



Saint Regis Mohawk Tribe

Chief Michael Conners
Chief Eric Thompson
Chief Beverly Cook
Sub-Chief Agnes Jacobs
Sub-Chief Benjamin Herne
Sub-Chief Kenneth Jock

TRIBAL COUNCIL RESOLUTION

2020- *03*

ADOPT THE TRIBAL MEDICAL MARIJUANA ORDINANCE

WHEREAS, the Saint Regis Mohawk Tribal Council (the “Tribal Council”), is the duly recognized governing body of the Saint Regis Mohawk Tribe (the “Tribe”) and is responsible for the health, safety, education and welfare of all members of the Tribe; and

WHEREAS, the Tribal Procedures Act (TCR 2013-32) provides that Tribal Council shall exercise all executive and legislative powers, that include but are not limited to the power to take any action that may be necessary to carry out the sovereign authority of the Tribe which is the authority to take any and all actions necessary to promote the health, safety, education and general welfare of the Tribe and its members; and

WHEREAS, the ability to exercise the Tribe’s sovereign authority necessarily requires the development of our economy so the Tribe may fund policies and initiatives benefitting Tribal Membership; and

WHEREAS, in TCR 2016-78, the Tribal Council authorized the Election Board to administer a referendum on *Tsiothóhrha*/December 3, 2016 to “explore options to legalize, license, and regulate the cultivation, production, and distribution of Medical Marijuana,” that was affirmed by vote of Tribal Membership; and

WHEREAS, in TCR 2019-43 the Tribal Council authorized the Election Board to administer a Referendum on adoption of a Tribal Medical Marijuana Ordinance (the “Ordinance”); and

WHEREAS, the Tribe held several public information sessions on the proposed Ordinance to provide Members an opportunity to participate;

WHEREAS, on *Tsiothóhrha*/December 14, 2019 a Referendum question asked: "Do you support the Saint Regis Mohawk Tribal Council Adopting the Tribal Medical Marijuana Ordinance?", and the Election Board issued the official results, which Tribal Membership voted in favor of adopting the Ordinance by a vote of 175-29.

NOW, THEREFORE, BE IT RESOLVED, the Saint Regis Mohawk Tribal Council hereby adopts the "Saint Regis Mohawk Tribe Medical Marijuana Ordinance," as attached hereto, and effective upon the date of this Resolution.

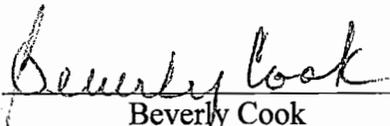
SAINT REGIS MOHAWK TRIBAL COUNCIL



Michael Conners
Tribal Chief

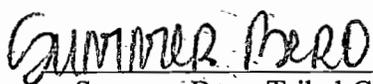


Eric Thompson
Tribal Chief



Beverly Cook
Tribal Chief

CERTIFICATION: This is to certify that the Saint Regis Mohawk Tribal Council pursuant to the authority vested therein duly passed the above resolution.



Summer Bero, Tribal Clerk

Tsiothohrko:wa January 8, 2020

Date

SAINT REGIS MOHAWK TRIBE
MEDICAL MARIJUANA ORDINANCE

CHAPTER 1. GENERAL

Section 1.1 Title

This Ordinance shall be known as the “Saint Regis Mohawk Tribe Medical Marijuana Ordinance”.

Section 1.2 Authority

(a) The Saint Regis Mohawk Tribal Council (“Tribal Council”) is the duly recognized governing body of the Saint Regis Mohawk Tribe (“Tribe”) and is responsible for the health, safety, education and welfare of all members of the Tribe.

(b) The Tribe has the inherent authority to regulate business activities within its Territory subject to the requirements of applicable Tribal law. This authority includes the licensing of businesses on Tribal Territory and establishing regulatory regimes that apply to such businesses.

Section 1.3 Purpose

(a) The purpose of this Saint Regis Mohawk Tribe Medical Marijuana Ordinance (“Ordinance”) is to legalize the possession, acquisition, use, delivery, transfer, transportation, manufacture and sale of medical marijuana on Tribal Territory subject to strict rules and regulations that are set forth herein.

(b) This Ordinance establishes a comprehensive Tribal regulatory process over all aspects of medical marijuana use including, but not limited to, possession, acquisition, use, delivery, transfer, transportation, manufacture, and sale of medical marijuana on Tribal Territory. To administer this process, the Tribe herein establishes two regulatory bodies: (1) the Akwesasne Public Health Authority that will serve as the administrator of the rules and regulations; and (2) the Akwesasne Medical Marijuana Advisory Board that will act as an advisory body on scientific and technical matters.

Section 1.4 Definitions

(a) The following are definitions of terms and words used in this Ordinance.

1. "Tribal Territory" or "Territory" means all lands within the 1796 Treaty with the Seven Nations of Canada (97 Stat. 55) and includes any other lands over which the Tribe exercises jurisdiction.
2. "Saint Regis Mohawk Tribe" or "Tribe" means the federally recognized Saint Regis Mohawk Tribe with government offices in Akwesasne, New York.
3. "Tribal Council", for purposes of this Ordinance, means the three duly elected Chiefs of the Saint Regis Mohawk Tribe.
4. "Tribal Member" or "Member" means a person who is enrolled under the Tribe's Membership Code or a person who is eligible to be enrolled regardless of where they reside. "Membership Code" means the 1986 Membership Code of the Tribe, as amended.
5. "Tribal Election and Referendum Ordinance" means the Tribal Election and Referendum Ordinance, as amended.
6. "Medical Marijuana" means all parts of the plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, intended for a certified medical use. Any form of medical marijuana not approved by the Authority pursuant to this Ordinance is expressly prohibited. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.
7. "Practitioner" means (a) a licensed physician; (b) a licensed nurse practitioner that is supervised by a licensed physician; (c) or a licensed physician assistant that is supervised by a licensed physician.
8. "Registered entity" means a means a for-profit business or not-for-profit business that is majority owned by a member of the Tribe. "Majority owned" means ownership of over 50% shares or interest in a business.

9. "Approved medical marijuana product" means the final manufactured product delivered to the patient that represents a specific brand with a defined cannabinoid content and active and inactive ingredients, prepared in a specific dosage and form, to be administered as recommended by the registered practitioner.

10. "Good moral character" refers to a personal history of honesty, fairness, and respect for the rights of others.

11. "Tribal Procedures Act" refers to the Tribal Procedures Act of 2013, as amended.

CHAPTER 2. TRIBAL REGULATORY AGENCIES

Section 2.1 Akwesasne Public Health Authority

(a) The Tribal Council establishes the Akwesasne Public Health Authority ("Authority") as the regulatory body to administer the provisions of this Ordinance.

(b) The powers and duties of the Authority shall include, but not be limited to:

1. Administer the provisions of this Ordinance including making and enforcing all decisions of the Authority;
2. Accept, review, approve, or disapprove applications required under this Ordinance including, but not limited to, applications for registration of certified patients, practitioners, registered entities;
3. Impose and collect any fees or fines necessary to the regulation of the Ordinance;
4. Adopt regulations and rules after consultation with the Advisory Board;
5. Issue orders required under the Ordinance including, but not limited to, orders to: cease and desist, closures of facilities, suspension and revocation of licenses as necessary to protect public safety;
6. Monitor and regulate all activities of registered entities;
7. Inspect and examine all facilities, buildings, real property used in manufacturing and dispensing of medical marijuana products; and

8. Keep accurate records of all matters within the duties of the Authority.

(c) The Authority shall have three (3) Members with one member serving as Chairperson. Each member shall be appointed by the Tribal Council, and shall serve staggered four-year terms Tribe.

(d) Qualifications for Members of the Authority shall be as follows:

1. Must be a member of the Saint Regis Mohawk Tribe;
2. Must be at least twenty-five (25) years old (on date of appointment);
3. Must possess good moral character and not have been convicted of a serious crime as defined in the Tribe's Election and Referendum Ordinance, as amended;
4. Must pass a background check administered by the Tribe and/or Tribal Police;
5. Must be willing and capable of maintaining communications through technology (email, texts, mobile phone) so as to be accessible to the Authority;
6. At least one member of the Authority shall have experience and expertise in public health, public Safety, and/or health care.

(e) The Authority may receive staff assistance from tribal agencies and departments including the Tribal Compliance Department.

(f) Subject to Tribal Council approval, the Authority may also negotiate cooperative agreements with state and federal governments on matters that are in the best interest of the Tribe and its members to ensure a lawful and well-regulated marijuana market. Such agreements will be submitted to the tribal membership under the Tribal Procedures Act for public comment before finally approved by the Tribal Council.

(g) Any person or entity aggrieved by a final, appealable decision of the Authority may seek review in the Saint Regis Mohawk Tribal Court under the Saint Regis Mohawk Tribal Civil Code.

Section 2.2 Akwesasne Medical Marijuana Advisory Board

(a) The Tribal Council establishes the Akwesasne Medical Marijuana Advisory Board (“Advisory Board”) to serve as a technical, scientific advisory board to provide expert advice to the Authority on all aspects of medical marijuana. The Advisory Board’s function, in that regard, is advisory and not regulatory.

(b) The Advisory Board’s duties and powers shall include, but not be limited to:

1. Serve as a scientific “expert” body that will provide expert advice on all aspects of medical marijuana to the Authority;
2. Provide advisory opinions and advice to the Authority on any technical or scientific issue or matter that may arise regarding the Ordinance and its interpretation; and
3. Submit recommendations to the Tribal Council and Authority regarding the need to amend the Ordinance based upon changed circumstances, changes in the law and any scientific trends.

(c) The Advisory Board shall have five (5) members with one member serving as Chairperson. Each member shall be appointed by the Tribal Council, and shall serve staggered four-year terms.

(d) Members of the Advisory Board shall have the following qualifications:

1. They must be at least twenty-five (25) years old (on date of appointment);
2. They must possess good moral character and not have been convicted of a serious crime as defined in the Tribe’s Election and Referendum Ordinance, as amended;
3. They must be willing to take, and must pass, a background check administered by the Tribe and/or Tribal Police;
4. They must be willing and capable of maintaining communications through technology (email, texts, mobile phone) so as to be accessible to the Advisory Board;
5. Three (3) Advisory Board members will be outside experts who must have knowledge and experience with medical marijuana and expertise in any one of the following areas:

- a. medicine and/or pharmacology;

- b. laboratory testing;
- c. professional engineer;
- d. agriculture and/or pesticide application.

6. Two (2) Advisory Board members will be Tribal members who must have experience and expertise in any one of the following areas:

- a. public health;
- b. public safety;
- c. business.

(d) Decisions of the Advisory Board are advisory in nature and will not be subject to judicial review.

Section 2.3 Other Board Requirements

(a) No member of the Authority or Advisory Board shall actively participate in, or be employed by, a Registered Entity or any other entity or business that is subject to regulation under this Ordinance.

(b) Authority and Advisory Board members will be entitled to compensation according to the standard schedule of fees and compensation provided for tribal boards, committees and commissions.

(c) The Authority and the Advisory Board will adopt their own Bylaws and will nominate a Chairperson by motion and majority vote for a one (1) year term or until a successor is elected. The Chairperson will preside over all meetings and perform all duties of that office as required under approved By-Laws. The Authority and Advisory Board will also nominate and elect other Officers (Vice-Chair, Treasurer, Secretary) with duties and requirements to be set forth in approved By-Laws. The Authority and the Advisory Board will schedule and hold regular meetings.

(d) Members of the Authority and Advisory Board may be removed by Tribal Council, either by the Council itself or upon recommendation by a board. Members may be removed based upon violation of any provision of this Ordinance, failure to perform duties as a Member,

excessive absences from meetings, failure to recuse oneself due to a conflict of interest or conduct unbecoming a Member.

(e) Member vacancies will be filled by the Tribal Council under the same procedure used for appointment. Members appointed to fill vacancies will serve the remainder of the vacant seat.

(f) The Authority and Advisory Board will provide regular reports to the Tribal Council summarizing, among other things, their official actions, activities, investigative reports, and reports received from registered entities to keep the Tribal Council fully informed as to the status of their activities.

CHAPTER 3. PRACTITIONER REGISTRATION

Section 3.1 Practitioner Registration

(a) A "Practitioner" means (a) a licensed physician; (b) a licensed nurse practitioner who is supervised by a licensed physician; or (c) a licensed physician assistant who is supervised by a licensed physician.

(b) In order to be registered by the Authority a practitioner must meet the following qualification:

1. Be licensed and in good standing with an applicable regulatory body;
2. Be qualified to treat patients with a qualifying serious condition as defined in Section 4.1, below;
3. Have successfully completed a two to four-hour course approved by the Authority;
4. Have applied to the Authority for a registration or a renewal of registration to issue patient certifications in a manner and format determined by the Authority; and
5. Have been granted such registration by the Authority.

(c) The Authority will approve at least one, if not more, courses for practitioners seeking to become registered, which shall be two to four hours in duration. The educational content of such course shall include: the pharmacology of marijuana; contraindications; side effects; adverse

reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; abuse and dependence; and such other components as determined by the Authority.

CHAPTER 4. PRACTITIONER CERTIFICATION OF PATIENTS

Section 4.1. Issuing Certifications (Prescriptions) to Patients

(a) A practitioner who is registered under Chapter 3, above, may issue certifications (prescriptions) to certified patients for the use of an approved medical marijuana products. Such certification shall contain:

1. The practitioner's name, business address, telephone number and email address;
2. The practitioner's registration number as issued by the Authority;
3. The practitioner's Drug Enforcement Administration registration number;
4. A statement that the practitioner is licensed and in good standing;
5. A statement that the practitioner is registered with the Authority to issue the certification;
6. A statement that the practitioner is caring for the patient in relation to the patient's qualifying serious condition;
7. The patient's name, date of birth, address, telephone number and email address if available;
8. The patient's diagnosis, limited solely to the specific severe debilitating or life-threatening condition(s) listed below;
 - a. cancer;
 - b. positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
 - c. amyotrophic lateral sclerosis;

- d. Parkinson's disease;
- e. multiple sclerosis;
- f. damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;
- g. epilepsy;
- h. inflammatory bowel disease;
- i. neuropathies;
- j. Huntington's disease;
- k. any severe debilitating pain that the practitioner determines degrades health and functional capability; where the patient has contraindications, has experienced intolerable side effects, or has experienced failure of one or more previously tried therapeutic options; and where there is documented medical evidence of such pain having lasted three months or more beyond onset, or the practitioner reasonably anticipates such pain to last three months or more beyond onset;
- l. post-traumatic stress disorder;
- m. pain that degrades health and functional capability where the use of medical marijuana is an alternative to opioid use, provided that the precise underlying condition is expressly stated on the patient's certification; or
- m. substance use disorder; or
- n. any other condition added by the Authority (based upon Advisory Board recommendation and Tribal Council approval).

9. The condition or symptom that is clinically associated with, or is a complication of the severe debilitating or life-threatening condition listed in Paragraph 8, above, of this Subsection. Clinically associated conditions, symptoms or complications are limited solely to:

- a. Cachexia or wasting syndrome;

- b. severe or chronic pain resulting in substantial limitation of function;
- c. severe nausea;
- d. seizures;
- e. severe or persistent muscle spasms;
- f. post-traumatic stress disorder;
- g. opioid use disorder; or
- h. such other conditions, symptoms or complications as added by the Authority.

10. A statement that by training or experience, the practitioner is qualified to treat the serious condition, which encompasses the severe debilitating or life-threatening condition listed pursuant to paragraph 8 of this subdivision and the clinically associated condition, symptom or complication listed pursuant to Paragraph 9 of this Subsection;

11. A statement that in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical marijuana for the serious condition;

12. Any recommendations or limitations the practitioner makes to the certified patient and/or the patient's designated caregiver concerning:

- a. the authorized brand, authorized form, administration method, dosage and any limitations in the use of the approved medical marijuana product; and
- b. the total amount of usable approved medical marijuana product that may be dispensed to the patient, in measurable controlled doses, which shall not exceed a thirty (30) day supply, if used as directed.

13. A statement that the practitioner has explained the potential risks and benefits of the use of medical marijuana to the qualifying patient and has documented in the patient's medical record that such explanation has been provided to the patient.

14. To the extent that a practitioner is seeking to authorize the use of an approved medical marijuana product by a patient who is under the age of eighteen or a person who

is otherwise incapable of consenting to medical treatment, the practitioner shall explain the potential risks and benefits of medical marijuana to the patient's parent or legal guardian, and if appropriate, to the minor patient. The practitioner shall document in the patient's medical record that such explanation has been provided as required herein.

15. A statement that the patient, or the patient's parent or legal guardian if applicable, has provided informed consent.

(b) The certification shall state the date upon which the certification shall expire, which shall be no longer than one year after the date it was issued, unless the patient is terminally ill. If the practitioner issues a certification to a patient who is terminally ill, the certification shall not expire until the patient's death or the practitioner revokes the certification.

(c) Practitioners shall utilize a form developed by the Authority for the certification required in this Section. The practitioner shall date and place his or her handwritten signature upon the printed certification, and provide the printed certification to the patient. The practitioner shall also maintain a copy of the signed certification in the patient's medical record.

(d) Prior to issuing, modifying or renewing a certification, the practitioner shall consult available data for the purpose of reviewing a patient's controlled substance history.

(e) The Authority may add additional qualifying conditions upon the recommendation of the Advisory Board with the approval of the Tribal Council.

CHAPTER 5. APPLICATION FOR REGISTRATION OF CERTIFIED PATIENTS AND CAREGIVERS

Section 5.1 Patient Eligibility for Registration Cards

(a) The following persons are eligible to be "certified patients" under this Ordinance to obtain Registration Identification Cards:

1. Persons who are enrolled or eligible for enrollment in the Tribe as determined by the Tribe's Enrollment Code and as certified by the Tribal Clerk;
2. Any person who is resident of New York State who is certified under this Ordinance;

3. Any person who possesses a certification issued by a registered practitioner;
4. Any person who is certified by the Authority under this Ordinance.

(b) The Authority is authorized to add eligible persons to the above list after consultation with the Advisory Board and approval of the Tribal Council following the amendment procedures under this Ordinance.

(c) Certified patients are entitled to obtain a Registration Identification Card. To obtain, amend or renew a registry identification card, a certified patient shall file a registry application with the Authority, on a form or in a manner determined by the Authority, which shall include the documentation required in Subsection 5.1 (a) above.

Section 5.2 Minors

(a) If the applicant for a registry identification card is under the age of eighteen or a person who is otherwise incapable of consenting to medical treatment, the application shall be made by an appropriate person over twenty-one years of age. In preparing the application, the applicant may designate up to two proposed designated caregivers who shall be either: (i) a parent or legal guardian of the certified patient; (ii) a person designated by a parent or legal guardian, or (iii) an appropriate person approved by the Authority upon a sufficient showing that no parent or legal guardian is appropriate or available.

(b) As a condition of registration of a certified patient who is a minor or is incapable of medical decision-making, the applicant shall consent, in a manner determined by the Authority, to the certified patient's use of an approved medical marijuana product, and shall acknowledge that the parent, legal guardian or other appropriate person, as applicable, will control the acquisition and possession of the medical marijuana and any device used for its administration.

(c) Once the certified patient who is a minor or is incapable of medical decision-making is registered, the proposed designated caregiver(s) may apply for and, if approved, receive a designated caregiver registration.

Section 5.3 Review of Application

(a) Prior to issuing or renewing a registry identification card, the Authority may verify the information submitted by the applicant. The applicant shall provide, at the Authority's request,

such information and documentation, including any consents or authorizations to contact treating practitioners that may be necessary for the Authority to verify the information.

(b) The Authority shall approve, deny, or determine incomplete or inaccurate an application to issue or renew a registry identification card within thirty (30) days of receipt of the application. If the application is approved within the 30-day period, the Authority shall issue a registry identification card as soon as is reasonably practicable.

(c) The Authority shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the Authority, if an application is incomplete or factually inaccurate, and shall explain what documents or information is necessary for the Authority to consider the application complete and accurate.

(d) An applicant shall have thirty (30) days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise, or substantiate information in the application. If the applicant fails to submit the required materials within such thirty-day time period, the application shall be denied by the Authority.

(e) Applicants whose applications are denied may submit a new application for an initial or renewal of a registry identification card, together with the applicable fee as set forth herein.

(f) A certified patient may designate up to two designated caregivers either on the application for issuance or renewal of a registry identification card or in another manner determined by the Authority.

(g) The application for issuance or renewal of a registry identification card shall include the following information:

1. The name of the proposed designated caregiver(s);
2. The address of the proposed designated caregiver(s);
3. The date of birth of the proposed designated caregiver(s), unless the proposed designated caregiver is not a natural person;
4. Any other individual identifying information concerning the proposed designated caregiver(s) required by the Authority.

Section 5.4 Designated Caregiver Registration

(a) A certified patient's designation of a designated caregiver shall not be valid unless and until the proposed designated caregiver successfully applies for and receives a designated caregiver registry identification card.

(b) A person selected by a certified patient as a designated caregiver may apply to the Authority for a registry identification card or renewal of such card on a form or in a manner determined by the Authority. The proposed designated caregiver shall submit an application to the Authority which shall contain the following information and documentation:

1. For a proposed designated caregiver the individual shall submit:

- a. the applicant's full name, address, date of birth, telephone number, email address if available, and signature;
- b. if the applicant has a registry identification card, the registry identification number;
- c. a statement that the applicant is not the certified patient's practitioner; and
- d. a statement that the applicant agrees to secure and ensure proper handling of all approved medical marijuana products.

(c) Prior to issuing or renewing a registry identification card, the Authority may verify the information submitted by the applicant. The applicant shall provide, at the Authority's request, such information and documentation, including any consents or authorizations that may be necessary for the Authority to verify the information.

(d) The Authority shall approve, deny or determine incomplete or inaccurate an initial or renewal application within thirty (30) days of receipt of the application. If the application is approved within the 30-day period, the Authority shall issue a registry identification card as soon as is reasonably practicable.

(e) The Authority shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the Authority if an application is incomplete or factually

inaccurate, and shall explain what documents or information is necessary for the Authority to consider the application complete and accurate.

(f) An applicant shall have thirty (30) days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise or substantiate information in the application. If the applicant fails to submit the required materials within such thirty-day time period, the application shall be denied by the Authority.

(g) Applicants whose applications are denied may submit a new initial or renewal application for a registry identification card, together with the applicable fee as set forth herein.

(h) The Authority shall deny a registry identification card for an applicant who:

1. is already a designated caregiver for five currently certified patients or has an application pending that, if approved, would cause the proposed designated caregiver to be a designated caregiver for more than five currently certified patients; or
2. in accordance this Section, fails to provide complete or factually accurate information in support of his or her initial or renewal application.

CHAPTER 6 REGISTERED ENTITIES

Section 6.1 Application for Initial Registration as A Registered Entity

(a) Businesses eligible to obtain registration as registered entities must be owned and controlled by Tribal Members. "Ownership" is defined as having at least 51% tribal member ownership. "Controlled" means that all material decisions of the business must be made by the Tribal Member owners.

(b) In order to operate as a registered entity, an entity must file an application on forms or in a manner prescribed by the Authority. The application shall set forth or be accompanied by the following:

1. The name, address, phone and email address of the applicant;

2. Identification of all real property, buildings and facilities that will be used in manufacturing, as defined in Chapter 5, and dispensing of the medical marijuana products;
3. Identification of all equipment that will be used to carry out the manufacturing, processing, transportation, distributing, sale and dispensing activities described in the application and operating plan;
4. An operating plan that includes a detailed description of the applicant's manufacturing processes, transporting, distributing, sale and dispensing policies or procedures. The operating plan shall also include:
 - a. detailed description of any devices used with approved medical marijuana products to be offered or sold by the registered entity;
 - b. policies and procedures related to security and control measures that will be in place to prevent diversion, abuse, and other illegal or unauthorized conduct relating to medical marijuana and are consistent with provisions set forth in this part;
 - c. a standard operating procedure manual for all methods used from cultivation of the medical marijuana through packaging, sealing and labeling of each lot of medical marijuana product. The procedures shall include use of good agricultural practices (GAPs). Standard operating procedures shall be able to be validated to demonstrate that the applicant will be able to produce and dispense consistent and reproducible medical marijuana product such that, for each form of each brand produced, there is homogeneity, absence of contamination and reproducibility of the brand profile in each lot as defined in this Ordinance;
 - d. quality assurance plans, including but not limited to plans to detect, identify and prevent dispensing errors;
 - e. policies and procedures to document and investigate approved medical marijuana product returns, complaints and adverse events, and to provide for rapid voluntary or involuntary recalls of any lot of medical marijuana product.

Such policies and procedures shall include a plan for any retesting of returned approved medical marijuana products, storage and disposal of marijuana and any manufactured medical marijuana products not passing requirements, and a requirement that adverse events and total recalls are reported to the Authority within twenty-four hours of their occurrence;

f. a quality assurance program to track contamination incidents and document the investigated source of such incidents, and the appropriate corrective action(s) taken;

g. detailed description of plans, procedures and systems adopted and maintained for tracking, record keeping, record retention and surveillance systems, relating to all medical marijuana at every stage including cultivating, possessing of marijuana, and manufacturing, delivery, transporting, distributing, sale and dispensing by the proposed registered entity;

h. proposed hours of operation for the manufacturing and dispensing facilities.

5. Copies of the organizational and operational documents of the applicant, including but not limited to, as applicable: the certificate of incorporation, bylaws, articles of the entity, partnership agreement, operating agreement and other applicable documents and agreements, and all amendments thereto;

6. The name, residence address and title of each of the board members, officers, managers, owners, partners, principal stakeholders, directors and any person or entity that is a member of the applicant.

7. A statement that the applicant is able to comply with all applicable tribal laws and regulations relating to the activities in which it intends to engage under the registration;

8. Copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the entity's real property interests, that shows that the

applicant possesses or has the right to use sufficient land, buildings, and other premises as specified in the application and equipment to properly carry on the activities for which registration is sought. a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application;

9. Architectural program and sketches of the applicant's proposed manufacturing and dispensing facility(ies) including the following:

- a. site plans;
- b. schematic architectural and engineering design drawings and single line sketches in an appropriate scale showing the relationship of various buildings to each other, room configurations, major exit corridors, exit stair locations, and circulation along with existing buildings if additions or alterations are part of the project;
- c. outline specifications for the type of construction proposed including a description of energy sources, type and location of engineering systems proposed for heating, cooling, ventilation and electrical distribution, water supply and sewage;
- d. a security plan indicating how the applicant will comply with the security requirement in this Ordinance and any other applicable law, rule, or regulation; and
- e. the registered entity shall submit detailed floor plans indicating the activities performed in each area and security plans (physical and cyber) consistent with the requirements of Chapter [Manufacturing];

10. A construction timetable;

11. A statement as to whether the applicant, any controlling person of the applicant, any manager, any sole proprietor applicant, any general partner of a partnership applicant, any officer and member of the board of directors of a corporate applicant, and corporate general partner had a prior discharge in bankruptcy or was found insolvent in any court action;

12. If any controlling person of the applicant, any manager, any sole proprietor applicant, any general partner of a partnership applicant, any officer and member of the Advisory Board of directors of a corporate applicant, or corporate general partner or a combination of such persons collectively, maintains a ten percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity or if such entity maintains a ten percent interest or greater in the applicant, and such entity will or may provide goods, leases, or services to the registered entity, the value of which is or would be five hundred dollars or more within any one year, the name and address of the entity shall be disclosed together with a description of the goods, leases or services and the probable or anticipated cost to the registered entity;

13. If the applicant is a corporate subsidiary or affiliate of another corporation, disclosure of the parent or affiliate corporation including the name and address of the parent or affiliate, the primary activities of the parent or affiliate, the interest in the applicant held by the parent or affiliate and the extent to which the parent will be responsible for the financial and contractual obligations of the subsidiary;

14. The most recent certified financial statement of the applicant, audited by an independent certified public accountant and prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis, including a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years, or such shorter period of time as the applicant has been in operation;

15. If construction, lease, rental or purchase of the manufacturing or dispensing facility has not been completed, a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction;

16. A staffing plan for staff involved in activities related to the cultivation of marijuana, the manufacturing and/or dispensing of approved medical marijuana products and/or staff with oversight responsibilities for such activities, which shall include:

a. a senior staff member with a minimum of one (1) year experience in good agricultural practices (GAP);

b. a quality assurance officer who shall exercise oversight of the entity's practices and procedures and who has documented training and experience in quality assurance and quality control procedures;

c. a requirement that all staff be twenty-one (21) years of age or older;

d. a requirement that all staff involved in the manufacturing be trained in and conform to general sanitary practices; and

e. policies and procedures to ensure that the proposed registered entity shall not employ anyone who would come in contact with or handle medical marijuana who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances;

17. Any other information as may be required by the Authority.

(c) An application under this section may be amended while the matter is pending before the Authority, if approved by the Authority upon good cause shown.

(d) The applicant shall verify the truth and accuracy of the information contained in the application. The Authority, in its discretion, may reject an application if it determines that information contained therein is not true and accurate.

Section 6.2 Consideration of Registered Entities Applications

(a) Applicants for approval to operate as registered entities shall submit an application to the Authority, containing the information required in Subsection 6.1, below, in a manner and format determined by the Authority.

(b) Applications shall be accompanied by a non-refundable application fee in the amount of \$1,000.

(c) In deciding whether to grant an application, or amendment to a registration, the Authority shall consider whether:

1. The applicant will be able to manufacture approved medical marijuana products, each with a consistent cannabinoid profile (the concentration of total tetrahydrocannabinol (THC) and total cannabidiol (CBD) will define the brand) and each able to pass the required quality control testing;
2. The applicant will produce sufficient quantities of approved medical marijuana products as necessary to meet the needs of certified patients;
3. The applicant will be able to maintain effective control against diversion of marijuana and medical marijuana products;
4. The applicant will be able to comply with all applicable state and local laws and regulations;
5. The applicant is ready, willing and able to properly carry on the activities set forth in this part;
6. The applicant possesses or has the right to use sufficient real property, buildings and equipment to properly carry on the activity described in its operating plan;
7. It is in the public interest that such registration be granted;
8. The number of registered entities in an area will be adequate or excessive to reasonably serve the area, including whether there is sufficient geographic distribution across the state;
9. The moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's entity; and
10. Evaluation of the applicant's proposed operating plan and suitability of the proposed manufacturing and dispensing facilities, including but not limited to the suitability of the location and architectural and engineering design of the proposed facilities. Authority

approval of the applicant's operating plan and architectural and engineering design of the proposed facilities shall be required for issuance of a registration.

- (d) The applicant shall allow reasonable access to the Authority and/or its authorized representatives for the purpose of conducting an on-site survey or inspection of the applicant's proposed manufacturing and/or dispensing facilities.
- (e) If the Authority is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within 30 days of the receipt of such notification, the applicant may submit additional material to the Authority or demand a hearing, or both.
- (f) Upon application to the Authority, a registered entity's registration may be amended. The Authority shall consider whether to grant or deny the application for amendment of the registration utilizing the criteria set forth in this Ordinance.
- (g) The Registration shall have a term of ten (10) years and be renewable under the conditions set forth in this Chapter.

Section 6.3 Applications for Renewal of Registration as Registered Entity

- (a) An application to renew any registration issued under this part shall be filed with the Authority not more than six months nor less than four months prior to the expiration thereof. If a renewal application is not filed at least four months prior to the expiration thereof, the Authority may determine that the registration shall have expired and become void on such expiration date.
- (b) The application for renewal shall include such information prepared in the manner and detail as the Authority may require, including but not limited to:
 - 1. Any material changes as determined by the Authority in the information, circumstances or factors listed in this Chapter;
 - 2. Every known complaint, charge or investigation, pending or concluded during the period of the registration, by any governmental or administrative agency with respect to:

a. each incident or alleged incidence involving the theft, loss, or possible diversion of medical marijuana manufactured, distributed, or dispensed by the registered entity; and

b. compliance by the applicant with laws or regulations of the Authority.

3. Information concerning the applicant's ability to carry on the manufacturing and distributing activity for which it is registered, including but not limited to approved medical marijuana product shortages or wait lists occurring during the registration period; and

4. A summary of quality assurance testing for all medical marijuana products produced in the prior year including but not limited to the percentage of lots of each brand and form passing all required testing, the percentage of lots failing contaminant testing, the percentage of lots failing brand requirements, all recalls of product lots and all adverse events reported.

(c) If the Authority determines that the applicant's registration should not be renewed, the Authority shall serve upon the applicant or his or her attorney of record, in person or by registered or certified mail, an order directing the applicant to show cause why his or her application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the Authority that the registration should be renewed.

(d) Within ten (10) business days of receipt of such an order, the applicant may submit additional material to the Authority or demand a hearing, or both. If a hearing is demanded, the Authority shall fix a date as soon as reasonably practicable.

(e) If the applicant fails to submit additional material to the Authority within ten (10) business days as requested, and the applicant does not demand a hearing within such time period, the application for renewal of registration shall be denied.

Section 6.4 Registrations Non-Transferable

(a) Registrations issued under this part shall be effective only for the registered entity and shall specify:

1. The name and address of the registered entity;

2. The name of the contact person for the registered entity;
3. The activities the registered entity is permitted to perform under the registration for each approved location; and
4. The real property, buildings and facilities that may be used for the permitted activities of the registered entity.

(b) Registrations are not transferable or assignable, including, without limitation, to another registered entity.

Section 6.5 Failure to Operate

(a) A registration shall be surrendered to the Authority upon written notice and demand if the registered entity fails to begin operations, to the satisfaction of the Authority, of a manufacturing and/or dispensing facility within six months of the date of issuance of the registration.

(b) A registered entity who is required to surrender its registration in accordance with this section shall not be entitled to any refund of fees paid to the Authority.

Section 6.6 Registered Entities; General Requirements

(a) In addition to other requirements otherwise set forth in this Ordinance, a registered entity shall comply with the following:

1. Make its books, records and manufacturing and dispensing facilities available to the Authority or its authorized representatives for monitoring, on-site inspection, and audit purposes, including but not limited to periodic inspections and/or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance;
2. Any deficiencies documented in a statement of findings by the Authority shall require that the registered entity submit a written plan of correction in a format acceptable to the Authority within 15 calendar days of the issue date of the statement of findings. A plan of correction shall address all deficiencies or areas of noncompliance cited in the statement of findings and shall:

- a. contain an assessment and analysis of the events and/or circumstances that led to the noncompliance;
- b. contain a procedure addressing how the registered entity intends to correct each area of noncompliance;
- c. contain an explanation of how proposed corrective actions will be implemented and maintained to ensure noncompliance does not recur;
- d. contain the proposed date by which each area of noncompliance shall be corrected; and
- e. address any inspection finding which the Authority determines jeopardizes the immediate health, safety, or well-being of certified patients, designated caregivers or the public. Such a finding shall be deemed a critical deficiency and shall require immediate corrective action to remove the immediate risk, followed by the submission of a corrective action plan within 24 hours of notification by the Authority of the critical deficiency. The Authority will acknowledge receipt within 24 hours and respond as soon as practicable to notify if the plan is accepted or needs modification. If the corrective action plan needs modification, the registered entity shall modify the plan until it is accepted by the Authority.

3. Upon written approval of the Authority, the registered entity shall implement the plan of correction.

4. Only manufacture and dispense approved medical marijuana products in on Tribal Territory in accordance this Ordinance;

5. Only manufacture and dispense approved medical marijuana products in an indoor, enclosed, secure facility located on Tribal Territory which may include greenhouses;

6. Submit approved medical marijuana product samples and manufacturing materials to the Authority upon request, for but not limited to, quality assurance testing or investigation of an adverse event. A subset of each lot of medical marijuana product shall be retained by the registered entity to allow for testing in the future if requested by the Authority and shall be stored unopened as indicated on the label and in the original packaging. This subset of medical marijuana product must be readily identifiable as

belonging to its specific lot. The quantity retained shall be a statistically representative number of samples to allow for complete testing of the product at least two times and shall be retained by the registered entity for at least thirty days following the date of expiration.

7. Implement policies and procedures to notify the Authority within 24 hours of the following:

- a. any adverse events;
- b. any incident involving theft, loss or possible diversion of medical marijuana products;
- c. any suspected or known security breach or other facility event that may compromise public health and/or safety, or which requires response by public safety personnel or law enforcement; and
- d. any vehicle accidents or incidents occurring during transport of medical marijuana products.

8. Within ten days of the occurrence of one of the above events, the registered entity shall submit a complete written incident report to the Authority detailing the circumstances of the event, any corrective actions taken, and where applicable, confirmation that appropriate law enforcement authorities were notified.

9. Quarantine any lot of medical marijuana product as directed by the Authority, and not transport, distribute or dispense such lot unless prior approval is obtained from the Authority;

10. Dispose of unusable medical marijuana products that have failed laboratory testing or any marijuana used in the manufacturing process pursuant to Chapter 19;

11. Maintain records for a period of five (5) years, unless otherwise stated, and make such records available to the Authority upon request. Such records shall include:

- a. documentation, including lot numbers where applicable, of all materials used in the manufacturing of the approved medical marijuana product to allow tracking

of the materials including but not limited to soil, soil amendment, nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, and herbicides;

- b. cultivation, manufacturing, packaging and labeling production records; and
- c. laboratory testing results.

12. Post the certificate of registration issued by the Authority in a conspicuous location on the premises of each manufacturing facility and dispensing facility.

(b) Registered entities shall not:

1. Grow marijuana or produce medical marijuana at any site other than a facility or site approved by the Authority and set forth in the registered entity's registration;
2. Distribute products or samples at no cost except as may be allowed by the Authority;
3. Make substantial alterations to the structure or architectural design of a manufacturing or dispensing facility without prior written approval of the Authority;
4. Change the composition of the entity which is the registered entity, including but not limited to, a change in sole proprietor, partner, director, stockholder, member or membership interest of the registered entity without the prior written approval of the Authority;
5. Materially modify or revise its operating plan, including its policies and procedures related to cultivation, processing, manufacturing, distributing or dispensing policies or procedures, without prior written approval of the Authority;
6. Locate a dispensing facility 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. The measurements in this paragraph of this subdivision are to be taken in

straight lines from the center of the nearest entrance of the premises sought to be used as a dispensing facility to the center of the nearest entrance of such school, church, synagogue or other place of worship; or

7. Be managed by or employ anyone who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances provided that this provision only applies to:

a. managers or employees who come into contact with or handle medical marijuana; and

b. a conviction less than ten years (not counting time spent in incarceration) prior to being employed, for which the person has not received a certificate of relief from disabilities or a certificate of good conduct under applicable correction law.

(c) In the event that a registered entity elects to cease operation of all permitted activities and to surrender its registration, the following provisions shall apply:

1. The registered entity shall notify the Authority in writing at least 120 days prior to the anticipated date of closure of the manufacturing and each dispensing facility.

2. Such written notice shall include a proposed plan for closure. The plan shall be subject to Authority approval in accordance with Authority protocols, and shall include timetables and describe the procedures and actions the registered entity shall take to:

a. notify affected certified patients and designated caregivers of the closure;

- b. properly destroy, transfer or otherwise dispose of all the registered entity's supply of medical marijuana and medical marijuana products;
- c. maintain and make available to the Authority all records required to be maintained under this part for a period of five years; and
- d. maintain compliance with these regulations and any other conditions required by the Authority until the approved closure date.

3. A registered entity shall take no action to close a manufacturing and dispensing facility prior to Authority approval of the plan for closure.

4. A registered entity's failure to notify the Authority of intent to cease any operations, failure to submit an approvable plan, and/or to execute the approved plan may result in the imposition of civil penalties, not to exceed \$2,000, and shall be a basis for the Authority to revoke the registration of the registered entity under such terms as the Authority determines is appropriate based on public health and safety considerations. In addition, the Authority reserves the right to exercise any other remedies available to it.

(d) If a registered entity's application for renewal of registration is denied, the registered entity shall submit a proposed plan for closure in accordance with this section.

CHAPTER 7. MANUFACTURING REQUIREMENTS

Section 7.1 Definitions

(a) Definitions. Wherever used in this part, the following terms shall have the following meanings:

1. "Approved medical marijuana product" is the final manufactured product delivered to the patient that represents a specific brand with a defined cannabinoid content and active and inactive ingredients, prepared in a specific dosage and form, to be administered as recommended by the practitioner.

2. "Brand" means a defined medical marijuana product that has a homogenous and uniform cannabinoid concentration (total THC and total CBD) and product quality, produced according to an approved and stable processing protocol and shall have the same inactive ingredients as that defined for that form of the brand.
3. "Form" of medical marijuana shall be a type of a medical marijuana product approved by the Authority and shall refer to the final preparation of an approved medical marijuana brand; for example, an extract in oil for sublingual administration, an extract for vaporization or an extract in a capsule for ingestion.
4. "Lot" means a quantity of a medical marijuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol specific to that brand and form of medical marijuana product, during the same cycle of manufacture.
5. "Lot unique identifier (Lot number or bar code)" means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of manufacturing, testing, holding, distribution or recall of a lot of medical marijuana product can be determined.
6. "Manufacturing" shall include, but not be limited to cultivation, harvesting, extraction (or other processing), packaging and labeling.

Section 7.2 Extraction Standards

(a) A registered entity shall use either carbon dioxide (CO₂, super-critical) or alcohol for cannabinoid extraction and shall only perform extraction of the leaves and flowers of female marijuana plants. A registered entity shall only use carbon dioxide that is of a supply equivalent to food or beverage grade of at least 99.5% purity; and alcohol used shall be of a grade that meets or exceeds specifications of official compendiums as defined in section 321 of Title 21 of the United States Code (USC). 21 USC §321. A registered entity shall obtain prior written approval from the Authority if it seeks to use other extraction methods.

Section 7.3 Brand Cannabinoid Contents

(a) A registered entity shall only produce such forms of medical marijuana as approved by the Authority according to the following requirements:

1. Each registered entity may initially produce up to five brands of medical marijuana product with prior approval of the Authority. These brands may be produced in multiple forms as approved by the Authority. Thereafter, additional brands may be approved by the Authority.

2. Each medical marijuana product brand, in its final form, shall be defined as having a specific concentration of total Tetrahydrocannabinol (THC) and total Cannabidiol (CBD) and shall have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, must be reported:

- a. Tetrahydrocannabinol (THC)
- b. Tetrahydrocannabinol acid (THCA)
- c. Tetrahydrocannabivarin (THCV)
- d. Cannabidiol (CBD)
- e. Cannabinadiolic acid (CBDA)
- f. Cannabidivarin (CBDV)
- g. Cannabinol (CBN)
- h. Cannabigerol (CBG)
- i. Cannabichromene (CBC)

j. Any other cannabinoid component at > 0.2 percent, for which there is a certified standard available at a customary cost.

2. The final medical marijuana product shall not contain less than 90 percent or more than 110 percent of the concentration of total THC or total CBD indicated on the label for this brand and shall have no more than 10mg total THC per dose. However:

3. Where the total THC concentration is less than 5 milligrams per dose, the concentration of total THC shall be within 0.5 milligrams per dose;

4. Where the total CBD concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose; and
5. the concentration of total THC and CBD in milligrams per single dose for each sample of a brand lot submitted for testing must be within 25 percent of the mean concentration of total THC and CBD in milligrams per single dose for that submitted lot with the exception that, for brands with a specified total THC and CBD concentration less than 2 milligrams per single dose, the concentration of each sample for that low concentration cannabinoid shall be within 0.5 milligrams per dose of the mean concentration.
6. The registered entity shall offer and make available to patients at least one brand that has a low THC and a high CBD content (e.g., a 1:20 ratio of THC to CBD).
7. The registered entity shall offer and make available at least one brand that has approximately equal amounts of THC and CBD.
8. For each brand offered, the registered entity shall only utilize a distinct name which has been approved by the Authority, consisting of only letters and/or numbers. The name shall not be coined or fanciful, and may not include any "street", slang or other name. No reference shall be made to any specific medical condition.
9. Each registered entity shall ensure the availability of at least a one-year supply of any offered brand unless otherwise allowed by the Authority.

(b) The registered entity shall not add any additional active ingredients or materials to any approved medical marijuana product that alters the color, appearance, smell, taste, effect or weight of the product unless it has first obtained prior written approval of the Authority. Excipients must be pharmaceutical grade and approved by the Authority.

Section 7.4 Agricultural Practices

(a) A registered entity shall:

1. Use good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State;

2. Use water from a public water supply or present a plan, approved by the Authority, which demonstrates the ability to obtain sufficient quantities of water of equal or greater quality as that from a public water supply and to monitor the quality of such water on an ongoing basis;
3. Upon prior written notice to the Authority, only use pesticides that are registered by the Tribe that specifically meet the United States Environmental Protection Agency registration exemption criteria for Minimum Risk Pesticides;
4. Process the leaves and flowers of the female plant only, in a safe and sanitary manner;
5. Perform visual inspection of the harvested plant material to ensure there is no mold, mildew, pests, rot or gray or black plant material;
6. Have a separate secure area for temporary storage of any medical marijuana or medical marijuana product that needs to be destroyed; and
7. Provide continual environmental monitoring for temperature, ventilation and humidity at all locations in the manufacturing facility where unprocessed leaf and flower material is stored, until further extraction or other processing is completed.

(b) Production of any approved medical marijuana product shall be in accordance with general sanitary conditions. Poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids and related cleaning compounds must be stored in a separate area from the marijuana and medical marijuana products in prominently and distinctly labeled containers, except that nothing herein precludes the convenient availability of detergents or sanitizers to areas where equipment, containers and utensils are washed and sanitized.

Section 7.5 Approved Forms of Administration

(a) Approved medical marijuana products shall be limited to the forms of administration approved by the Authority, including but not limited to:

1. metered liquid or oil preparations;

2. solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges);
3. metered ground plant preparations; and
4. topical forms and transdermal patches.

(b) medical marijuana may not be incorporated into food products by the registered entity, unless approved by the Authority.

(c) Smoking is not an approved route of administration.

Section 7.6 Packaging

(a) The registered entity shall package the final form of the approved medical marijuana product at the manufacturing site. The original seal shall not be broken except for quality testing at an approved laboratory, for adverse event investigations, by the Authority, by the certified patient or designated caregiver, or by the registered entity for internal quality control testing or disposal.

(b) The registered entity shall package the approved medical marijuana product such that it is child-resistant, tamper-proof/tamper-evident, light-resistant, and in a resealable package that minimizes oxygen exposure.

(c) The registered entity shall identify each lot of approved medical marijuana product with a lot unique identifier.

Section 7.7 Product Labelling

(a) Each approved medical marijuana product shall be affixed with a product label. Medical marijuana product labels shall be approved by the Authority prior to use. Each product label shall be applied at the manufacturing facility, be easily readable, firmly affixed and include:

1. The name, address and registration number of the registered entity;
2. The medical marijuana product form and brand designation;
3. The single dose THC and CBD content for the product set forth in milligrams (mg);
4. The medical marijuana product lot unique identifier (lot number or bar code);

5. The quantity included in the package;
6. The date packaged;
7. The date of expiration of the unopened product, based on stability studies in accordance with this Chapter, or a tentative expiration date approved by the Authority;
8. The proper storage conditions;
9. language stating:
 - a. “Medical marijuana products must be kept in the original container in which they were dispensed and removed from the original container only when ready for use by the certified patient”;
 - b. “Keep secured at all times”;
 - c. “May not be resold or transferred to another person”;
 - d. “This product might impair the ability to drive”;
 - e. “KEEP THIS PRODUCT AWAY FROM CHILDREN (unless medical marijuana product is being given to the child under a practitioner’s care)”;
 - f. “This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying practitioner, and in the case of breastfeeding mothers, including the infant’s pediatrician.”

Section 7.8 Samples for Lab Analysis

(a) For each lot of medical marijuana product produced, the registered entity shall submit a predetermined number of final medical marijuana products (e.g., sealed vials or capsules; with the number of samples submitted, based on statistical analysis, determined to be representative of the lot) to an independent laboratory/laboratory approved by the Authority. The laboratory verifying the cannabinoid content shall be approved for the analysis of medical marijuana product by the Authority. Such laboratory, or approved laboratories cumulatively, shall certify the medical marijuana product lot as passing all contaminant testing and verify that the content is

consistent with the brand prior to the medical marijuana product being released from the manufacturer to any dispensing facility.

1. Any lot not meeting the minimum standards or specifications for safety shall be rejected and destroyed by the registered entity in accordance with Chapter of this Part.
2. Any lot not meeting the minimum standards or specifications for brand consistency shall be reported to the Authority and not dispensed by a registered entity without prior written approval from the Authority.
3. The registered entity shall keep and maintain records documenting submission of medical marijuana products to approved laboratories as required herein, and the results of the laboratory testing. The registered entity shall provide the Authority with such records upon request.

(b) The registered entity shall demonstrate the stability of each approved medical marijuana product produced (each brand in each form) by testing both the unopened and opened product at an approved laboratory under Chapter 10.

1. The stability of opened products shall be validated under the conditions (light, temperature and humidity), specified for storage of the product and an expiration date for opened product shall be determined;
2. The stability of unopened products (e.g., sealed packages or vials) shall be validated by ongoing stability testing and an expiration date for unopened products shall be determined.
3. Specifications regarding storage conditions must address storage at the manufacturing facility once the package is sealed, during transport, at the dispensing facility, in the patient's home and for samples retained for future testing.

(c) No synthetic marijuana additives nor any cannabinoid preparation not produced by a registered entity in an approved manufacturing facility shall be used in the production of any medical marijuana product.

(d) The registered entity's approved standard operating procedure for the aforementioned activities must be followed, unless otherwise approved by the Authority.

CHAPTER 8. REQUIREMENTS FOR DISPENSING FACILITIES

Section 8.1 General Requirements

(a) Medical marijuana products shall not be dispensed or handled unless an individual with an active licensed pharmacist license, who has completed a four-hour course pursuant to Chapter 3 of this Ordinance, is on the premises and supervising the activity within the facility.

(b) Dispensing facilities shall only sell approved medical marijuana products, related products necessary for the approved forms of administration of medical marijuana, and items that promote health and well-being subject to disapproval of the Authority and only in such a manner as does not increase risks of diversion, theft or loss of approved medical marijuana products or risk physical, chemical or microbial contamination or deterioration of approved medical marijuana products.

(c) No approved medical marijuana products shall be vaporized or consumed on the premises of a dispensing facility.

(d) Dispensing facilities shall not dispense approved medical marijuana products to anyone other than a certified patient or designated caregiver.

(e) When dispensing approved medical marijuana products, the dispensing facility shall:

1. Not dispense an amount greater than a thirty (30) day supply to a certified patient, and not until the patient has exhausted all but a seven-day supply provided pursuant to any previously dispensed medical marijuana product by any registered entity;
2. Ensure that medical marijuana product packaging shall not be opened by dispensing facility staff;

3. provide a patient specific log of medical marijuana products (brand, administration form, and dosage, and dates dispensed and any return of product) to the patient, the patient's designated caregiver, if applicable, or the patient's practitioner upon request;

Section 8.2 Confidentiality and Access

(a) The registered entity shall be responsible for maintaining the confidentiality of patients and the integrity of the security of the facility at all times. Access to medical marijuana storage areas and areas within the dispensing facility where security equipment and recordings are stored shall be restricted to:

1. Registered entity employees;
2. Employees of the Authority or its authorized representatives;
3. Emergency personnel responding to an emergency, and;
4. Other persons authorized by a manager of the registered entity for the sole purpose of maintaining the operations of the facility.

(b) The dispensing facility shall maintain a visitor log of all persons, other than registered entity employees or emergency personnel responding to an emergency, that access these secured areas, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the Authority at all times during operating hours and upon request.

Section 8.3 Product Package Labelling/Safety Inserts

(a) The dispensing facility shall affix to the approved medical marijuana product package a patient specific dispensing label approved by the Authority, that is easily readable, and firmly affixed and includes:

1. The name and registry identification number of the certified patient and designated caregiver, if any;
2. The certifying practitioner's name;

3. The dispensing facility name, address and phone number;
4. The dosing and administration instructions;
5. The quantity and date dispensed;
6. Any recommendation or limitation by the practitioner as to the use of medical marijuana; and
7. The expiration date of the product once opened;

(b) The dispensing facility shall place the approved medical marijuana product in a plain outer package when dispensing to the patient or designated caregiver.

(c) The dispensing facility shall ensure that each patient receives approved medical marijuana product from no more than two distinct lots for any 30-day supply dispensed.

(d) The dispensing facility shall include with each product package dispensed to a patient, an Authority approved package safety insert. Information provided shall include but not be limited to:

1. The medical marijuana product and brand;
2. A list of any excipients used;
3. A warning if there is any potential for allergens in the medical marijuana product;
4. Contraindications;
5. More specific dosage directions and instructions for administration;
6. Warning of adverse effects and/or any potential dangers stemming from the use of medical marijuana;
7. Instructions for reporting adverse effects as may be determined by the Authority;
8. A warning about driving, operation of mechanical equipment, child care or making important decisions while under the influence of medical marijuana;
9. Information on tolerance, dependence and withdrawal and substance abuse, how to recognize what may be problematic usage of medical marijuana and obtain appropriate services or treatment;

10. Advice on how to keep the medical marijuana product secure;
11. Language stating that the certified patient may not distribute any medical marijuana product to anyone else;
12. Language stating that unwanted, excess, or contaminated medical marijuana product must be disposed of according to Chapter 21 of Ordinance; and
13. Language stating that “this product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks.”

Section 8.4 Product Storage and Returns

(a) The dispensing facility shall store the medical marijuana product in a manner to ensure that there is no contamination or deterioration of the medical marijuana product or its packaging.

(b) If an approved medical marijuana product is returned to the dispensing facility, the dispensing facility shall:

1. Dispose of such product pursuant to Chapter 21;
2. Provide the following information to the Authority:
 - a. the name and registry identification number of the certified patient for whom the product was dispensed;
 - b. the date of the return;
 - c. the brand and form being returned;
 - d. the quantity and/or weight being returned;
 - e. the reason for the return;
 - f. the name of the dispensing facility employee accepting the return; and
 - g. any other information required by the Authority;

(c) ensure the returned marijuana product is securely stored, separate from working inventory while awaiting disposal.

CHAPTER 9. SECURITY REQUIREMENTS FOR MANUFACTURING AND DISPENSING FACILITIES

Section 9.1 General Requirements

(a) All facilities operated by a registered entity, including any manufacturing facility and dispensing facility, shall have a security system to prevent and detect diversion, theft or loss of marijuana and/or medical marijuana products, utilizing commercial grade equipment, which shall, at a minimum, include:

1. A perimeter alarm;
2. Motion detectors;
3. Video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The manufacturing facility or dispensing facility shall direct cameras at all approved safes, approved vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being manufactured, stored, handled, dispensed or disposed of. At entry and exit points, the manufacturing facility or dispensing facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;
4. Twenty-four (24) hour recordings from all video cameras, which the manufacturing facility or dispensing facility shall make available for immediate viewing by the Authority or the Authority's authorized representative upon request and shall be retained for at least 90 days. The registered entity shall provide the Authority with an unaltered copy of such recording upon request. If a registered entity is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the registered entity shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the registered entity that it is not necessary to retain the recording;
5. A duress alarm, which for purposes of this section means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;

6. A panic alarm, which for purposes of this section, means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;
7. A holdup alarm, which for purposes of this section, means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;
8. An automatic voice dialer or digital dialer, which for purposes of this section, means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch, or other Authority approved industry standard equivalent;
9. A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the manufacturing facility or dispensing facility within five minutes of the failure, either by telephone, email, or text message;
10. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);
11. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
12. The ability to remain operational during a power outage.

(b) A registered entity shall ensure that any manufacturing facility and dispensing facility maintains all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

Section 9.2 Additional Security Requirements

(a) In addition to the requirements listed above in this Section, each manufacturing facility and dispensing facility shall have a back-up alarm system approved by the Authority that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment.

(b) A registered entity shall limit access to any surveillance areas solely to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the Authority or the Authority's authorized representative, and others when approved by the Authority. A registered entity shall make available to the Authority or the Authority's authorized representative, upon request, a current list of authorized employees and service employees who have access to any surveillance room. A manufacturing facility and dispensing facility shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

(c) A registered entity shall keep illuminated the outside perimeter of any manufacturing facility and dispensing facility that is operated under the registered entity's license.

(d) All video recordings shall allow for the exporting of still images in an industry standard image format (including .jpeg, .bmp, and .gif). Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A registered entity shall erase all recordings prior to disposal or sale of the facility.

(e) A registered entity shall keep all security equipment in full operating order and shall test such equipment no less than semi-annually at each manufacturing facility and dispensing facility that is operated under the registered entity's registration. Records of security tests must be maintained for five years and made available to the Authority upon request.

(f) The manufacturing facility of the registered entity must be securely locked and protected from unauthorized entry at all times.

1. The registered entity shall be responsible for ensuring the integrity of the security of the manufacturing facility and the maintenance of sanitary operations when permitting access to the facility.

2. The manufacturing facility shall maintain a visitor log of all persons other than registered entity employees or emergency personnel responding to an emergency that access any secured areas, which shall include the name of the visitor, date, time and

purpose of the visit. The visitor log shall be available to the Authority at all times during operating hours and upon request.

Section 9.3 Storage of Marijuana

(a) All marijuana must be stored in a secure area or location within the registered entity accessible to the minimum number of employees essential for efficient operation and in such a manner as approved by the Authority in advance, to prevent diversion, theft or loss.

1. Registered entities shall return marijuana to its secure location immediately after completion of manufacture, distribution, transfer or analysis.

(b) All medical marijuana must be stored in such a manner as to protect against physical, chemical and microbial contamination and deterioration of the product.

(c) All approved safes, vaults or any other approved equipment or areas used for the manufacturing or storage of marijuana and approved medical marijuana products must be securely locked or protected from entry, except for the actual time required to remove or replace marijuana or approved medical marijuana products.

(d) Keys shall not be left in the locks or stored or placed in a location accessible to individuals who are not authorized access to marijuana or manufactured medical marijuana products.

(e) Security measures, such as combination numbers, passwords or biometric security systems, shall not be accessible to individuals other than those specifically authorized to access marijuana or manufactured medical marijuana products.

Section 9.4 Transporting Marijuana

(a) Prior to transporting any medical marijuana, a registered entity shall complete a shipping manifest using a form determined by the Authority.

1. A copy of the shipping manifest must be transmitted to the destination that will receive the products and to the Authority at least two business days prior to transport unless otherwise expressly approved by the Authority.

2. The registered entity shall maintain all shipping manifests and make them available to the Authority for inspection upon request, for a period of 5 years.

3. Approved medical marijuana products must be transported in a locked storage compartment that is part of the vehicle transporting the marijuana and in a storage compartment that is not visible from outside the vehicle.

(c) An employee of a registered entity, when transporting approved medical marijuana products, shall travel directly to his or her destination(s) and shall not make any unnecessary stops in between.

(d) A registered entity shall ensure that all approved medical marijuana product delivery times are randomized.

(e) A registered entity shall staff all transport vehicles with a minimum of two employees. At least one transport team member shall remain with the vehicle at all times that the vehicle contains approved medical marijuana products.

(f) A transport team member shall have access to a secure form of communication with employees at the registered entity's manufacturing facility at all times that the vehicle contains approved medical marijuana products.

(g) A transport team member shall possess a copy of the shipping manifest at all times when transporting or delivering approved medical marijuana products and shall produce it to the Authority, the Authority's authorized representative or law enforcement official upon request.

CHAPTER 10. LABORATORY TESTING REQUIREMENTS FOR MEDICAL MARIJUANA

Section 10.1 General Requirements

(a) Medical marijuana products produced by a registered entity shall be examined in a laboratory approved for the analysis of medical marijuana by the Authority.

(b) No Advisory Board member, officer, manager, owner, partner, principal stakeholder or member of a registered entity, or such persons' immediate family member, shall have an interest or voting rights in the laboratory performing medical marijuana testing.

(c) For final product testing, the registered entity shall submit to the laboratory a statistically significant number of samples containing the final medical marijuana product equivalent to the sealed medical marijuana product dispensed to the patient (e.g., liquid extract in a sealed bottle or intact sealed bottle of capsules). Upon prior written approval of the Authority, a registered entity may submit to the laboratory the final medical marijuana product sample 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.

(d) Testing of the final medical marijuana product is mandatory. However, at the option of the registered entity, testing may be performed on components used for the production of the final medical marijuana product including but not limited to water or growing materials. Testing may also be performed on the final marijuana extract e.g. for cannabinoid profile verification or contaminant testing.

Section 10.2 Testing of Lots

(a) Sampling and testing of each lot of final medical marijuana product shall be conducted with a statistically significant number of samples and with acceptable methodologies, approved by the Authority, such that there is assurance that all lots of each medical marijuana product are adequately assessed for contaminants and the cannabinoid profile is consistent throughout.

(b) Testing of the cannabinoid profile shall include, at a minimum, those analytes in Chapter 8.

(c) Testing for contaminants in the final medical marijuana product shall include but shall not be limited to those analytes listed below. The Authority shall make available a list of required analytes and their acceptable limits as determined by the Authority.

Analyte:

coli

Pseudomonas (for products to be vaporized)

Salmonella species

Enterococcus species

Bile tolerant gram negative bacteria, specifically including Klebsiella species

Clostridium botulinum

Aspergillus species

Mucor species

Penicillium species

Thermophilic Actinomycetes species

Aflatoxins B1, B2, G1, G2

Ochratoxin A

Antimony

Arsenic

Cadmium

Chromium

Copper

Lead

Nickel

Zinc

Mercury

Any pesticide used during production of the medical marijuana product

Any growth regulator used during production of the medical marijuana product

Any other analyte as required by the Authority

Section 10.3 Final Product/Stability Testing

(a) Laboratories performing final product testing pursuant to this section must report all results to the Authority, in a manner and timeframe prescribed by the Authority.

(b) Stability testing shall be performed on each brand and form of medical marijuana product as follows:

1. For testing of open products, stability testing shall be performed for each extract lot, at time zero when opened and then, at a minimum, at 60 days from the date of first analysis. This shall establish use of the product lot within a specified time once opened.
2. For testing of unopened products, until stability studies have been completed, a registered entity may assign a tentative expiration date based on available stability information. The registered entity must concurrently have stability studies conducted by an approved laboratory to determine the actual expiration date of an unopened product.
3. For stability testing of both opened and unopened products, each brand shall retain a total THC and total CBD concentration in milligrams per single dose that is required in Chapter 7. If stability testing demonstrates that a product no longer retains a consistent concentration of THC and CBD pursuant to Chapter 8 the product shall be deemed no longer suitable for dispensing or consumption. The Authority may request further stability testing of a brand to demonstrate the ongoing stability of the product produced over time.
4. The Authority may waive any of the requirements of this subsection upon good cause shown.

(c) The laboratory shall track and use an approved method to dispose of any quantity of medical marijuana product that is not consumed in samples used for testing. Disposal of medical marijuana shall mean that the medical marijuana has been rendered unrecoverable and beyond reclamation.

(d) Any submitted medical marijuana products that are deemed unsuitable for testing shall be returned to the registered entity under chain of custody.

CHAPTER 11 PRICING

Section 11.1 Definitions

(a) For purposes of this section, the following terms have the following meanings:

1. "Cost analysis" shall mean the review and evaluation of the separate cost elements and profit of a proposed price and the application of judgment to determine how well the proposed costs represent what the price per unit for approved medical marijuana products should be, assuming reasonable economy and efficiency.
2. "Price" shall mean the cost to manufacture, market and distribute approved medical marijuana products plus a reasonable profit.

Section 11.2 Determination of Price

(a) A registered entity shall only charge a price for an approved medical marijuana product that has been approved by the Authority.

(b) The Authority shall set the per unit price of each form of approved medical marijuana product sold by any registered entity, as follows:

1. Registered entities shall submit a proposed price per unit for each form of medical marijuana indicated in its registration. Registered entities shall submit such information and documentation, in a manner and format determined by the Authority, sufficient for the Authority to perform a cost analysis of the proposed price. In particular, the registered entity shall, in a manner and format determined by the Authority, provide a detailed breakdown of, and submit information and documentation concerning, all costs it factored to arrive at its proposed price, including but not limited to its fixed and variable costs such as materials and services; direct labor; and indirect costs.
2. The registered entity shall provide cost or pricing data that is accurate and reliable, and shall certify, at the time of submission of its price proposal, that to the best of its knowledge and belief, the cost or pricing data were accurate, complete, and current as of the date of submission.
3. The Authority shall determine the reasonableness of the proposed costs. In making this determination, the Authority may consider whether the costs represent inefficient and uneconomical practices; are not costs appropriately attributable to the price; and/or are costs unsupported by sufficient documentation

or information to justify their inclusion in the proposed price. If the registered entity has been granted a renewal of its registration, any relevant historical price, cost and/or sales data of the registered entity; and any other information the Authority deems appropriate.

4. The Authority may approve the proposed price, refuse approval of a proposed price, or modify or reduce the proposed price.

Section 11.3 Examination of Records/Data

(a) The registered entity shall grant the Authority or the Authority's authorized representative the right to examine records that formed the basis for the proposed price, including the registered entity's books, records, documents and other types of factual information that will permit an adequate evaluation of the proposed price.

(b) Correction of Insufficient Price Data. If the registered entity or Authority determines that the cost or pricing data submitted is inaccurate, incomplete or noncurrent prior to the Authority's approval of the price, the registered entity shall submit new data to correct the deficiency, or consider the inaccuracy, incompleteness, or noncurrency of the data.

Section 11.4 Duration of Price Determination

(a) The Authority's approved price shall be in effect for the entire period of the registered entity's registration; provided, however, that at the conclusion of the first year of the registration period, or prior to that time based upon documented exceptional circumstances, the registered entity may request that the price be modified based upon a material change in the registered entity's costs. The registered entity shall fully support its request with sufficient information and documentation, in a manner and format determined by the Authority, to justify its request. If the Authority denies such request, the registered entity shall only charge prices previously approved by the Authority.

(b) If the Authority has approved a price, the registered entity shall immediately notify the Authority of any cost or pricing data submitted that it determines was inaccurate, incomplete, or noncurrent as of the date of the Authority's approval of the price. If the registered entity provides such notice, or if the Authority independently learns of such inaccurate, incomplete or

noncurrent data, the Authority may require the registered entity to provide new data to correct the deficiency, or consider the inaccuracy, incompleteness, or noncurrency of the data. The Authority may adjust the price per dose if the defective data significantly increased the price approved by the Authority.

Section 11.5 Audits

(a) The Authority may perform audits, which may include site visits. The registered entity shall provide reasonable access to the Authority of its facilities, books and records.

CHAPTER 12. MEDICAL MARIJUANA MARKETING AND ADVERTISING BY REGISTERED ENTITIES

Section 12.1 No Advertising on Physical Structures

(a) All physical structures owned, leased or otherwise utilized by a registered entity, including any dispensing facility, shall:

1. Not advertise medical marijuana brand names or utilize graphics related to marijuana or paraphernalia on the exterior of the physical structures; and
2. Not display medical marijuana products and paraphernalia so as to be clearly visible from the exterior of a physical structure.

(b) All restrictions listed in Subsection (a), above, shall apply to any item located on any real property on which a registered entity's physical structures is located.

(c) All restrictions listed in Subsection (a), above, shall apply to all vehicles owned, leased or utilized by a registered entity.

Section 12.2 No Advertisement as to Effectiveness of Products

(a) All advertisements, regardless of form, for approved medical marijuana products that make a statement relating to effectiveness, side effects, consequences or contraindications shall present a true and accurate statement of such information.

(b) An advertisement does not satisfy the requirement that it presents a “true and accurate statement” of information relating to effectiveness, side effects, consequences, and contraindications if it fails to present a fair balance between information relating to effectiveness, side effects, consequences, and contraindications in that the information relating to effectiveness is presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

Section 12.3 Misleading Advertisements

(a) An advertisement is false, lacking in fair balance, or otherwise misleading if it:

1. Contains a representation or suggestion that one marijuana brand or form is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other marijuana brands or forms, unless such a claim has been demonstrated by substantial scientific or clinical experience;
2. Contains favorable information or opinions about a marijuana product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;
3. Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;
4. Uses a study on persons without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;
5. Uses data favorable to a marijuana product derived from patients treated with a different product or dosages different from jurisdictions;
6. Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

7. Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.

(b) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(c) An advertisement for any approved medical marijuana product shall not contain:

1. Any statement that is false or misleading;
2. Any statement that falsely disparages a competitor's products;
3. Any statement, design, or representation, picture or illustration that is obscene or indecent;
4. Any statement, design, representation, picture or illustration that encourages or represents the use of marijuana for a condition other than a qualifying condition as defined in Chapter 5, Section 5.1 paras. 8-9;
5. Any statement, design, representation, picture or illustration that encourages or represents the recreational use of marijuana;
6. Any statement, design, representation, picture or illustration related to the safety or efficacy of marijuana, unless supported by substantial evidence or substantial clinical data;
7. Any statement, design, representation, picture or illustration portraying anyone under the age of 18, objects suggestive of the presence of anyone under the age of 18, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of 18;
8. Any offer of a prize, award or inducement to a certified patient, designated caregiver or practitioner related to the purchase of marijuana or a certification for the use of marijuana; or
9. Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the Authority, New York State or any other

jurisdiction, provided that this shall not preclude a factual statement that an entity is a registered entity.

Section 12.4 Submitting Advertisements for Approval

(a) Any advertisement for an approved medical marijuana product, which makes any claims or statements regarding efficacy, must be submitted to the Authority at least 10 business days prior to the public dissemination of the advertisement.

(b) The submitter of the advertisement must provide the following information to the Authority in addition to the advertisement itself:

1. A cover letter that:
 - a. provides the following subject line: Medical marijuana advertisement review package for a proposed advertisement;
 - b. provides a brief description of the format and expected distribution of the proposed advertisement; and
 - c. provides the submitter's name, title, address, telephone number, fax number, and email address;
2. An annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;
3. Verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;
4. Verification that a spokesperson who is represented as an actual patient is indeed an actual patient;
5. Verification that an official translation of a foreign language advertisement is accurate;
6. Annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and

7. A final copy of the advertisement, including a video where applicable, in a format acceptable to the Authority.

(c) Advertising packages that are missing any of the elements in Subsection (b) above, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the Authority receives an incomplete package, it shall so notify the submitter.

(d) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of any approved medical marijuana product may cause fatalities or serious damage to a patient.

Section 12.5 Other Requirements

(a) A registered entity, its officers, managers and employees shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a practitioner. Nothing contained within this section prevents a registered entity from educating practitioners about approved medical marijuana products offered by the registered entity.

(b) The Authority may:

1. Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the Authority determines that the advertisement would be false or misleading without such a disclosure; or
2. Require that changes be made to the advertisement that are:
 - a. necessary to protect the public health, safety and welfare; or
 - b. consistent with dispensing information for the product under review.

CHAPTER 13. REPORTING DISPENSED MEDICAL MARIJUANA PRODUCTS

Section 13.1 General Requirements

(a) A record of all approved medical marijuana products that have been dispensed shall be filed electronically with the Authority, utilizing a transmission format acceptable to the Authority, not

later than 24 hours after the marijuana was dispensed to the certified patient or designated caregiver.

(b) The information filed with the Authority for each approved medical marijuana product dispensed shall include but not be limited to:

1. A serial number that will be generated by the dispensing facility for each approved medical marijuana product dispensed to the certified patient or designated caregiver;
2. An identification number which shall be populated by a number provided by the Authority, to identify the registered entity's dispensing facility;
3. The patient name, date of birth and sex;
4. The patient address, including street, city, state, zip code;
5. The patient's registry identification card number;
6. If applicable, designated caregiver's name and registry identification card number;
7. The date the approved medical marijuana product was filled by the dispensing facility;
8. The metric quantity for the approved medical marijuana product;
9. The medical marijuana product drug code number, which shall be populated by a number provided by the Authority, to represent the approved medical marijuana brand that was dispensed to the certified patient or designated caregiver, as applicable;
10. The number of days' supply dispensed;
11. The registered practitioner's Drug Enforcement Administration number;
12. The date the written certification was issued by the registered practitioner; and
13. The payment method.

(c) When applicable, a registered entity shall file a zero report with the Authority, in a format acceptable to the Authority. For the purposes of this section, a zero report shall mean a report that no approved medical marijuana product was dispensed by a registered entity during the

relevant period of time. A zero report shall be submitted no later than 14 days following the most recent previously reported dispensing of an approved medical marijuana product or the submission of a prior zero report.

CHAPTER 14. PROHIBITION THE USE OF APPROVED MEDICAL MARIJUANA PRODUCTS IN CERTAIN PLACES

Section 14.1 General Requirements

(a) Approved medical marijuana products shall not be vaporized in a public place. In no event shall approved medical marijuana products be consumed through vaporization in any location in which smoking is prohibited under tribal law, including:

1. Places of employment;
2. Bars;
3. Food service establishments;
4. Enclosed indoor areas open to the public containing a swimming pool;
6. Public means of mass transportation, including, buses, vans, taxicabs and limousines;
7. Ticketing, boarding and waiting areas in public transportation terminals;
8. Youth centers and facilities for detention;
9. Any facility that provides child care services;
10. Child day care centers;
11. Group homes for children;
12. Residential treatment facilities for children and youth;
13. All public and private colleges, universities and other educational and vocational institutions, including dormitories, residence halls, and other group residential facilities that are owned or operated by such colleges, universities and other educational and vocational institutions;

14. General hospitals and residential health care facilities;
15. Commercial establishments used for the purpose of carrying on or exercising any trade, profession, vocation or charitable activity;
16. Indoor arenas;
17. Zoos;
18. Bingo facilities

(b) Vaporization of approved medical marijuana products shall not be permitted and no person shall vaporize an approved medical marijuana product within one hundred feet of the entrances, exits or outdoor areas of any public or private elementary or secondary schools; however, that the provisions of this Subsection shall not apply to vaporization in a residence, or within real property boundary lines of such residential real property.

(c) Consumption of approved medical marijuana product shall not be permitted in any motor vehicle, either public or private, that is located upon public highways, private roads open to motor vehicle traffic, parking area of a shopping center or any parking lot.

CHAPTER 15. REPORTING REQUIREMENTS FOR REGISTERED PRACTITIONERS, CERTIFIED PATIENTS AND DESIGNATED CAREGIVERS

Section 15.1 Death or Change in Serious Condition

(a) A practitioner shall report to the Authority, in a manner determined by the Authority, the death of a certified patient or change in status of a qualifying condition involving a certified patient for whom the practitioner has issued a certification if such change may affect the patient's continued eligibility for certification for use of approved medical marijuana product. A practitioner shall report such death or change of status not more than five (5) business days after the practitioner becomes aware of such fact.

(b) If a practitioner re-issues a patient's certification to terminate the certification on an earlier date, then the registry identification card shall expire on such earlier date and shall be promptly returned to the Authority by the certified patient or designated caregiver.

(c) A practitioner shall report patient adverse events to the Authority, in a manner determined by the Authority, not more than five business days after the practitioner becomes aware of such adverse event, except that serious adverse events shall be reported not more than one business day after the practitioner becomes aware of such adverse event.

(d) A certified patient or designated caregiver, who has been issued a registry identification card, shall notify the Authority of any change in the information provided to the Authority not later than ten (10) business days after such change. A certified patient or designated caregiver shall report changes that include, but are not limited to, a change in the certified patient's name, address, contact information, medical status. A certified patient or designated caregiver shall report such changes on a form, and in a manner, determined by the Authority. Should a certified patient cease to have the qualifying condition noted on his or her certification, the certified patient or designated caregiver shall notify the Authority of such within 10 days and the certified patient's and designated caregiver's registry identification cards shall be considered void and shall be returned promptly to the Authority.

(e) If a certified patient's or designated caregiver's appearance has substantially changed such that the photograph submitted to the Authority does not accurately resemble such certified patient or designated caregiver, such person shall submit, in a timely manner, an updated photograph that meets the requirements set forth by the Authority.

Section 15.2 Reporting by Designated Caregivers

(a) If a certified patient has a designated caregiver, that designated caregiver may notify the Authority of any changes on behalf of the certified patient using the same forms and process prescribed for certified patients.

(b) If a certified patient or designated caregiver notifies the Authority of any change that results in information on the registry identification card being inaccurate or the photograph needing to be replaced, the certified patient or designated caregiver shall obtain a replacement registry identification card. The Authority shall thereafter issue the certified patient or designated caregiver a new registry identification card. Upon receipt of a new registry identification card, the certified patient or designated caregiver shall destroy in a non-recoverable manner the registry identification card that was replaced.

(c) If a certified patient or designated caregiver becomes aware of the loss, theft or destruction of the registry identification card of such certified patient or designated caregiver, the certified patient or designated caregiver shall notify the Authority, on a form and in a manner prescribed by the Authority, not later than ten days of becoming aware of the loss, theft or destruction. The Authority shall inactivate the initial registry identification card upon receiving such notice and issue a replacement registry identification card upon receiving the applicable fee provided the applicant continues to satisfy the requirements of this Ordinance. Prior to issuance of the first replacement registry identification card, a certified patient or designated caregiver shall submit to the Authority a fee of \$25, transmitted in a fashion as determined by the Authority. For each subsequent replacement registry identification card, a certified patient or designated caregiver shall submit to the Authority a fee of \$50, transmitted in a fashion as determined by the Authority.

Section 15.3 Change in or Termination of Designated Caregiver

(a) If a certified patient wishes to change or terminate his or her designated caregiver, the certified patient shall notify the Authority, in a manner determined by the Authority, and shall notify his or her designated caregiver as soon as practicable.

1. The Authority shall issue a notification, in a format determined by the Authority, to the designated caregiver and the certified patient that the designated caregiver's registration card is invalid;
2. In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the Authority within 10 business days;

3. In the event that the certified patient has selected another designated caregiver, the proposed designated caregiver must register with the Authority as defined in Chapter 4.
- (b) If a designated caregiver wishes to terminate his or her relationship with a certified patient, the designated caregiver shall notify the Authority, in a manner determined by the Authority, and shall notify the certified patient, as soon as practicable.
1. The Authority shall issue a notification, in a format determined by the Authority, to the certified patient and the designated caregiver that the designated caregiver has terminated his or her relationship with the certified patient.
 2. In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the Authority within ten business days.

CHAPTER 16. PROPER DISPOSAL OF MEDICAL MARIJUANA PRODUCTS BY CERTIFIED PATIENTS OR DESIGNATED CAREGIVERS

Section 16.1 General Requirements

- (a) A certified patient or designated caregiver shall dispose of all approved medical marijuana product in the certified patient's or designated caregiver's possession no later than ten calendar days after the expiration of the patient's certification, if such certification is not renewed, or sooner should the patient no longer wish to possess medical marijuana.
- (b) A certified patient or designated caregiver shall complete disposal of approved medical marijuana products by one of the following methods:
1. Rendering the approved medical marijuana product non-recoverable beyond reclamation in accordance with the Authority's guidance; or;
 2. Returning the approved medical marijuana product to the dispensing facility from which it was purchased or any dispensing facility associated with the registered entity which manufactured the approved medical marijuana product, to the extent that the registered entity accepts product returns.

CHAPTER 17. GENERAL PROHIBITIONS

Section 17.1 General Prohibitions

- (a) No person, except for a certified patient or designated caregiver or an approved laboratorian shall open or break the seal placed on an approved medical marijuana product packaged by a registered entity and provided to a certified patient.
- (b) No person associated with a registered entity shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing facility at which the certified patient or designated caregiver will purchase approved medical marijuana products.
- (c) No approved medical marijuana product shall be sold, dispensed or distributed via a delivery service without prior written approval to the registered entity by the Authority, except that a designated caregiver may deliver the approved medical marijuana product to the designated caregiver's certified patient.
- (d) No employee of a registered entity shall counsel a certified patient or designated caregiver on the use, administration of, and the risks associated with approved medical marijuana products, unless the employee is a physician, nurse practitioner, physician assistant or pharmacist approved under this Ordinance, or the employee is under the direct supervision of, and in consultation with, such physician, nurse practitioner, physician assistant, or the pharmacist on-site in the dispensing facility.
- (e) No certified patient or designated caregiver shall be in possession of approved medical marijuana products without having in his or her possession his or her registry identification card. The certified patient or designated caregiver, upon request by the Authority or law enforcement, shall present such card to verify that the certified patient or designated caregiver is authorized to possess approved medical marijuana products.

CHAPTER 18. PRACTITIONER PROHIBITIONS

Section 18.1 General Prohibitions

(a) A practitioner that is registered with the Authority shall not:

1. Directly or indirectly accept, solicit, or receive any item of value from a registered entity;
2. Offer a discount or any other item of value to a certified patient based on the patient's agreement or decision to use a particular practitioner, registered entity, brand or specific form of approved medical marijuana product produced by a registered entity;
3. Examine a qualifying patient for purposes of diagnosing a debilitating medical condition at any location owned or operated by a registered entity, or where medical marijuana products or related products necessary for the approved forms of administration of medical marijuana are acquired, distributed, dispensed, manufactured, sold, or produced; or
4. Directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

Section 18.2 No Financial Interests, Conflicts

(a) A practitioner that issues written certifications, and such practitioner's co-worker, employee, spouse, parent, child, or sibling shall not have a direct or indirect financial interest in a registered entity or any other entity that may benefit from a certified patient's or designated caregiver's acquisition, purchase or use of approved medical marijuana products, including any formal or informal agreement whereby a registered entity provides compensation if the practitioner issues a written certification for a certified patient or steers a certified patient to a specific dispensing facility.

(c) A practitioner shall not issue a certification for himself/herself or for the practitioner's family members, employees or co-workers.

(d) A practitioner shall not receive or provide product samples containing marijuana.

(e) A practitioner shall not be a designated caregiver for any patients that he or she has certified under this Ordinance.

CHAPTER 19. DESIGNATED CAREGIVER PROHIBITIONS AND PROTECTIONS

Section 19.1 General Requirements

(a) An individual shall not serve as a designated caregiver for more than five certified patients at any given time.

(b) A designated caregiver may only obtain payment from the certified patient to be used for the cost of the approved medical marijuana product purchased for the certified patient in the actual amount charged by the registered entity; provided, however, that a designated caregiver may charge the certified patient for reasonable costs incurred in the transportation, delivery, storage and administration of approved medical marijuana products.

(c) Designated caregivers acting within their scope of employment shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for an action or conduct in accordance with this Ordinance.

CHAPTER 20. REGISTERED ENTITIES; DISPOSAL OF MEDICAL MARIJUANA

Section 20.1 General Requirements

(a) The disposal of medical marijuana shall mean that the medical marijuana has been rendered unrecoverable and beyond reclamation.

Section 20.2 Approval by Authority

(a) Registered entities must dispose of any medical marijuana that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for manufacturing or dispensing,

or any plant-based waste created as a by-product of the manufacturing processes. Registered entities shall:

1. Obtain Authority approval of disposal methods; and
2. Dispose of liquid and chemical waste in accordance with applicable tribal or federal laws and regulations.

Section 20.3 Records

(a) Registered entities shall maintain records of disposal, which shall include:

1. The type of plant material being disposed, if the material is a by-product of the manufacturing process;
2. The brand and form of approved medical marijuana product being disposed, if a finished product;
3. The weight of the disposed material, the number of plants, or in the case of a finished product, the quantity of the disposed product; and
4. The signatures of at least two registered entity staff members who witnessed the disposal.

(b) All records of disposal shall be retained for at least five years and be made available for inspection by the Authority.

CHAPTER 21. MISCELLANEOUS

Section 21.1 Sovereign Immunity

(a) Nothing in this Ordinance shall be interpreted as waiving or diminishing the sovereign immunity of the Saint Regis Mohawk Tribe or its subordinate entities, agencies, officers, agents, employees, instrumentalities, or authorize in any form a prospective waiver of such sovereign immunity.

(b) Tribal sovereign immunity is hereby found and stated to be an essential element of self-determination and self-government; and as such will be waived by the Tribal Council only under

such circumstances as the Tribal Council finds to be in the interests of the Tribe in promoting economic or commercial development or for other Tribal purposes. Any such specific waivers shall be interpreted narrowly and limited to the explicit terms of the waivers; and any such waivers shall not by implication or interpretation be extended in any manner or fashion beyond their narrow, explicit terms.

Section 21.2 Regulations

(a) The Authority may issue Regulations as appropriate for the proper administration of this Ordinance. Regulations will be approved by the Tribal Council pursuant to the rules applicable to approval of Tribal Ordinances with the circulation of Draft regulations and public meeting for comments.

Section 21.3 Effective Date

(a) The effective date of this Ordinance shall be the approval of the Ordinance by the Tribal Council after it has been approved by Referendum vote.

Section 21.4 Amendments

(a) This Ordinance may be amended by: (1) a duly conducted Referendum; or (2) by the Authority or Advisory Board recommending amendment, provided the amendment is confirmed by a vote of the Tribal Council. The amendment shall be processed following the Tribal Procedure Act and include notice to, and review by, the Community.

(b) An amendment may include an agreement entered into by the Tribe with the State or other governmental agency needed to effectuate or implement this Ordinance. Such Amendments will be processed following the Tribal Procedure Act and include notice to, and review by, the Community.

Section 21.5 Severability

(a) The provisions of this Ordinance shall be severable and if any part or provision shall be held void by any Court of competent jurisdiction, the decision of the Court so holding shall not affect or impair any of the remaining parts or provisions of this Ordinance.

Section 21.6 Repeal of Prior Laws

(a) This Ordinance repeals any other Tribal Council Resolutions, Ordinances, Acts or Laws that are inconsistent herein.