on firm science and consider approval of any internationally accepted ingredients, including any isolates naturally found in cannabis. They also suggest that the Office consider a less restrictive approach related to ingredients that can be used for inhaled products that better aligns with products available in other adult use and medical cannabis markets, are not linked to adverse outcomes, and provides the Office with necessary flexibility to ensure a diversity of products available in the market to the benefit of patients.

RESPONSE: Excipients proposed for use in vaporized cannabis products, such as botanically derived terpenes and flavorings, are reviewed by the Office as part of a vaporized product submission review. The manufacturer must demonstrate a proposed excipient in a vaporized product will not cause harm. Due to the nature of the heating and inhalation of vaporized products, and a paucity of evidence related to vaporization in general, additional scrutiny of vaporized product formulation is warranted. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested the Office consider allowing single-use products to be exempt from the packaging requirements that they be in resealable packaging that minimized oxygen exposure due to the fact that single-use products are meant to be fully consumed at one time, making the resealing of packaging, and minimizing oxygen exposure not necessary.

RESPONSE: A definition for “resealable” was added to the regulations and means a package that maintains its child-resistant effectiveness, as well as preserving the integrity of cannabis products for multiple doses. The proposed regulations were amended as a result of this comment.

COMMENT: One commenter suggested that the Office require that products that contain CBD and THC be reflected on labeling as a ratio of CBD:THC rather than THC before CBD, as requiring ratios to be reflected as CBD:THC reflects the industry standard.

RESPONSE: The proposed regulations do not require the ratio to be listed on the label, instead requires total milligrams of CBD and TCH for both per dose and per package. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested the Office consider allowing stability testing data collected in other medical or adult use cannabis jurisdictions be accepted as demonstrative of the stability of a substantially similar product produced in New York. The commenter stated allowing such a practice still ensures the stability of products but reduces costs for operators that may have already conducted such testing elsewhere.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter recommended stronger packaging requirements to prevent accidental ingestion, such as prohibiting depictions of food and drinks and brightly colored packages. The commenter stated they believe that plain packaging is most appropriate for medical cannabis product.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: Comments were received urging the Office to consider removing the requirement that a pharmacist be employed by registered organizations to supervise the dispensing process or consider permitting a pharmacist to remotely supervise more than one dispensing facility at a time. The commenter stated that allowing dispensary employees who are not pharmacists and/or supervised by pharmacists to dispense medical cannabis is a practice permitted in other mature medical and adult use markets, it does not add to patient care or safety, and it slows down the dispensing process both to the detriment of patients and operators alike.

RESPONSE: Pharmacist oversight is an essential component to providing certified patients with quality care when obtaining their medical cannabis. Access to pharmacists provide certified patients with an opportunity to discuss their medical conditions and identify appropriate treatment options. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested the Office consider requiring that physical patient safety inserts be made available to patients only upon request or upon a patient's first purchase of a product and/or allowing such information to be included in a QR code that can be made available to patients.

RESPONSE: Pursuant to section 34(6) of the Cannabis Law, when a registered organization sells, delivers, distributes, or dispenses medical cannabis, it shall provide a safety insert. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested requiring registered organizations to document returns but would only require that the information be provided to the Office upon request or for registered organizations to provide the requested information to the Office on a monthly or quarterly basis. The commenter believes these proposed amendments would alleviate the burden on operators and the Office, which would reduce correspondence from operators each time there is a return.

RESPONSE: The Office acknowledges this comment and agrees that registered organizations may retain records pertaining to patient returns for review upon request of the Office. The proposed regulations were amended as a result of this comment.

COMMENT: Two commenters suggested a revision to the subparagraph lettering in section 113.13 between (f) and (g). The commenter stated that it appears to have two letter (i) subsections before the (g) subsection.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: Two commenters recommended that the Office should clarify that ROs may sell medical cannabis products that comply with the regulations, and do not additionally require office approval on a product-by-product basis and that only “items that promote health and well-being” are subject to office disapproval.

RESPONSE: Brands and forms, manufactured in accordance with the requirements set forth in this Part, no longer require approval by the Office. The proposed regulations were amended as a result of these comments.

COMMENT: One commenter suggested allowing some flexibility in section 113.13(a) for at-home consultations by an in-house pharmacist for certain vulnerable or homebound populations who cannot travel to a medical cannabis dispensary. Otherwise, all supervision should be done onsite.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Two commenters recommended requiring ROs to use only TL-rated safes, and/or safes that are approved in writing by the RO’s insurance policy. The commenters stated that sometimes insurance policies will only cover thefts involving specific types of safes.

RESPONSE: It is incumbent upon the registered organization to comply with any terms of their insurance policy. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Two commenters suggested the Office provide clarity in sections 113.14(1)(4) and (5) with regard to what is an “unnecessary stop” and what it means for delivery times to be “randomized” as these standards are not clearly defined and likely to lead to confusion and disputes.

RESPONSE: The Office acknowledges this comment. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested that the Office reduce the amount of time shipping manifests must be maintained to 3 years as it is a more reasonable period to maintain such records and better aligns with industry standard practice.

RESPONSE: The Office acknowledges this comment. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter asked if there were any special requirements to perform criminal background checks of employees of a cannabis testing laboratory.

RESPONSE: Cannabis Law Section 138 authorizes the Board to review the criminal history of any person seeking a registration, license, permit, or authorization. In doing so, the Board will review all criminal history

in accordance with the Corrections Law Article 23-A. No changes were made to the proposed regulation as a result of this comment.

COMMENT: One commenter asked that the list of regulated analytes be included in Part 113. They were included in Part 1004. Additionally, the commenter indicated having the list in regulation would allow the public to be involved in any changes to the rulemaking process, including removal of any contaminants.

RESPONSE: The Office intends to supply the list of analytes in guidance. The list is not exhaustive and will be modified by the Office as necessary. No changes were made to the proposed regulation as a result of this comment.

COMMENT: One commenter suggested that the Office needs to expand the number of operational labs and comprehensively update lab testing guidance. The commenter also recommended putting lab testing requirements in regulations instead of guidance documents in order to give operators regulatory certainty to efficiently and effectively run businesses and have a proper forum to weigh in on such standards through public comment. Additional comments emphasized the importance of preparing independent laboratory testing facilities testing both medical and adult-use cannabis and suggested the Office prioritize medical cannabis testing. The commenter encouraged the office to expand laboratory testing in order to avoid supply-chain disruption of medical cannabis product.

RESPONSE: The Office is actively working to increase laboratory testing facility participation in the medical cannabis program to test medical cannabis. In addition, the Office is currently revising the list of regulated analytes and the associated acceptance limits. The list will be posted to the public website. The Office also routinely consults with stakeholders and experts to solicit feedback on current and future testing policies. No changes were made to the proposed regulation as a result of this comment.

COMMENT: One commenter suggested that in terms of laboratory analyses, the RO's should also provide a statistically determined sample of their products, which have passed all of the commercial laboratory tests, to a State Reference Laboratory for further analysis and quality control. The Office received additional comments seeking the state to establish its own State Reference Laboratory to accept and examine a statistical determined sample size of every whole flower medical product produced within the state. The commenter suggested that this will serve not only as a quality control for the commercial labs within the state, but also as an extensive database to determine the full chemical analysis and profile of cannabis products beyond that which is listed by each of the commercial laboratories.

RESPONSE: As determined by the Office, samples may be collected and given to the New York State Department of Health's Public Health laboratory, which will continue to serve as the state reference laboratory, for confirmatory analysis and testing medical cannabis. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested replacing the prior written approval requirement in section 113.15(c) with "upon notification to the Office, and no denial issued by the Office" as it aligns with current industry practice and communication with the Office regarding notification of transportation and would alleviate the burden on both registered organizations and the Office in seeking and granting approval.

RESPONSE: Considering 3rd party or lab sample collection and gathering a statistically significant sample from the registered organization manufacturing facility, allowing the final medical cannabis product sample to be packaged in a quantity less than that which would be provided to the patient if the sample is prepared and packaged in the identical manner as the product provided to the patient is no longer feasible and will not be permitted. The proposed regulations were amended to remove this reference.

COMMENT: One commenter expressed concern about the effect that consolidating companies will have on pricing of medical cannabis products.

RESPONSE: Section 113.16(c) of the proposed regulations permits the Office to modify the price per dose for any medical cannabis product, if necessary, in order to maintain access for certified patients. Registered organizations are prohibited from holding multiple registrations. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested that medical cannabis businesses retain the discretion to set pricing in order to ensure competition and affordability. The commenter expressed concern about the precedent that granting this broad discretion to adjust prices would set and stated that Office must understand the importance of ensuring patients have access to affordable cannabis products.

RESPONSE: Registered organizations are responsible for determining the cost of their own medical cannabis products. The Office modifies the price per dose for medical cannabis products only when necessary to maintain access for certified patients. The Office does understand the importance of ensuring certified patients have access to affordable medical cannabis products. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested amending section 113.16 to change the number of days that registered organizations shall submit documentation or changes regarding pricing per dose for medical cannabis to the Office from fifteen days to thirty days.

RESPONSE: The proposed rulemaking is in consistent with Section 45 of Article 3 of the Cannabis Law. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Several commenters suggested allowing the advertisement of medical cannabis on or in public transit vehicles, stations, and billboards. One commenter stated that restricting medical cannabis advertising limits the ability for registered organizations to reach patients and that advertising for other forms of medicine is allowed on transit, stations, and billboards within New York.

RESPONSE: Pursuant to Section 86(4)(b) of the Cannabis Law, any broadcast, cable, radio, print, and digital communications can only be placed where the audience is reasonably expected to be twenty-one years of age or older, as determined by reliable, up-to-date audience composition data. Section 86(2)(k) prohibits advertising in the form of a billboard. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested allowing cannabis to be visible and the ability to smell the cannabis while at the RO so that patients can determine if it is something they like before purchase.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter asked if RO's are permitted to implement "loyalty" programs for their patients and if so, are patients under 21 years of age allowed to enroll in these programs.

RESPONSE: The proposed regulations restrict the advertisement of reward programs; however, they do not prohibit a registered organization from offering discounts or a discount program to any certified patients or designated caregivers for the purchase of medical cannabis products. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested that the Board consider revising the regulations to narrow their scope and identify and shorten the pre-publication review timeline of advertisements. In addition, the commenter requested a definition with examples of what is meant by "obscene or indecent."

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter stated that the inability to market a product as “better” fails to recognize the diverse marketplace that exists to evaluate and compare different products in the cannabis marketplace and requests that the Office permits the use of the term “better” so long as providers and brands do not make any scientific or medical claims without the appropriate evidence.

RESPONSE: Section 113.17 of the proposed regulations clarifies that an advertisement stating that one medical cannabis product, brand, or form is better or more effective than another is not considered false or misleading if the claim has been demonstrated by substantial scientific evidence or clinical experience. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested clarification of what suffices with respect to the information that can be presented to substantiate a true and accurate statement relating to effectiveness, side effects, consequences, or contraindications. The commenter suggested the Office consider requiring that any document or study relied on by an operator be made available to the Office or the general public upon request. The commenter believes that providing such guidance to registered organizations would ensure all licensees are operating on a level playing field and ultimately ensure the intent of the regulation is met. The commenter suggested a similar standard should be ascribed to the use of any statement, design, representation, picture, or illustration related to the safety or efficacy of medical cannabis, as reflected in section 113.17(h)(5) and that the standard for making such claims be the ability to provide substantiation that the information is truthful and not misleading.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter proposed that advertising should not contain images portraying anyone under 25 years old, suggestive of the presence of someone under 25 years old, or the use of imagery typically associated with anyone under 25 years old.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter requested the Office reduce the period of review for the submission of advertisements as a full two-month review process for such advertising materials is challenging for operators, and such a lengthy review process could functionally serve to prohibit registered organizations from engaging in advertising that educates patients about products. In addition, the commenter requested the Office consider allowing the use of claims language in future advertising if approved previously by the Office, avoiding unnecessary delays and additional review work by the Office.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter expressed concern with the provision in section 113.17(a)(1) and requested that the Office specify and limit the uses and styles of graphic that the provision would permit. The commenter also stated that the Office should expand appropriate, accessible communications avenues for people with qualifying conditions to learn about medical cannabis and how to find a provider.

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter recommended that a record of all medical cannabis products dispensed be maintained and available to the Office upon request, and not automatically filed electronically after being dispensed. The commenter also suggested amending section 113.18(a) to only require filing a zero report only

when requested by the Office as the information is always available via seed-to-sale software should the Office want to review it. The commenter stated these amendments would ease compliance-related burdens on both registered organizations and the Office. Another commenter recommended removing section 113.3(f) as it could lead to unnecessary denials of medical cannabis.

RESPONSE: Requirements that practitioners and registered organizations use the prescription monitoring program (PMP) registry are expressly included in the statute and proposed regulations. Pursuant to Cannabis Law § 30(4), every practitioner shall consult the PMP registry prior to making or issuing a certification. Pursuant to Cannabis Law § 34(5)(b), all dispensing sites must consult the PMP registry prior to dispensing medical cannabis to a certified patient. The proposed regulations further require dispensing facilities to submit dispensing data to I-STOP within 24 hours. This includes zero reports that identify that there was no product dispensed. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter recommended that non-binary/gender non-conforming options be incorporated in section 113.18(b)(3).

RESPONSE: The Office acknowledges the commenter's recommendation and may make future changes. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter proposed adding the following language to section 113.21(a) "that exceeds the personal possession limits for adult use cannabis set forth in the Cannabis Law no later than 30 calendar days" to align with the possession limits articulated in the Marihuana Regulation and Taxation Act. The commenter suggests that patients who possess cannabis that exceeds adult use possession limits be given a longer grace period than 10 days in which to dispose of the same.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter asked if previous practitioner prohibitions in section 1004.22(c) are still in effect or if they have been updated.

RESPONSE: Part 1004 will be repealed when the medical cannabis regulations are adopted. Under Section 113.23(c), a practitioner is prohibited from issuing a certification for themselves. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Some commenters requested clarification on the number of certified patients a designated caregiver can serve. The commenters indicated section 113.5(b)(1)(vii) indicates a designated caregiver cannot have more than four certified patients and section 113.24(a) indicates a designated caregiver cannot have more than five certified patients.

RESPONSE: The proposed regulations were amended as a result of these comments.

COMMENT: A few commenters suggested using “unusable” instead of “unrecoverable and beyond reclamation” in section 113.25(a). The commenters state that doing this would prevent medical cannabis waste from being misclassified or mistreated, while still allowing for the recycling of medical cannabis waste. They also stated that rendering items “beyond reclamation” is inconsistent with the goal of promoting recycling within the industry and it would prohibit companies who want to implement a recycling program under section 113.12(i)(2).

RESPONSE: The proposed regulations were amended as a result of this comment.

COMMENT: One commenter requested that section 113.25(d) be amended to reduce the amount of time that records be maintained from five years to three years. The commenter stated that three years is a more reasonable period to maintain such records, and that it would not be to the detriment of security, safety, or patient care. The commenter also asked the Office to clarify that electronic records can be maintained rather than hard copy record particularly given that records must be maintained for several years.

RESPONSE: The Office acknowledges this comment and may consider it in the future. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested including a comparison document when issuing future revised regulations. The commenter stated that when revising or updating existing regulations that other states provide a separate document comparing the existing version to the proposed versions, and that shows proposed deletions, additions, and changes.

RESPONSE: The Office acknowledges this comment and may consider it in the future. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested adding language permitting non-residents with medical cards to be able to purchase and consume medical cannabis while in New York State. The commenter stated that the ability for non-resident patients to purchase their medicine remains essential and that many states support some sort of reciprocity in their medical programs.

RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: Some commenters questioned how the process for public comment works, how much time occurs between the end of the comment period and when the regulations are published in the register, and when the current medical regulations will go live.

RESPONSE: The Office must adhere to the New York State Administrative Procedure Act which governs the rulemaking process in New York State. The proposed regulations were posted on the Office of Cannabis Management webpage and published in the State Register on March 9, 2022, for the required initial 60-day public comment period, which ended on May 9, 2022. The Office reviewed the public comments received with this assessment of public comment and is filing the proposed revised rulemaking, which is subject to a 45-day public comment period prior to adoption in the State Register. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter stated that NYS advertises to smoke safely but patients are told not to combust. They indicated that medical stores are the only pathway to get tested cannabis and questioned why everyone can smoke grey market product, but medical patients can't smoke or have access to pre-rolls.

RESPONSE: The Cannabis Law has removed the prohibition on smoking in the medical cannabis program. Metered ground plant preparations and whole flower cannabis are approved forms of medical cannabis. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter questioned if there will be a data entry location to enter CBD and CBDA into BioTrack. The commenter stated that currently there is only an entry area for THC and THCA potencies.

RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: One commenter asked if NYS medical patients who home cultivate will be able to get their cannabis tested so that they can know the potency and how to dose.

RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: A few commenters suggested amending section 113.13 to authorize registered organizations the ability to sell medical cannabis wholesale to tribal nations such as the Shinnecock Nation, which have enacted medical cannabis laws and internal regulatory governance. One commenter stated that the tribal nation's cultivation and processing facility is ready to dispense medical cannabis to registered patients in coordination with multiple registered organizations that are willing to supply medical cannabis products. Another commenter stated that NYS should enter a MOU with tribes regulating cannabis activity. A commenter also stated that they live near the reservation and would like to be able to buy medical cannabis locally.

RESPONSE: The Office acknowledges these comments; however, it is beyond the scope of the proposed regulations.

COMMENT: Many commenters suggested not allowing pharmacists to work remotely. They believe that the idea undermines the purpose of a pharmacist being on site and opens registered organizations up to more risk. One commenter stated that having a remote pharmacist doesn't allow for the registered organization to be under direct supervision of what product is being dispensed and if the product is at an accurate day's supply. One commenter stated that allowing remote pharmacists could cause significant abuse of the provision potentially leading to the damage of the integrity of the medical program and that it contravenes with Part 80.6 (d) of NY's Rules and Regulations governing Controlled Substances. One commenter stated that individuals without a license should not be dispensing without a medical professional on site. Another commenter stated that regular

medications are not dispensed without a pharmacist present and that we should treat medical cannabis the same. Other commenters stated that there are patients that require pharmacist oversight due to serious medical conditions, medication interactions, and dosing questions. The commenters believe that in-person consultations with a pharmacist are the best way to engage with the patient and make them feel comfortable. Many commenters were concerned that patients would not get the medical guidance and help they would need and expressed the importance that the pharmacist carries within the dispensaries. The commenters believe that by removing the pharmacist would be removing the medical aspect of the program and fails to put patients first.

RESPONSE: The Office acknowledges the comments received in support of the presence of a pharmacist in person and comments in opposition of the remote pharmacists at medical dispensaries policy. The proposed regulations were amended as a result of these comments.