

# FOR CONSULTATION PURPOSES ONLY

## BERMUDA

### MEDICINAL CANNABIS (LICENSING) REGULATIONS 2019

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The Minister responsible for drug prevention, in exercise of the power conferred by section 34 of the Medicinal Cannabis Act 2019, makes the following Regulations:

### Part 1

#### Preliminary

##### Citation

1 These regulations may be cited as the Medicinal Cannabis (Licensing) Regulations 2019.

##### Interpretation

2 (1) In this Act—

“applicant” means a person who makes an application under these Regulations;

“analytical services” includes services for the testing or abstraction of medicinal cannabis;

“cultivation” includes harvesting, drying, trimming curing and packaging;

“cultivation site” means the premises specified in a cultivation licence as the licensed premises on which medicinal cannabis plants are authorised to be cultivated in accordance with the licence;

“dispose” in relation to medicinal cannabis, means destroying the medicinal cannabis in accordance with guidelines or codes of practice issued by the Authority for the purposes of these Regulations;

“manufacture” means to compound, blend, extract, infuse, or otherwise make or produce medicinal cannabis;

“original application” in relation to a licence, means the first successful application for that licence made by the applicant concerned and the words “original licence” shall be construed accordingly;

“premises” means any land or building, and includes any vehicle or receptacle located on such land or in any such building used for the conduct of activities authorised under a licence;

“production” has the meaning assigned to it under the Single Convention on Narcotic Drugs, 1961;

“vehicle” includes an aircraft or a vessel.

(2) In these Regulations, the cultivation of medicinal cannabis includes—

(a) sowing a seed of a medicinal cannabis plant;

(b) planting, growing, tending, nurturing and harvesting a medicinal cannabis plant,

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the premises or in a building located on the premises, but does not include the separation of medicinal cannabis material from a medicinal cannabis plant.

### Part 2

#### General Provisions for Licensing

##### Matters taken into account; licensing individual or body corporate

3 Without limiting the matters to which the Authority may have regard in deciding whether to grant a licence, an applicant shall satisfy such due diligence requirements specified by guidelines issued by the Authority and as such, the Authority shall, in relation to each applicant, conduct or cause to be conducted, such due diligence checks as it considers necessary or appropriate.

##### Spent convictions and exceptions

4 (1) Nothing in regulation 3 shall affect the operation of any enactment which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and requires a person who is aware of such convictions to disregard them.

(2) The Minister may, acting on the recommendation of the Authority, approve the issue a licence if it is satisfied that the conduct of an applicant in relation to a serious offence—

- (a) involves the cultivation, obtaining , production, possession or supply of medicinal cannabis material; and
- (b) this information was fully disclosed in an application for a licence made to the Authority;

and the Minister is satisfied that, based on the particulars submitted to it for consideration, the applicant would comply with the requirements of the Act and these regulations if the licence is so granted.

(3) For the avoidance of doubt, paragraph (2) does not require the Minister to grant the licence even if it so satisfied.

##### Application for a licence

5 (1) An application may be made to the Authority, in accordance with these Regulations, for—

- (a) a cultivation licence, being a licence in Part 3 A;
- (b) a manufacturing licence, being a licence in Part 3 B;
- (d) an import licence, being a licence in Part 3 C;
- (e) an export licence, being a licence in Part 3 D;
- (f) an research licence, being a licence in Part 3 E;

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(g) a transport licence, being a licence in Part 3 F.

(2) Notwithstanding any provisions of these Regulations, the Minister may issue guidelines to exempt a person who makes an application for a cultivation licence from one or more of the requirements of these Regulations.

(3) An applicant for a licence shall submit to the Authority—

- (a) a completed application form containing such information as the Authority may require;
- (b) proof to the satisfaction of the Authority that the applicant meets the basic qualification requirements set out in regulation 6;
- (c) the relevant licence application fee, which shall not be refundable;
- (d) the required information mentioned in regulation 7 in respect of the applicant's employees;
- (e) a police criminal record check in respect of the applicant, in the case of—
  - (i) an individual, a report on that individual;
  - (ii) a body corporate, a report in respect of each of the directors of the body corporate;
- (f) Evidence that the applicant owns the premises on which the activities which are the subject of the licence will be carried on or the written agreement with the owner of those premises to use the premises for those activities, together with—
  - (i) in the case of land, proof that all applicable land tax in respect of the land have been paid up to date; and
  - (ii) a survey plan of the land comprising the premises or on which the premises are situated;
- (g) where the applicant is a company, a copy of the Certificate of Incorporation;
- (h) any other information required under regulation 9(4) or Part 3 to be submitted with an application for the particular type of licence.

(4) Pursuant to paragraph (3)(a), the information is as follows—

- (a) if the applicant—
  - (i) is an individual, his name and date of birth;
  - (ii) is a company, the name of the company.
- (b) the address, telephone number and email address for—
  - (i) the persons for whom the licence is sought; and
  - (ii) where applicable, each building within the premises where the proposed activities are to be conducted;

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- (c) the mailing address for the premises for which the licence is required;
- (d) the proposed activities to be conducted on the premises, the purpose for conducting those activities and where applicable the substances in respect of which each of the activities is to be conducted;
- (e) a detailed description of the security measures at the premises for which the licence is sort, subject to these Regulations and any guidelines issued by the Authority; and
- (f) a detailed description of the method the applicant proposes to use for record keeping, which shall allow for—
  - (i) compliance with the provisions of these Regulations;
  - (ii) the Authority to inspect and monitor the activities of the licensee; and
  - (iii) the reconciliation of orders for medicinal cannabis and shipments and inventories of medicinal cannabis, where applicable.

(5) Where an applicant intends to conduct any activity for which a licence is required under the Act on more than one premises, a separate application shall be submitted for each premises.

Basic qualification requirements; applicant

6 Pursuant to regulation 5(3)(b), the basic qualification requirements in relation to an applicant are that the applicant—

- (a) is either—
  - (i) a person who possesses Bermudian status; or
  - (ii) a company incorporated in Bermuda.
- (b) is not disqualified under regulation 8 from applying for a licence.

Information relating to employees

7 For the purposes of regulation 5(3)(d), the required information in respect of the applicant's employees are all persons to be employed by the applicant in connection with the activity that is the subject of the licence, together with the following in respect of each employee—

- (a) a recent police criminal record check;
- (b) proof that each employee has attained the 21 years of age; and
- (c) a photograph of the employee that is certified by a notary public.

Disqualification from holding licence

8 An applicant shall be disqualified from holding a licence if the applicant does not satisfy the due diligence requirements pursuant to regulation 3.

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### Authority to make determination on application

9 (1) Where a person has made an application for a licence, the Authority shall decide to issue, or refuse to issue the licence.

(2) The Authority may, subject to paragraph (3) and regulation 10, make a recommendation to refuse to issue a licence if the Authority considers it appropriate in all the circumstances to do so.

(3) For the purposes of deciding whether to issue or refuse to issue a licence, the Authority—

- (a) shall have regard to the following—
  - (i) the information and documents provided by the applicant;
  - (ii) any advice, information or documents received in response to a due diligence check conducted under paragraph (4), and any advice provided by an agency of government in relation to the application; and
- (b) may have regard to any other matter relating to the conduct of activities authorised by the licence;
- (c) may have regard to any other matter the Authority considers relevant; and
- (d) may require the applicant to provide access to an inspector of the premises at which activities proposed to be authorised by the licence will be carried out, for the purposes of inspecting the premises.

(4) The Authority may, by notice in writing, require an applicant to give to the Authority such further information or documents in relation to the application as the Authority reasonably requires.

(5) The Authority may, subject to the provisions of this regulation and Part 3—

- (a) if the Authority is satisfied that the application is made in accordance with the Act and these Regulations, make a recommendation to the Minister to approve the application for the issue of a licence, on such terms and conditions proposed by the Authority; or
- (b) subject to regulation 10, make a recommendation to the Minister to refuse the application, and where the Minister refuses the application to issue the licence, thereafter, notify the applicant in writing, within seven days from the date of refusal of the decision and the reasons therefor and of the applicant's right of appeal under Part 7 of the Act.

### Authority may refuse a licence

10 (1) The Authority may refuse to grant a licence if—

- (a) the Authority is not satisfied on reasonable grounds that—
  - (i) the applicant has satisfied the due diligence requirements pursuant to regulation 3; and

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- (ii) each of the applicant's relevant business associates in relation to the application, whether a business relating to the proposed activity for which the licence is sought, or in relation to any other business, has not satisfied the due diligence requirements;
- (b) the Authority is satisfied, on reasonable grounds, that to grant the licence would not be consistent with Bermuda's international obligations;
- (c) the Authority is not satisfied, on reasonable grounds, that the applicant will take all reasonable measures to ensure the physical security of the premises at which the activity authorised under a licence will be carried out;
- (d) the Authority is not satisfied, on reasonable grounds, of the suitability of the location of the premises or proposed security arrangements at the premises where activities authorised by the licence will be carried out;
- (e) the application fee has not been paid; or
- (f) the applicant has not complied with a requirement under these Regulations in relation to the application.

(2) A business associate of the applicant is a relevant business associate in relation to an application if the Authority considers it is reasonable, in the circumstances of the application, to take that business associate into account.

### Authority may impose conditions

11 The Authority shall grant a licence subject, but not limited to, the conditions provided in regulation 15.

### Notification of decision

12 Pursuant to regulation 11, the Authority shall, as soon as practicable—

- (a) notify the applicant, in writing, of the Minister's decision; and
- (b) issue to the applicant a licence specifying the matters provided in regulation 13 to the applicant.

### Matters to be specified in a licence

13 A licence shall be granted after payment of the prescribed fee and a security bond and shall include, among other things, the following—

- (a) the name of the licensee;
- (b) the activities authorised by the licence and the extent to which those activities are authorised only in accordance with a licence held by the licensee;
- (c) the extent of the premises on which the activity that is authorised by the licence is to be conducted;



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- (d) the persons authorised by the licence to engage in activities authorised by the licence;
- (e) the conditions (if any) imposed by the Authority in accordance with regulation 15;
- (f) the period for which the licence is in force;
- (g) that the Authority may, in accordance with regulation 24, require the disposal of medicinal cannabis in the possession of, or under the control of, the licensee.

### Period of validity of a licence

14 A licence shall cease to be in force

- (a) at the end of the period for which it is expressed to be in force; or
- (b) if it is revoked earlier, when it is revoked.

### Terms and conditions

15 The following terms and conditions shall be deemed to be terms and conditions of every licence, in addition to any other terms and conditions which may apply to any such licence by virtue of any other provision of these Regulations—

- (a) that the licensee shall take all reasonable steps not to engage or employ a person to carry out any activity authorised by the licence if the person is under 21 years of age;
- (b) that the licensee carries out any activity authorised by the licence in accordance with the licence;
- (c) that the licensee complies with the guidelines and directives issued by the Authority, from time to time;
- (d) that the licensee displays the licence (or a copy thereof duly certified by a Notary Public) in a conspicuous location on the premises on which the activity which is the subject of the licence is carried on;
- (e) that the required information referred to in regulation 7, in respect of each new employee be submitted to the Authority prior to engaging the employee, and the employee shall not be engaged without that approval;
- (f) that the licensee shall notify the Authority as soon as reasonably practicable after any of the following matters come to the attention of the licensee—
  - (i) a matter that may affect the due diligence requirements of the licensee or a business associate of the licensee (in relation to a business relating to the licence or in relation to any other business);
  - (ii) a breach of the licence; or

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- (iii) any other matter that may require or permit the Authority to revoke the licence;
- (g) that the licensee shall permit an inspector to enter the premises at which the person is present and where the activity which is the subject of the licence is being conducted, for the purposes of the following—
  - (i) inspecting or monitoring the activity;
  - (ii) ensuring whether or not the activity is being carried out as authorised by the licence and whether the licence conditions are being complied with; and
  - (iii) taking samples of anything at such land or premises and remove and test such samples;
- (h) that the licensee shall provide to the Authority, at such intervals as the Authority may require, a full accounting of all transactions, including the price for which medicinal cannabis was purchased by the licensee and sufficient information relating thereto as would enable the Authority to trace, back to the supplier, the medicinal cannabis purchased by the licensee;
- (i) that the licensee shall provide to the Authority a monthly reconciliation statement in respect of all medicinal cannabis handled, and all medicinal cannabis disposed of, by the licensee;
- (j) that any medicinal cannabis which constitutes waste material or by-products of the activities carried on under the licence—
  - (i) shall be disposed of in accordance with these Regulations and guidelines issued by the Authority; and
  - (ii) before such disposal, shall be packaged in a manner approved by the Authority and made available for inspection by the Authority; and
- (k) that the licensee shall keep a log, in a form approved by the Authority, of all persons entering and exiting the premises on which the activities which are the subject of the licence are carried on, and shall make the log available to the Authority for inspection on request.

### Variation of licence

- 16 (1) The Authority may vary a licence by giving notice in writing to the licensee—
- (a) at any time, on the Authority's own initiative; or
  - (b) on application made by the licensee.
- (2) The Authority may vary a licence if the Authority considers it appropriate in all the circumstances to do so.
- (3) A variation made under this regulation may include an amendment extending the period of validity, in the case of a cultivation licence, for such further period as may be

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necessary for the completion of the cultivation of medicinal cannabis on the premises, being in any event a period not extending beyond the duration of the crop cycle.

- (4) Without limiting paragraph (1), the Authority may vary a licence—
  - (a) to impose conditions or additional conditions;
  - (b) to remove or vary conditions that were imposed by the Authority by virtue of these Regulations; or
  - (c) to extend, modify or reduce the activities authorised by the licence or the licensee.

- (5) A variation of a licence takes effect on the day specified in the notice under paragraph (1).

### Application for variation of licence

17 (1) An application for variation of a licence shall be in writing, and shall contain the following information—

- (a) a detailed document outlining the proposed variation as well as any additional information that is relevant to the proposed variation; and
- (b) a copy of the original licence.

(2) The application for a variation must be accompanied by the relevant application fee provided in the Act.

(3) The licensee may withdraw an application at any time before a decision is made on the application, but the application fee shall be non-refundable.

(4) If an application has been made for variation of a licence the Authority may refuse to vary the licence.

### Duration of licences and obligations; fees and security bond

18 (1) A licence granted under these Regulations shall, subject to regulation 20, be valid for the period specified in paragraph (2), unless renewed for a further period in accordance with regulation 19 or surrendered at an earlier date by notice in writing given by the licensee to the Authority.

- (2) The period mentioned in paragraph (1) is—
  - (a) in the case of a cultivation licence, a period of one year from the date of issue of the licence; and
  - (b) in the case of any other licence, a period of three years from the date of issue of the licence.

(3) The relevant licence fee specified in the Act shall be payable by the licensee annually to the Authority on the anniversary of the date of issue of the licence so long as the licence is valid.

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(4) Upon the revocation, surrender or expiration of a licence, any security bond paid by the licensee in relation to the licence shall be refunded by the Authority, less any costs offset, in accordance with regulation 58.

### Renewal of licences

19 (1) A licensee may apply for renewal of the licence by submitting to the Authority a completed application in accordance with Form 1 of this Schedule, together with—

- (a) the original licence;
- (b) the relevant licence renewal application fee and any amounts required to replenish the relevant security bond set out in the Act; and
- (c) all supporting documentation as would be required on an original application for the licence, other than any documentation expressly exempted by the Authority from time to time for the purposes of the renewal.

(2) An application for the renewal of a licence shall be submitted to the Authority at least 30 calendar days prior to the expiration date of the current licence and no application for renewal shall be accepted by the Authority more than 60 calendar days prior to the expiration date of the current licence.

(3) If a completed application for renewal is submitted within the 30 calendar days period specified under paragraph (2), the licensee may continue to operate until the Minister approves or refuses the application for renewal.

(4) After the expiration of the licence and within the 60 calendar day period specified under paragraph (2), a licensee shall submit a late fee of \$1,000 which shall be paid in addition to the required renewal fee in order to renew the licence.

(5) A licensee who does not submit an application for renewal within the 60 day calendar period after the expiration of the licence, shall forfeit his eligibility to apply for a renewal and instead shall be required to submit a new application in accordance with regulation 5, in addition to being required to submit a late fee of \$1,000 along with the original application fee, in order to renew the licence.

(6) The Authority, in determining an application for renewal under this regulation, shall take into account the factors required under these regulations that are to be taken into account on the original application, and may also take into account any information garnered during the course of the original licence and any subsequent renewal thereof.

(7) The provisions of regulation 18 shall apply, with the necessary modifications, to a licence that is renewed under this regulation.

(8) A licence renewed under this regulation may include such terms and conditions as the Authority thinks fit, including any term or condition not included in the original licence or a subsequent renewal thereof.

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### Revocation of licence

20 (1) The Authority shall, by notice in writing given to the licensee, revoke a licence if the Authority is satisfied on reasonable grounds—

- (a) that the licensee, or if the licensee is a company, any of the directors of the company, has engaged in conduct that constitutes a serious offence since the licence has been granted;
- (b) that the licensee no longer satisfies the due diligence requirements pursuant to regulation 3; or
- (c) that a business associate of the licensee no longer satisfies the due diligence requirements pursuant to regulation 3; (whether in relation to a business relating to the licence or in relation to any other business);
- (d) that the licensee is disqualified under regulation 8;
- (e) that the licence is lost or has been stolen.

(2) The Authority may, by notice in writing given to the licensee, revoke or suspend a licence, if the Authority is satisfied on reasonable grounds—

- (a) that a condition of the licence has been breached; or
- (b) that the licensee has engaged in conduct that an offence under the Misuse of Drugs Act 1972, the Criminal Justice (International Co-operation) (Bermuda) Act 1994 and the Proceeds of Crime Act 1997;
- (c) that the licence was obtained or varied on the basis of information that—
  - (i) was false or misleading in a material particular;
  - (ii) omitted a matter or thing without which the information was misleading in a material particular;
- (d) that the location, facilities or security arrangements at the premises at which activities authorised by the licence take place are not suitable for those activities;
- (e) that the licensee has ceased to carry on all activities authorised by the licence;
- (f) that activities authorised by the licence to be undertaken at the premises by the licensee have been undertaken by the licensee other than at those premises;
- (g) that the licensee is not taking all reasonable measures to ensure the physical security of the medicinal cannabis or medicinal cannabis material in the licensee's possession or control; or
- (h) that the licensee has not provided information required by a notice given under regulation 9(4) within the time specified in the notice.

(3) The revocation of a licence takes effect on the day specified in the notice under paragraph (1) or (2).

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### Authority to notify of proposed revocation

21 (1) Before revoking or suspending a licence under regulation 20, the Authority shall give written notice of the proposed revocation to the licensee.

(2) A notice under paragraph (1) in relation to a licence shall—

- (a) state that the Authority proposes to revoke or suspend the licence and the reasons for the proposed revocation or suspension; and
- (b) invite the licensee to make a written submission to the Authority about the proposed revocation or suspension.

(3) A notice under paragraph (1) shall specify a period within which the licensee may make a submission under paragraph (2)(b) and such period shall not end earlier than thirty days after the day on which the notice was given.

### Ceasing of suspended activities and reinstatement

22 (1) If a licence is suspended in respect of any or all activities set out in the licence, the licensee shall cease conducting those activities for the duration of the suspension.

(2) The Authority shall, by notice to a licensee, reinstate a licence, in respect of any or all activities affected by the suspension if the licensee demonstrates to the Authority that—

- (a) the failure which gave rise to the suspension has been rectified; or
- (b) the suspension was unfounded.

### Report of loss or theft

23 (1) Where a licensee is in possession of medicinal cannabis that is stolen or there is an unusual waste or disappearance of medicinal cannabis that cannot be explained on the basis of normally accepted business activities, the licensee shall—

- (a) immediately report the occurrence to an inspector; and
- (b) provide a written report to the Authority, within 48 hours after becoming aware of the occurrence.

(2) The provisions of section 14 of the Act shall apply mutatis mutandis in relation to the procedure regarding the loss of a licence issued under these regulations.

### Disposal of medicinal cannabis

24 (1) Where by virtue of any provision of these regulations, a licence is suspended, revoked or surrendered, or has expired, the Authority shall give to the licensee such written directions as the Authority considers appropriate for the safe custody or disposal, as the case may require, of any medicinal cannabis in the custody or control of the licensee and not lawfully held under any other licence and the licensee shall comply with those directions.

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(2) The security bond paid under these regulations by a licensee on the issue of the licence may be applied by the Authority to offset any costs reasonably incurred by the Authority in disposing of any medicinal cannabis, due to—

- (a) the licensee's failure to comply with directions issued under paragraph (1) to the licensee;
- (b) the licensee's failure to dispose of the medicinal cannabis in any case where disposal becomes necessary (for example, in the case of medicinal cannabis, where it is infected, or the medicinal cannabis exceeds the quantity that the licensee is permitted to handle under the licence); or
- (c) any circumstances from which the Authority may reasonably conclude that the licensee has abandoned the licence or the medicinal cannabis.

(3) Where a licensee intends to surrender a licence or does not make an application for the renewal of a licence under these regulations, the licensee shall, not later than sixty days before the surrender or expiration of the licence, make a written report to the Authority setting out a disposal plan for all medicinal cannabis estimated to be left in the licensee's possession on the date of the termination.

(4) A licensee shall comply with such written directions as may be issued to the licensee by the Authority in response to a report made by the licensee under paragraph (3).

### Inspection of premises to issuance

25 (1) Prior to considering an application for a licence, the Authority shall cause an inspection to be made of the proposed premises on which the activities which are the subject of the licence are to be carried on, by an inspector who shall have power to—

- (a) enter onto the premises for the purpose of conducting the inspection;
- (b) require any person who would be required or authorised to give any report under these regulations if the licence were to be issued, to submit to an interview for the purpose of assessing the person's capability to provide the report;
- (c) take photographs of the premises; and
- (d) traverse the premises in order to establish the boundaries thereof.

(2) Pursuant to paragraph (1), the inspector shall promptly submit a report of the inspection to the Authority, together with the photographs taken.

(3) The Authority may cause to be conducted any further inspections as are necessary to ensure full compliance with the requirements of these regulations for the issuance of a licence, and particularly with a view to inspecting the working of surveillance systems at the proposed premises concerned.

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### Part 3

#### Provisions Applicable to Specific Types of Licence

##### *A. Cultivation Licences*

###### Activities authorized by cultivation licence

26 Without limiting the matters that the Authority may specify in a cultivation licence, a cultivation licence shall authorise one or more of the following—

- (a) the types and strains of medicinal cannabis plants that may be cultivated;
- (b) the maximum size of the medicinal cannabis crop that may be cultivated;
- (c) the maximum number of medicinal cannabis plants that a licensee may have in his possession or control at any time for the normal conduct of business; and
- (d) the period during which the medicinal cannabis plants may be cultivated.

###### Additional requirements for cultivation

27 (1) Subject to regulation 5, where the applicant for a cultivation licence is an individual, there shall be submitted with the application—

- (a) two passport-sized photographs of the applicant; and
- (b) copies of two Government issued forms of identification, certified by a Notary Public.

(2) The Authority shall not recommend to the Minister the approval of an application for a cultivation licence unless, in addition to the requirements set out in Part 2, the following additional requirements are satisfied—

- (a) arrangements satisfactory to the Authority are in place for the off-site security surveillance of the premises where the medicinal cannabis is to be cultivated, whether by electronic means or otherwise;
- (b) the premises where the medicinal cannabis is to be cultivated is not situated within six hundred metres of any school or place of worship;
- (c) the premises where the medicinal cannabis is to be cultivated consists of an area having clearly defined boundaries and ownership of the proposed premises is clearly established in accordance with regulation 5(3)(h);
- (d) the Authority is satisfied that approving the application would not be inconsistent with any requirements under any Act or any action taken by the appropriate authority in exercise of functions under that Act and any other applicable laws concerning the issue of licences with respect to the carrying on of any activity in the geographical area concerned;



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- (e) in the case of an application for a licence, the applicant has submitted, to the satisfaction of the Authority, a draft security contract that includes provision for—
  - (i) off-site web-enabled electronic surveillance;
  - (ii) regular physical inspections and written reports thereon; and
  - (iii) a panic alarm system tied to a base operation that is operated, by a security company that is included on a list of approved security companies published by the Authority from time to time;
- (f) the applicant has submitted, to the satisfaction of the Authority, a proposal for the implementation of a system to monitor, track and trace all medicinal cannabis cultivated on the proposed premises;
- (g) the applicant meets the qualifications set out in regulation 28 in respect of the licence Tier applied for.

(3) In making a recommendation to the Minister in relation to the approval of an application for a cultivation licence, the Authority shall give preference to an applicant who has an agreement or arrangement with a proposed manufacturer for the crop harvested from the premises.

### Issue a cultivation licence

28 (1) Where based on the recommendation made by the Minister, the Authority approves an application for a cultivation licence, the Authority shall issue to the applicant, upon receipt of the applicable licence fee and applicable security bond specified in the Act, a licence in the form the Authority may require, being—

- (a) a Tier 1 cultivation licence in the case of premises—
  - (i) comprising land of up to 2 acres (outdoor) or a building of up to 4,000 square feet (indoor);
  - (ii) the boundaries of which are secured in compliance with guidelines issued by the Authority; and
  - (iii) which satisfies the requirements set out in paragraph (2);
- (b) a Tier 2 cultivation licence in the case of premises—
  - (i) comprising land of more than 2 acres but not exceeding 5 acres (outdoor) or a building of more than 4,000 square feet but not exceeding 6,000 square feet (indoor);
  - (ii) the boundaries of which are secured in accordance with guidelines issued by the Authority; and
  - (iii) which satisfies the requirements set out in paragraph (2); or
- (c) a Tier 3 cultivation licence in the case of premises—

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- (i) comprising land of more than 5 acres (outdoor) and a building of more than 6,000 square feet (indoor);
- (ii) the boundaries of which are secured by guidelines issued by the Authority; and
- (iii) which satisfies the requirements set out in paragraph (2).

(2) The requirements mentioned in paragraph (1) are that there is a clearly defined area for each aspect of the cultivation process (for example, a plant nursery, a planting area, and a harvesting and drying area).

### Terms and conditions applicable to cultivation licence

29 (1) For the avoidance of doubt, it is hereby declared that all medicinal cannabis that is cultivated in accordance with a cultivation licence shall not be sold or disposed of in any manner without the written approval and certification of the Authority.

(2) Without prejudice to paragraph (1) and the power of the Authority to impose terms and conditions on a cultivation licence, the following additional terms and conditions shall be deemed to be included—

- (a) the licensee undertakes to ensure that, prior to the sale of the entire medicinal cannabis crop produced on the licensed premises, the Authority shall approve the written contract agreement entered into between the licensee and the manufacturer, researcher or exporter, as the case may be, and such agreement shall include, as part of its terms and conditions, a requirement that—
  - (i) the standards required by the manufacturer, researcher or exporter, if any, be stipulated in the contract agreement; and
  - (ii) any security bond required to be paid under these regulations by the manufacturer, researcher or exporter be forfeited to the licensee in event of failure to complete the written contract;
- (b) cultivation by the licensee on the premises shall not exceed the acreage of land or square footage of the building specified in the Tier for which the licence is issued;
- (c) each medicinal cannabis plant on the cultivation site shall be tagged with a unique identifier issued by the Authority;
- (d) compliance with the guidelines issued by the Authority relating to the procedure, conditions and requirements for the storage of the medicinal cannabis;
- (e) a report on the activities conducted on the cultivation site shall be made to the Authority—
  - (i) at monthly intervals, in the case of a Tier 1, Tier 2 or Tier 3 licence;
  - (ii) forthwith in the case of any exceptional event; and

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- (iii) at such other times as may be reasonably required by the Authority;
- (f) any medicinal cannabis cultivated on the licensed premises—
  - (i) in excess of the amount permitted under the licence;
  - (ii) which remains un-dried for more than twenty-one days after harvesting; or
  - (iii) otherwise than in accordance with the licence or any provision made by or under the Act,
    - shall be disposed of in accordance with directions issued by the Authority;
- (g) all medicinal cannabis harvested from the cultivation site shall be dealt with in accordance with regulation 30;
- (h) the licensee shall notify the Authority, at least one month in advance of carrying out any harvesting of medicinal cannabis on the premises and shall not carry out any such harvesting unless an inspector is present;
- (i) any drying or curing of medicinal cannabis harvested from the cultivation site shall be completed within four months after the harvesting, and the licensee shall facilitate the conduct of a site inspection by the Authority on completion of the process; and
- (j) the licensee shall undertake to conduct an agricultural project or other approved project subject to the approval of the Minister.

### Harvesting medicinal cannabis

30 With respect to a licence under this Part—

- (a) where the licensee harvests medicinal cannabis that is to be exported uncured, the licensee shall dispose of the harvested medicinal cannabis over, within four months after the harvesting, in a manner approved by the Authority;
- (b) where the licensee harvests medicinal cannabis that is to be exported cured, the licensee shall dispose of the cured medicinal cannabis in the manner approved by the Authority and the licensee shall ensure that the harvested medicinal cannabis remains tagged as required by regulation 29(1)(c) at all times during that period;
- (c) where the licensee does not, at the time of harvesting medicinal cannabis, have a manufacturer, researcher or exporter to purchase the medicinal cannabis or an arrangement with a manufacturer, researcher, or exporter subsequently fails, the licensee shall be permitted to—
  - (i) store the medicinal cannabis securely for not more than 4 months after the date of the harvesting while attempting to find a manufacturer, researcher or an exporter to purchase the medicinal cannabis; and

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- (ii) bag or cure the medicinal cannabis if prior approval to do so is obtained from the Authority.

### Testing, packaging and labelling

31 (1) All medicinal cannabis harvested on licensed premises shall be packaged in the official bags provided by the Authority.

(2) The Authority may charge a reasonable fee for the supply of bags under this regulation.

(3) The bags provided by the Authority under this regulation shall be labelled with identifiers unique to the licensee, which may include the relevant licence number, a unique lot number and the result of any potency or safety tests done.

(4) For the purposes of this regulation, the Authority may at any stage of cultivation of medicinal cannabis by a licensee, require the licensee to have any medicinal cannabis at the licensed premises tested by an analytical service provider and the results of the test furnished to the Authority.

(5) A person who, without lawful excuse or authority, is in possession of, or uses, any bag, label or other unique identifier devised by the Authority for the purposes of these regulations commits an offence and shall be liable on summary conviction to a fine not exceeding \$25,000 or to a term of imprisonment not exceeding three months or both.

### *B. Manufacturing Licences*

#### Matters to be authorised by manufacturing licence

32 Without limiting the matters that the Authority may specify in a manufacturing licence, such licence shall authorise the manufacturing of medicinal cannabis products, including activities related to such manufacture.

#### Additional requirements for manufacturing licence

33 The Authority shall not make a recommendation to the Minister for the approval of an application for a manufacturing licence unless, in addition to the requirements set out in Part 2, the following requirements are met—

- (a) the applicant submits the following information, where applicable, regarding the premises to be used to conduct the manufacturing activity—
  - (i) the physical address of the proposed premises;
  - (ii) the type of manufacturing activity that will be conducted on the premises;
  - (iii) the type of medicinal cannabis products that will be manufactured;
  - (iv) the name and address of the person in charge of the manufacturing activity to be carried out on the premises;
  - (v) the anticipated gross annual income from the medicinal cannabis products to be manufactured on the premises;

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- (vi) a site plan of the premises, showing all boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, and common or shared entryways, including the areas in which manufacturing activities will be conducted;
  - (vii) a description of inventory control procedures sufficient to demonstrate how the applicant will comply with the requirements of these regulations;
  - (viii) a description of quality control procedures sufficient to demonstrate how the applicant will comply with all the applicable requirements specified in these or other regulations addressing quality control;
  - (ix) a description of the transportation process to be used by the applicant that is in compliance with Part 3 F;
  - (x) a description of security procedures sufficient to demonstrate how the applicant will comply with regulation 37 any guidelines relating to same that is issued by the Authority;
  - (xi) a description of the waste disposal procedures sufficient to demonstrate how the applicant will comply with any guidelines relating to same that is issued by the Authority;
  - (xii) a written statement signed by the owner of the premises, identifying the physical location of the property and acknowledging and consenting to the manufacturing of medicinal cannabis on the premises;
- (b) the applicant has satisfied all applicable requirements under any Act or any other standards prescribed under this Act;
  - (c) the Authority is satisfied that the recommendation to the Minister for approval would not be inconsistent with any requirements under the Bermuda National Parks Act 1986 or any action taken in the exercise of functions under that Act and any other applicable laws concerning the issue of licences with respect to the carrying on of any business or activity in the geographical area concerned; and
  - (d) the matters referred to in regulation 34 have been verified.

### Pre-licensing security verification

34 Before making a recommendation to the Minister for approval of an application for a manufacturing licence, the Authority shall cause an inspection to be made of the premises to be used for the proposed manufacturing activity to be carried out under the licence, and in particular to verify that—

- (a) the area for receiving the medicinal cannabis is secure;
- (b) an electronic surveillance system for off-site monitoring, which captures all access points to the premises, is in place and in good working order;

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- (c) the proposed premises are fit for that purpose and are secured in accordance with guidelines issued by the Authority and consist of an enclosed building that has—
  - (i) clearly defined areas for receiving, storing and processing medicinal cannabis;
  - (ii) entrances and exits that are the subject of strict access control systems and monitoring procedures;
  - (iii) a logged access control system in place, which includes additional security mechanisms for the areas designated for storage of medicinal cannabis products and that access to those storage areas is limited to the smallest number of persons as is reasonably practicable for the purposes; and
- (d) all designated security posts on the premises are adequately staffed.

### Issue of manufacturing licence

35 (1) Where the Authority issues a manufacturing licence upon receipt of an approval from the Minister, the Authority shall, upon receipt of the applicable licence fee, and the applicable security bond specified in Part B of this Schedule, issue to the applicant a Tier 1 licence or a Tier 2 licence in the form the Authority may require.

(2) A Tier 1 licence shall be issued in respect of a licence to process medicinal cannabis products on premises not exceeding 150 square meters.

(3) A Tier 2 licence shall be issued in respect of a licence to process medicinal cannabis products on premises exceeding 150 square meters.

### Security Plan

36 (1) A licensee under this Part shall develop and implement a security plan.

(2) At a minimum, the security plan shall include a description of the security measures to be taken to—

- (a) prevent access to the licensed premises by any unauthorized personnel and protect the physical safety of employees, including, but is not limited to—
  - (i) establishing physical barriers to secure perimeter access and all points of entry onto a premises (such as locking primary entrances with commercial grade, non-residential door locks, or where applicable, and subject to guidelines issued by the Authority, providing fencing around the premises, driveway, and any secondary entrances including windows, roofs, or ventilation systems);
  - (ii) installing a security alarm system to notify and record incident(s) where physical barriers have been breached;
  - (iii) establishing an identification and sign-in/sign-out procedure for authorized personnel, suppliers, and/or visitors;

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- (iv) maintaining the premises such that visibility and security monitoring of the premises is possible; and
    - (v) establishing procedures for the investigation of suspicious activities;
  - (b) prevent against theft or loss of medicinal cannabis including but not limited to—
    - (i) establishing an inventory system to track medicinal cannabis and medicinal cannabis products and the personnel responsible for processing it throughout the manufacturing process;
    - (ii) limiting access of personnel within the premises to those areas necessary to complete job duties and to those time-frames specifically scheduled for completion of job duties;
    - (iii) supervising tasks or processes with high potential for diversion (including the loading and unloading of medicinal cannabis transportation vehicles) to be used in the transporting of medicinal cannabis;
    - (iv) providing designated areas in which personnel may store and access personal items;
    - (v) secure and back up electronic records in a manner that prevents unauthorized access and that ensures the integrity of the records is maintained.
- (3) At a minimum, the licensed premises shall have a complete digital video surveillance system, which shall be able to effectively and clearly record images of the area under surveillance.
- (4) The video surveillance system shall be capable of supporting remote access by the licensee.
- (5) To the extent reasonably possible, all video surveillance cameras shall be installed in a manner that prevents intentional obstruction, tampering with, or disabling.
- (6) Areas that shall be recorded on the video surveillance system include, but are not limited to, the following—
  - (a) areas where medicinal cannabis or medicinal cannabis products are weighed, packaged, stored, quarantined, loaded or unloaded for transportation, or moved within the premises;
  - (b) limited-access areas;
  - (c) security rooms;
  - (d) areas containing surveillance-system storage devices, in which case, at least one camera shall record the access points to such an area; and
  - (e) the interior and exterior of all entrances and exits to the premises.
- (7) The surveillance system shall record continuously twenty-four hours per day.

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(8) All recording and monitoring equipment shall be located in secure rooms or areas of the premises in an access-controlled environment.

(9) All surveillance recordings shall be kept on the licensee's recording device for a minimum of ninety days.

(10) All video surveillance recordings shall be subject to inspection by the Authority and shall be copied and sent, or otherwise provided, to the Authority upon request.

(11) The video recordings shall display the current date and time of recorded events.

### Terms and conditions of manufacturing licence

37 Without prejudice to the power of the Authority to impose terms and conditions in relation to any manufacturing licence, it shall be deemed to be a term and condition of every manufacturing licence that the licensee shall, for the duration of the licence, remain compliant with all applicable requirements of applicable laws relating to standards or intellectual property.

### *C. Import Licences*

#### Application for import licence

41 (1) The Authority shall not make a recommendation to the Minister for the approval of an application for an import licence unless, in addition to the requirements set out in Part 2, the applicant submits the following additional information—

- (a) in respect of any medicinal cannabis product to be imported—
    - (i) its description;
    - (ii) its intended use;
    - (iii) if applicable, its brand name;
    - (iv) its quantity;
  - (b) the name and address of the exporter in the country of export;
  - (c) the port of entry into Bermuda;
  - (d) the address of the premises to which the medicinal cannabis product is to be delivered; and
  - (e) each mode of transportation used, the country of export and, where applicable, any country of transit or transshipment.
- (2) An application for an import licence shall—
- (a) be signed and dated by the applicant; and
  - (b) include a statement, indicating that all information submitted in support of the application is correct and complete to the best of the applicant's knowledge.



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### Contents of import licence

- 42 (1) An import licence shall contain the following—
- (a) the licence number;
  - (b) the information referred to in regulation 41;
  - (c) the effective date of the import licence;
  - (d) its expiry date;
  - (e) if applicable, any conditions that the licensee shall meet in order to reduce any potential public health, safety or security risk, including the risk of the imported substance being diverted to an illicit market or use.
- (2) An import licence shall be valid until—
- (a) its expiry date or the date on which it is suspended or revoked in accordance with these Regulations;
  - (b) the expiry date of the manufacturer licence.
- (3) An import licence under these Regulations is valid only for the importation in respect of which it is issued.
- (4) For the avoidance of doubt, only medicinal cannabis products may be imported.

### Refusal to issue import licence

- 43 The Authority may recommend to the Minister the refusal of an application for an import licence, if—
- (a) the applicant does not hold a manufacturer licence in relation to the medicinal cannabis that is to be imported; or
  - (b) the Minister has reasonable grounds to believe that—
    - (i) the shipment for which the import licence is requested would contravene the laws of the country of export or any country of transit or transshipment; or
    - (ii) the importation is for the purpose of re-exporting the medicinal cannabis product.

### Provision of import licence

- 44 On request of a customs officer, the holder of an import licence shall provide a copy of the import licence to the customs officer, sufferance warehouse or bonded warehouse, as the case may be, at the port of entry in Bermuda.

### Declaration after release from customs

- 45 The holder of an import licence shall provide the Authority, within 15 days after the day of release of a shipment that contains the imported medicinal cannabis product, in

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accordance with the Revenue Act 1898, with a declaration that contains the following information—

- (a) the name of the licensee and a copy of the import licence in respect of the shipment;
- (b) the date of release of the shipment; and
- (c) in respect of the imported medicinal cannabis product—
  - (i) its description;
  - (ii) its intended use;
  - (iii) if applicable, its brand name; and
  - (iv) its quantity.

Transportation of imported substance

46 The holder of an import licence shall ensure that, after the imported medicinal cannabis product is released, it is transported directly to the premises specified in the import licence.

### *D. Export Licences*

Application for export licence

47 (1) The Authority shall not make a recommendation to the Minister for the approval of an application for an export licence unless, in addition to the requirements set out in Part 2, the applicant submits the following additional information—

- (a) in respect of the medicinal cannabis to be exported;
  - (i) its description;
  - (ii) its intended use;
  - (iii) if applicable, its brand name;
  - (iv) its quantity; and
  - (v) in the case of dried medicinal cannabis, the percentages of delta-tetrahydrocannabinol w/w and cannabidiol w/w;
- (b) the name and address of the importer in the country of final destination;
- (c) the port of exit from Bermuda and, if applicable, any country of transit or transshipment;
- (d) the address of the customs office, sufferance warehouse or bonded warehouse at which the shipment is to be presented for export;
- (e) each mode of transportation used; and

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- (f) a declaration that, to the best of the knowledge of the applicant, the shipment does not contravene any laws of the country of final destination or any country of transit or transshipment.
- (2) An application for an export licence shall be accompanied by a copy of the import licence issued by a competent authority in the country of final destination that sets out the name and address of the site of the importer in the country of final destination.
- (3) An application for an export licence shall—
  - (a) be signed and dated by the applicant; and
  - (b) include a statement, signed and dated by the applicant, indicating that all information submitted in support of the application is correct and complete to the best of the signatory's knowledge.

### Contents of export licence

- 48
- (1) An export licence shall contain the following—
    - (a) the licence number;
    - (b) the information referred to in regulation 47;
    - (c) the effective date of the export licence;
    - (d) its expiry date;
    - (e) the expiry date of the import licence issued by a competent authority in the country of final destination; and
    - (f) if applicable, any conditions that the licensee shall meet in order to reduce any potential public health, safety or security risk, including the risk of the exported substance being diverted to an illicit market or use.
  - (2) An export licence shall be valid until—
    - (a) its expiry date or the date on which it is suspended or revoked in accordance with these Regulations; and
    - (b) the expiry date of the import licence that applies to the medicinal cannabis to be exported which is issued by a competent authority in the country of final destination or the date on which that licence is suspended or revoked.
  - (3) An export licence issued under these Regulations is valid only for the exportation in respect of which it is issued.

### Refusal to issue export licence

- 49
- The Authority may recommend to the Minister, the refusal of an application for an export licence if—
- (a) the applicant does not hold a licence in respect of the medicinal cannabis that is to be exported;

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- (b) the Authority has reasonable grounds to believe that the shipment for which the export licence is requested would contravene the laws of the country of final destination or any country of transit or transshipment; or
- (c) the shipment would not be in conformity with the import licence issued by a competent authority of the country of final destination.

### Provision of copy of export licence

50 On request of a customs officer, the holder of an export licence shall provide a copy of the export licence to the customs officer, sufferance warehouse or bonded warehouse, as the case may be, at the port of exit from Bermuda at the time of exportation.

### Declaration after export

51 The holder of an export licence shall provide to the Authority, within 15 days after the day on which a shipment of the medicinal cannabis product is exported, a declaration that contains the following information—

- (a) the name of the licensee and a copy of the export licence in respect of the shipment;
- (b) the date of export; and
- (c) in respect of the exported medicinal cannabis—
  - (i) its description and an indication as to whether it is in the form of seeds, plants or dried medicinal cannabis;
  - (ii) its intended use;
  - (iii) if applicable, its brand name;
  - (iv) its quantity; and
  - (v) in the case of dried medicinal cannabis, its percentages of delta-9-tetrahydrocannabinol w/w and cannabidiol w/w.

### *E. Research Licences*

#### Additional requirements for application for research licence

52 The Authority shall not recommend to the Minister the approval of an application for a research licence authorizing—

- (a) the provision of analytical services unless the Authority is satisfied that the applicant is duly qualified to provide those services;
- (b) the conduct of any research or development unless the Authority is satisfied that the applicant is duly qualified to conduct the research or development.

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### Issue of research licence

53 Where the Authority approves an application for a research licence, the Authority shall, upon receipt of the applicable licence fee and the applicable security bond, respectively, issue to the applicant a research licence in the form the Authority may require, being a licence authorizing—

- (a) the conduct, for experimental purposes, of research utilising medicinal cannabis, which shall be described as a research (experimental purposes) licence; or
- (b) the provision of analytical services in respect of medicinal cannabis, which shall be described as a research (analytical services) licence.

### Terms and conditions of research licence

54 Without prejudice to the power of the Authority to impose terms and conditions for a research licence, it shall be deemed to be a term and condition of every research licence that the licensee shall keep a log, in the form approved by the Authority, of all persons entering and exiting the premises on which the activities which are the subject of the licence are carried out.

## *F. Transport Licences*

### Issue and scope of transport licence

55 (1) Where the Authority approves an application for a transport licence, the Authority shall upon receipt of the applicable fee, issue a transport licence in the form the Authority may require.

(2) A licence issued under paragraph (1) shall be construed as authorising, in the licensed vehicle, the transportation of medicinal cannabis to or from a location specified in paragraph (3), for use for any medicinal or research purpose.

- (3) The locations mentioned in paragraph (2) are—
  - (a) any cultivation site; or
  - (b) any premises on which a licensee is permitted to process or carry out any research or development on medicinal cannabis.

### Additional terms and conditions of transport licence

56 Without prejudice to the power of the Authority to impose terms and conditions for any transport licence, the following terms and conditions shall be deemed to be included in the terms and conditions of a transport licence—

- (a) prior to the transportation of any medicinal cannabis, the proposed transportation time and route shall be submitted for the approval of a person designated by the Authority for that purpose, and the approved route shall be entered in a log kept in a form approved by the Authority;
- (b) real time access to the tracking of the vehicle, while transporting medicinal cannabis, shall be provided to the Authority;

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- (c) all medicinal cannabis to be transported in the vehicle shall be placed in a compartment of the vehicle and sealed therein prior to the transportation, and upon arrival at the delivery location the seal shall be checked to verify that it has not been tampered with;
- (d) during transportation of medicinal cannabis, the vehicle shall not divert from the logged transportation route except in accordance with the prior written approval of the Authority, which approval shall—
  - (i) specify the time and place of the diversion, the circumstances warranting the diversion and the name of the official who gave the approval on behalf of the Authority; and
  - (ii) be entered by that official in the log referred to in sub-paragraph (a);
- (e) the licensee shall permit an inspector of the Authority to accompany the vehicle during any transportation of medicinal cannabis, and to observe the delivery of the medicinal cannabis to the delivery location;
- (f) a log of all persons accessing the vehicle shall be kept by the licensee in a form approved by the Authority and the log made available to the Authority for inspection on request; and
- (g) all times for transportation approved under paragraph (a) or (d) shall be between the hours of 5 o'clock in the morning and 6 o'clock in the afternoon.

### PART 4

#### GENERAL

##### Issuance of Codes

57 The Authority may from time to time, with the approval of the Minister, issue codes of practice, or directives, on any matter concerning the regulation of medicinal cannabis.

##### Special provision for fees and security bond

58 (1) The Authority may, in respect of any category of licences and with the prior approval of the Minister, after consultation with the Minister of Finance—

- (a) waive the payment of any fee or security bond payable under these regulations or defer the payment thereof for a specified period; or
- (b) enter into an agreement with any entity, from which any fee or security bond is payable under these regulations, for the fee or security bond (as the case may be) to be paid in increments over a stated period of time.

(2) For the avoidance of doubt, a requirement under these regulations for the payment of a fee or security bond by an applicant or licensee shall be construed as subject to any waiver, deferment or agreement made pursuant to this regulation, in respect of payment of that fee or security bond (as the case may be) by that applicant or licensee.

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### Offences

59 A person who wilfully—

- (a) obstructs, hinders, assaults or resists an inspector or any other person exercising any power or duty;
- (b) provides any false or materially misleading information in any application, report or other document required to be furnished to the Authority; or
- (c) fails or refuses to produce any document or other information which the person is required to produce,

commits an offence and shall be liable on summary conviction to fine not exceeding \$25,000 or imprisonment for a term of six months or both.