

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

New York State recognizes that possession and use of marijuana is illegal in the United States. However, the State also recognizes the benefit in making available medical marijuana to qualified individuals with debilitating and life threatening illnesses and conditions. To that end, the Compassionate Care Act (PHL §3360 et. seq.) (the “Act”) is balanced legislation that ensures appropriate access through comprehensive regulations and safeguards.

The State subsequently developed the regulations through this very critical lens to ensure that the entire program would not be subject to enforcement action or legal challenges. Expanding the initial set of regulations would have subjected the State to unnecessary scrutiny and jeopardized the program’s ability to move forward in any meaningful manner. The Compassionate Care Act and the proposed regulations strike the required balance by implementing a strong and effective medical marijuana program in New York State.

The Department of Health (the “Department”) received comments from hundreds of stakeholders (many of whom were affiliated with the same entity or organization). A summary of the comments received is set forth below. The full text of the regulations and the full assessment of public comment are available on the Department’s website.

The Department reviewed and assessed each comment. Some comments were not incorporated as they were inconsistent with the statutory authority underlying the rulemaking or concerned issues outside the scope of the rulemaking. Other comments appeared to warrant further consideration as to whether clarification would be helpful in guidance or for possible inclusion in

future rulemaking. Revisions were determined to be unnecessary for other comments, as the regulations are adequate to address the topic areas raised.

Several comments were received on similar topics, including the following:

- Comments were received concerning practitioner education requirements, and the exclusion of health care practitioners (other than physicians) from those authorized to issue patient certifications. The regulations require practitioners complete a four hour course, which is consistent with the Act. The course will be available online. With respect to issuance of certifications, Public Health Law (PHL) § 3360 (12) defines “practitioner” as a licensed physician, and authorizes the Commissioner of Health to consider the inclusion of nurse practitioners. The Commissioner will consider adding nurse practitioners in the future.
- Commenters recommended expanding the list of serious conditions, and including a transparent process for adding new conditions. PHL § 3360(7)(a) authorizes the Commissioner to add conditions to those already included in statute, and to consider expanding the list of conditions in the future. The Department will issue guidance concerning the process to add new conditions.
- Comments were received concerning the patient certification process as well as the financial hardship waiver of the registry identification card application fee. A single electronic system for practitioners to issue certifications, and for patients and designated caregivers to apply for registry identification cards, will be utilized to ensure a more timely process. The Department is authorized to waive application fees and will provide guidance for applying for a hardship waiver.
- Comments were received concerning whether a registered organization must perform both manufacturing and dispensing activities in order to obtain a registration, and recommended

that registered organizations be allowed to manufacture and dispense from the same location.

The Act requires registered organizations to manufacture and dispense medical marijuana.

With respect to authorizing such activities at the same location, however, there is a risk of theft and diversion in allowing co-location of these facilities, and it is therefore prohibited.

- Comments were received concerning the qualifications and consideration of applicants seeking to become a registered organization. PHL § 3360(17) defines a registered organization applicant as “a for-profit entity or not-for-profit corporation.” Although New York State residency, or formation of the entity or corporation in New York State, is not a requirement of the statute, all manufacturing, processing, and dispensing must occur within the State. Upon receipt the Department will evaluate the application pursuant to the criteria in Section 80-1.6.
- Commenters wanted to increase the number of registered organizations, and to allow for delivery services. The Act and the regulations provide that the Commissioner shall register no more than five registered organizations, but the Commissioner may register additional registered organizations thereafter as needed. The regulations are consistent. Delivery services are prohibited unless prior written approval has been obtained from the Department.
- Commenter wanted to know how the Department would consider whether an applicant is ready to begin operations. The Department will carefully review an applicant’s operating plans and other documentation to ensure that the registered organization will be able to successfully begin operations within six months of the date of issuance of the registration, and will issue guidance if necessary.
- Comments were received concerning how the registered organization will ensure availability of at least a one year supply of any offered brand. The regulations require the registered

organization to demonstrate, through their standard operating procedures, that they are able to ensure availability of the brand for a one year time period. The regulation does not require physical availability of a one year supply of product.

- Comments were received concerning the one thousand foot prohibition as it relates to the location of a dispensing facility. Section 80-1.10(7) provides that a dispensing facility may not be located on the same street or avenue *and* within one thousand feet of a building occupied exclusively as a school, church, synagogue or other place of worship. Accordingly, the restriction only applies if both conditions are met. Should it be determined that this limitation restricts access, the Department will consider revising its policy in subsequent rulemaking.
- Comments were received concerning a registered organization's ability to transfer or wholesale marijuana or approved products between registered organizations or from one dispensing facility to another. While the regulations allow a registered organization that intends to cease operations to transfer its supply, it must first submit a plan to DOH for doing so. With respect to transfers between dispensing facilities, the regulations limit transporting medical marijuana from a manufacturing site to a dispensing site, and to a laboratory for submission of samples for required testing.
- Comments were received concerning the use of pesticides or, in the alternative, imposing labeling requirements to show all elements in the product. The regulations allow a registered organization to use pesticides, fungicides or herbicides if approved by the NYS Department of Agriculture and Markets. With respect to labeling, the Department must approve a registered organization's package safety insert which must include a list of excipients used.

- Comments were received regarding limits on brands, forms and extraction methods. Section 80-1.11(c)(1) provides that each registered organization may initially produce up to five brands of medical marihuana, and thereafter, the Department has discretion to approve additional brands. Section 80-1.11 (g) authorizes the Commissioner to approve additional forms of medical marijuana. Similarly, with respect to extraction methods, Section 80-1.11(b) allows the use of other extraction methods than those listed in the regulations (carbon dioxide (CO₂, super-critical) or alcohol for cannabinoid extraction) with the prior written approval from the Department.
- Comments were received objecting to the prohibitions on whole plant and plant based products. PHL § 3360 (8) provides that any form of medical marihuana not approved by the Commissioner is expressly prohibited. At this time, the Commissioner has not approved medical marihuana in plant form. Section 80-1.11 authorizes the Commissioner to approve additional forms.
- Comments were received concerning why a pharmacist must be on-site at dispensing facilities and over liability. Pharmacists have the training and skill-set necessary to identify drug-related issues that a patient may face. The regulations require the pharmacist complete a course approved by the Department, which is the same as that required of physicians who seek registration to certify patients. With respect to liability concerns, the statute makes clear that medical marihuana is not deemed a “drug” for purposes of Article 137 of the Education Law, in relation to the practice of pharmacy (PHL § 3368 (1)(b)). In addition, PHL § 3369 (1) provides protection from arrest, prosecution or penalty in any manner, including but not limited to disciplinary actions by a professional licensing board, to employees of registered organizations, which would include pharmacists.

- Comments were received in opposition to the prohibition on consuming food or drink, and limitation of visitors, on the premises of the dispensing facility. The regulations allow food or beverage consumption if necessary for medical reasons. With respect to visitors, the limitation is a proper security measure to ensure that only individuals authorized to obtain medical marihuana products are permitted on the premises of a dispensing facility, unless waived by the Department upon prior written request. The regulations provide that if an unforeseen circumstance requires the presence of a visitor and makes it impractical for the dispensing facility to obtain a waiver, the dispensing facility shall record in the visitor log, the name of the visitor, date, time, purpose of the visit and the facts upon which the access was granted.
- Comments were received concerning the Commissioner's ability to set prices for medical marijuana, and affordability and access to medical marihuana by low income patients. PHL § 3369-d requires the Commissioner to set the price per dose for each form of medical marihuana sold, and to take into account the fixed and variable costs of producing the form of marihuana in approving such price. The statute does not provide for differentiation of price based on income. Although the regulations prohibit distribution of products or samples at no cost, they allow exceptions to be authorized by the Commissioner, which could include a charity program offered by a registered organization.
- Comments were received concerns restrictions on advertising. PHL § 3364 authorizes the Commissioner to make rules and regulations restricting the advertising and marketing of medical marihuana, which must be consistent with the federal regulations governing prescription drug advertising and marketing. The advertising requirements in the regulations are consistent with federal regulations.

- Comments were received concerning the prohibition of the use of approved medical marihuana products in certain places. PHL § 3362 (2)(a) provides that possession of medical marihuana shall not be lawful if it is consumed or vaporized in a public place. No changes have been made to the regulations in response to these comments.
- Commenters indicated that the regulations fail to provide expedited access to medical marihuana, including for children who suffer from intractable epilepsy. Compassionate Care Act establishes a comprehensive system for the manufacture, dispensing, obtaining and use of medical marihuana in this State. The Department is moving forward aggressively to implement the provisions of the Act.
- Finally, technical, non-substantive clarifications have been made to the regulations as a result of comments received. The Department made a technical change in the numbering of the regulations. A new Part 1004 is added entitled “Medical Use of Marihuana”. This document refers to the regulations as numbered in the published Notice of Proposed Rulemaking. In addition, the following technical, non-substantive clarifications have been made: (1) § 80-1.5(b)(4)(vi) was revised to change the word “incidence” to “incidents”; (2) § 80-1.5(b)(13) was revised to clarify that any prior bankruptcy of the applicant entity must be disclosed, as it must with its owners, managers and others listed in this section; (3) § 80-1.12(h)(2) was revised to change the word “ordering” to “certifying”; (4) § 80-1.14(f) was revised to correctly reference § 80-1.11(c)(2); (5) § 80-1.21 (c) was revised to remove an inaccurate citation and (6) § 55-2.15(c)(2)(iii)(a) was revised to reference contaminants listed in § 80-1.14(g).