MEDICAL CANNABIS AUTHORIZATION AND USE REGULATIONS

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1. Citation

(1) These Regulations shall be known and may be cited as the Medical Cannabis Authorization and Use Regulations.

(2) This Regulation articulates the standard of practice and ethical requirements for all registered medical practitioners using their clinical skill, knowledge, and judgment in authorizing cannabis for medicinal purposes, and addresses general parameters for access to and use of medical cannabis by patients.

2. Interpretation

For the purposes of these regulations:

(1) "Cannabis" means all parts of the plant Cannabis sativa Linnaeus, Cannabis indica, or Cannabis ruderalis, whether growing or not; the seeds thereof; the resin, whether crude or purified, extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin.

(2) "Cannabinoid" means a substance found in the plant of the genus cannabis which reacts with specific receptors in the human brain and body to give a therapeutic effect.

(3) "Full Registration" means no limitations or conditions of registration and practice.

(4) "Informed Consent" means a process in which patients are given important information including possible risks and benefits about a medical treatment, in order for them to decide on accepting said treatment.

(5) "Registered Medical Practitioner" means a person who is registered and holds a valid practicing certificate under the Health Practitioners Act, Cap. 11.06.; and issued a Class Two Medicinal Cannabis Prescription Registration.

(6) “Medicinal Cannabis” or “medicinal cannabis product” means cannabis or a cannabis product, respectively, intended to be sold or donated for use by a medicinal cannabis patient who possesses a physician’s authorization.

(7) “Medically Significant” means that a medical practitioner has made a clinical determination that may include, but is not limited to, any of the following:

(a) The treatment or medication is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the qualified patient if administered or used in conjunction with THC or medicinal cannabis, based on the known clinical characteristics of the patient and the known characteristics and history of the patient’s treatment or medication regimen.

(b) The treatment or medication is expected to be ineffective based on the known clinical characteristics of the qualified patient and the known characteristics and history of the patient’s treatment or medication regimen.

(c) The treatment or medication, when administered or used in conjunction with THC or medicinal cannabis, is not clinically appropriate for the qualified patient because the treatment or medication is expected to do any of the following, as determined by a medical practitioner:

(i) Worsen a comorbid condition.

(ii) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.

(iii) Pose a significant barrier to adherence to, or compliance with, the qualified patient’s drug regimen or plan of care.

(d) Any other clinically or medically significant determination.

(8) “Patient” means a person who suffers from a qualifying medical condition.

(9) “Regulation” means a local ordinance, regulation, policy, or practice.

(10) “Regulated Substances Authority (RSA)” the body responsible for providing all registrations under the Cannabis and Industrial Hemp Act.

PART 1

REGISTRATION TO AUTHORIZE ACCESS AND USE OF MEDICINAL CANNABIS

Authorization to prescribe Medicinal Cannabis

1. Only a registered medical practitioner can prescribe the use of class 2 medicinal cannabis or class 1 in the case of a person under the age of 21. The medical practitioner must meet the following requirements:
    (a) The medical practitioner must hold a valid practicing certificate issued as under the Health Practitioners' Act Cap. 11.06.
    (b) Must have Full Registration status with the St Lucia Medical and Dental Council.
    (c) Must be registered with the Regulated Substances Authority

Registration to prescribe or authorize of Medicinal Cannabis Access and Use

2. A medical practitioner submitting an application for registration to the RSA prescribe Medicinal Cannabis must include:

(a) An application form

(b) A Copy of a valid practicing certificate

Approval of an application for Registration to Authorize Access and Use to Medicinal Cannabis

3. (1) A medical practitioner whose application is approved by the RSA shall be informed in writing within twenty-one business days of its approval.

(2) On being informed of registration of a Medicinal Cannabis Prescription Registration, the applicant will pay the prescribed non-refundable registration fee.

(3) A medical practitioner who is registered pursuant to these regulations

shall register on to the seed -to -sale platform of the RSA within 6 weeks of being duly registered to prescribe medicinal cannabis.

(4) the Medical and Dental Council Shall be informed of the registration of the Medical Practitioner

(5) Only upon receipt of the registration pursuant to subsection 3(1) and 3(3) will the medical practitioner be eligible to prescribe Class two medicinal cannabis

Refusal of an application for Registration to Authorize Access and Use of Medicinal Cannabis

4. (1) Where the RSA refuses an application for a Medicinal Cannabis Prescription Registration, the medical practitioner shall be informed in writing within twenty-one business days of its refusal.

(2) An applicant whose application is refused by the RSA can reapply once they successfully attain/correct the missing criteria outlined in their refusal.

Renewal of a for Registration to Authorize Access and Use to Medicinal Cannabis

5.

(1) A Medicinal Cannabis Prescription Registration is valid for the duration of the medical practicing certificate.

(2) A registered medical practitioner must apply for renewal of the Medicinal Cannabis Prescription Registration within 60 days of expiry of his or her Medicinal Cannabis Prescription Registration. Failure to apply within the stipulated timeframe will result in the need for a new application.

(3) An application for renewal of the registration must be accompanied by:

a. A renewal form

b. A copy of a valid practicing certificate

(4) The registration renewal fee may be paid once the registration renewal has been approved.

(5) A medical practitioner should not proceed with prescribing medicinal cannabis until they have been issued the new registration.

Suspension or Revocation of Registration to Authorize Access and Use to Medicinal Cannabis

6.

(1) A medical practitioner cannot continue to prescribe class two medicinal cannabis if his Medicinal Cannabis Prescription Registration is suspended for any of the reason set out in these regulations or the Cannabis and Industrial Hemp Act.

(2) A medical practitioner cannot continue to prescribe class two medicinal cannabis or recommend class one medicinal cannabis if his Medical Practice Licence is revoked for any of the reasons under the Health Practitioners Act.

PART 2

PRESCRIPTION OF CLASS TWO MEDICINAL CANNABIS

Display of Documents and Notices

7.

(1) A registered medical practitioner shall display his or her Medicinal Cannabis Prescription Registration in a prominent place at his or her place of operation.

Authorizing Access and Use to Medicinal Cannabis

8.

(1) Medical practitioners in prescribing medical cannabis should do so consistent with guidelines set out in the Health Practitioners Act.

(2) In order to permit access to and use of class two medicinal cannabis or class one medicinal cannabis to a patient under 21 years of age a medical practitioner who holds a Medicinal Cannabis Prescription Registration must issue a qualified patient with:

(a) Prescription *(See Appendix 3 - Medical Authorization/Prescription Form)*

(b) A Medicinal Cannabis Certificate *(See Appendix 4 – Medicinal Cannabis Certificate)*

(3) The medical practitioner should discuss the risks, benefits and alternatives of the use of cannabis with the patient as well as informing them on the proper use of Cannabis for Medicinal purposes. The medical practitioner should use professional judgement to decide if prescribing cannabis for medicinal use is the appropriate treatment for

the patient and weight the benefits to the patient as against the risks associated with the treatment using medicinal cannabis.

(4) Treatment using medicinal cannabis should be with the informed consent of the patient, who must evidence this consent by way of the Informed Consent Form *(see Appendix 6 for Informed Consent Form).*

(5) If the patient is a minor, then the patient's parent of guardian will need to consent to the treatment.

Minimum Standard for Cannabis Prescription

9.

(1) A medical practitioner who issues a cannabis prescription must first provide a medicinal Cannabis Certificate of registration to the patient. The Medicinal Cannabis Certificate must include all of the following information in a manner that is fully legible*:*

(a) The full name, registration number and signature of the medical practitioner

(b) The full name, Date of Birth, Nationality, NIC number, address, contact information and signature of the patient

(c) A statement that the medical practitioner is satisfied that the patient suffers from a qualifying medical condition listed in the Schedule to the Act and the diagnosis of the patient

(d) The duration of treatment and number of refills where appropriate

(2) A medical practitioner who issues a cannabis prescription must include on the prescription all of the following information in a manner that is fully legible

(a) The medical practitioner's full name and signature and registration number

(b) The patient's full name and date of birth

(c) The full name of the medication

(d) The medication concentration where appropriate

(e) The medication strength where appropriate

(f) The dosage

(g) The amount prescribed or duration of treatment

(h) The administration route

(i) The number of refills where appropriate

(3) The information on the Medical Cannabis Certificate of Registration and prescription above must be placed in the Seed to Sale platform authorized by the RSA

(4) A medical practitioner cannot issue a verbal prescription to a Class two dispensary in order to authorize dispensing of cannabis or cannabis product to a patient.

Standard of Practice for Authorizing Cannabis for Medicinal Purposes

10.

(1) Every medical practitioner is professionally responsible for each medicinal cannabis authorization they provide to a patient. In deciding whether to authorize medicinal cannabis, each medical practitioner must exercise the level of clinical judgment expected by the profession.

(2) A medical practitioner must only authorize medicinal cannabis:

(i) for a patient under their professional care; and

(ii) when the medicinal cannabis authorized is required for the condition for which the patient is receiving treatment

(3) After review of the medical history and prior to the initiation of treatment, the following contraindications should be considered:

(a) History of hypersensitivity to any cannabinoid

(b) Severe and unstable cardio-pulmonary disease (angina, peripheral

vascular disease, cerebrovascular disease, and arrhythmias) or risk factors for cardiovascular disease — THC acts through the CB1 receptors to decrease blood pressure, increase cardiac demand and causes vasodilation

(c) Severe liver or renal

(d) Current, active drug dependence, including illicit drugs, alcohol, and prescription medications

(e) previous drug dependence, including illicit drugs, nicotine, alcohol and prescription medications

(f) Personal or family history of schizophrenia or any psychotic disorder

(g) Cannabis should not be used if a patient is planning to become pregnant or during pregnancy unless the potential risks to the fetus and/or embryo are considered to be outweighed by the benefit of treatment. There is insufficient experience in humans regarding the effects of cannabis on reproduction. Therefore, men and women of child bearing potential should take reliable contraceptive precautions for the duration of therapy and for three months after discontinuation of therapy. Reports of pre-term labour and low birth weight have been associated with cannabis use.

(h) Breastfeeding — considerable levels of cannabinoids are likely to be present in maternal breast milk and there are potential impacts on an infant

(i) Patients aged 18 years old and under because of the potential effects of THC on the developing brain

(j) Concomitant medications, especially sedatives such as opioids and benzodiazepines and medicines metabolized by cytochrome p450 isoenzymes

(k) Whether the patient is elderly — as metabolism in the elderly is slower it is likely they will be more sensitive to the pharmacological effects of cannabis. Treatment should therefore be initiated at low doses and titrated slowly.

(4) Prior to authorizing cannabis for medicinal purposes, a medical practitioner must:

(a) make a diagnosis using the principles of good medical

care set out in the Health Practitioner's Act 2021;

(b) Assess the Risk of dependency, abuse or cannabis induced illness in the patient

(c) advise the patient as to material risks and benefits and the level of scientific evidence supporting the efficacy of the proposed treatment;

(d) discuss any other drug use, including recreational cannabis use and the risk for diversion;

(e) advise that cannabis may cause impairment, including advising the patient of the dangers associated with driving, operating heavy machinery, performing safety sensitive tasks, and providing child or elder care while impaired; and

(f) establish a plan for follow up and management.

(5) In authorizing cannabis for medicinal purposes, a medical practitioner must:

(a) document on the patient record, how the requirements of section 3 of this Standard are satisfied, including notation of:

(i) relevant discussions with the patient

(ii) the clinical reasons for which the medicinal cannabis is authorized

(iii) the rationale for the amount authorized; and

(iv) make reasonable efforts to communicate with other health care providers

involved in the patient's care, including the patient's primary health care provider, as appropriate, and document same.

(6) A medical practitioner who authorizes medicinal cannabis must:

(a) Not be legally or beneficially involved with a licenced producer/dispenser, other than for the purpose of providing expert

opinion, independent and impartial education, or conducting clinical research approved by an ethics board;

(b) Not be a licenced producer/dispenser;

(c) Not have a clinical encounter with patients at the same premises of any licenced producer/dispenser unless the medical clinic is located within a pharmacy that is a licenced dispenser; or

(d) Not otherwise contravene the Conflict-of-Interest provisions in the Standards of Practice of Medicine.

(7) A medical practitioner must not under any circumstances dispense or provide medicinal cannabis to any patient.

(8) A medical practitioner who is treating a patient admitted in a health care facility, or resident in a personal care home, and who also has privileges therein, may order that the patient may use medicinal cannabis if the medical practitioner is satisfied that:

(a) the patient has previously been provided with an authorization to obtain cannabis for medicinal purposes by another medical practitioner that continues in effect;

(b) the order is limited to the amount of cannabis needed for the period of admission or residency; and

(c) medicinal cannabis is required to ensure continuity of care with respect to the diagnosis for which medicinal cannabis was authorized.

(9) A medical practitioner who is treating a patient admitted in a health care facility or resident in personal care home must comply with all sections of this Standard in order to authorize medicinal cannabis, including where a prior authorization has expired.

Prescribing Medicinal Cannabis

11.

(1) May issue a medicinal Cannabis prescription for up to three months subject to repeat.

(2) Has to be uploaded in the seed to sale platform

Treatment of Reports of Serious Adverse Reaction Not Life Threatening

12.

(1) All adverse reactions should be reported as per section 22 of the Health Practitioners Act of 2021

(2) In the case of adverse reaction of suspected side effect the Healthcare practitioner shall be guided by the Healthcare Practitioners Act and report any suspected side effects to the RSA. All non-life-threating adverse effects should be reported by detailed completion of the Adverse Drug Reaction Reporting Form *(see Appendix 5)* and submitted to the RSA.

Ethical Requirements

13.

(1) Authorizing a patient's use of cannabis for medicinal purposes is a clinical decision and is comparable to prescribing any other medication. Medical practitioners should be guided by Section 55(a) of the Health Practitioners Act of 2021

Accessing Medicinal Cannabis

14.

(1) Where a registered medical practitioner, after applying the standards criteria and process provided in these regulations and the Healthcare Practitioner Act, opines that a patient would benefit from the use of cannabis or cannabis products, the medical practitioner may

a. prescribe class two medicinal cannabis or recommend class one medicinal cannabis to a person over the age of 21 or,

b. prescribe class one or class two medicinal cannabis in the in the case of a patient under the age of 21, and

provide medical advice on the use of the prescribed, recommended or otherwise available cannabis or cannabis product.

(2) The patient or caregiver who has been issued a prescription and medical cannabis certificate pursuant to the Act and these regulations shall within 21 working days present the Certificate to the Regulated Substances Authority to obtain the Medicinal Cannabis Card.

(3) Upon receipt of the prescription and/or medical advice the patient may obtain and utilize the cannabis or cannabis product by –

a. In the case of Herbal application, by using cannabis cultivated by the patient within the parameters provided by the Cannabis and Industrial Hemp Act subject to the medical advice of the practitioner

b. In the case of a person under the age of 21, by accessing the class one or class two medicinal cannabis or cannabis product, from a licensed class two dispensary for use subject to and as advise of the practitioner

c. In the case of a person over the age of 21,

i. accessing class one medicinal cannabis, from a licensed class one or class two dispensary for use subject to and as advised by the practitioner,

ii. accessing class two medicinal cannabis or cannabis products, from a class two dispensary for use subject to and as advised by the practitioner

(4) In the circumstances outlined in subsection 14 (2) (a) and 14(b) a registered and duly authorised caregiver may administer the cannabis or cannabis product to the patient under their care subject to and as advised by the practitioner.

(5) A registered authorized patient or caregiver shall keep the Cannabis Card on his/ her person at all times where he/she is in possession of prescribed cannabis.

Restriction no additional fees

15.

(1) (1) A patient shall not be discriminated based on the possible application of use of cannabis or cannabis product. No separate fee shall be charge to a patient for a consultation at which –

(a) Cannabis is discussed.

(b) A patient is assessed for cannabis use

(c) An authorization under these regulations is prepared or submitted

(d) or cannabis or cannabis products are prescribed

(2) Notwithstanding subsection x above, a practitioner is at liberty to charge patients such amounts as can reasonably be charged to a patient for services by that said practitioner otherwise. The appropriate billing for the visit is an insured service.

16. Renewal of Medical Documents (Prescriptions and authorization)

(1) Cannabis authorization may be issued for a period of up to two years with a renewal of up to two years in a single instance.

(2) A cannabis prescription may be granted for a period not

exceeding 3 months in any instance.

(3) Renewal of a Cannabis prescription requires a repeat clinical encounter with the registered medical practitioner to determine:

(a) Clinical response to therapy (success or failure)

(b) Adverse reactions

(c) Need for continued therapy using medicinal cannabis

(d) Need for dosage adjustment based on (a)

(4) A renewal of a prescription for cannabis or cannabis products cannot be issued more than two weeks prior to expiration of an existing valid prescription for the same product.

17. APPENDIX

Appendix 1.

Application/Renewal Form – Medicinal Cannabis Authorization

Medical practitioners can apply to become an Authorized Prescriber (AP) of medicinal cannabis and its byproducts to patients with particular a medical condition or symptom. To become an Authorized Prescriber, a medical practitioner must apply and register with the RSA.

❑ New Application

❑ Renewal

NAME

Fist Name: _____ Last Name:_____

Contact Information

Email Address: _____ Contact Number: _____

Credentials

Physician Registration Number: _____ Physician Registration Number: ___

Physical address where you will authorize the use of cannabis for medicinal purpose:

_____
_____
_____

Please provide evidence of prior education in medicinal cannabis that can support your application.

FOR OFFICIAL USE ONLY

❑ Certified copy of medical licence
❑ Evidence of prior education

Collected by: …….. Date: ……..

Decision of the RSA:
❑ Approved
❑ Not Approved

Reason for Decision: ……

……

Signature…… Name (in BLOCK letters):……. Date:……

Appendix 2.


Class Two Medicinal Cannabis Prescription Licence
LICENCE NUMBER
This serves to certify that
Dr. Jane Doe
Having satisfied the requirements of the Regulated Substances Authority(RSA), is licenced to prescribe Medicinal Cannabis to patients under his/her care.
DATE OF ISSUANCE
RSA SIGNATURE
DATE OF EXPIRY
This licence is valid unless expired, suspended or revoked.

Appendix 3.

Medical Authorization / Prescription Form

Patient's Personal Information

Date	dd/mm/yyyy		
Last Name			
Middle Name			
First Name			
Gender			
Date of Birth	dd/mm/yyyy		
Contact Number 1		Contact Number 2	
Email Address			
Residential Address			

Prescription

Product Name	Usage Instruction	Period of Use

Medical Practitioner's Information

Last Name			
First Name			
Registration Number			
Business Address			
Contact Number 1		Contact Number 2	
Email Address			

By signing this document, the healthcare practitioner is attesting that the information contained in this document is correct and complete.

Healthcare Practitioner's Signature			
Healthcare Practitioner's Stamp			
Dispensary's Name (in BLOCK letters) and Stamp			
Signature		Date	dd/mm/yyyy

Appendix 4.

INSERT MEDICAL PRACTIONER LETTER HEAD HERE

CERTIFICATE FOR THE USE OF MEDICINAL CANNABIS

I, Dr..... Medical

Practitioner, do hereby certify that I have made a thorough and complete examination of Mr./Miss/Mrs.....and found him/her to meet the requirements to qualify for use of medicinal cannabis.

I further certify that I have inquired into his/her mental and family history.

……..	……
Medical Practitioner Signature	Patient Signature
	Patient NIC # …….
Date: ……..	Date……

Appendix 5.

ADVERSE DRUG REACTION REPORTING FORM

A. Patient Information	D. Medicinal Cannabis/Product Infor
1. Name: 2. Date of Birth:	11. Where was the product purchased /obtained
3. Sex: M ❑ F ❑ Other ❑ 4. Weight (in Kg.)	(Name and address of Business/Dispensary)
5. Medical History and other related information	
(allergies, pregnancy, smoking, alcohol use, etc.)	
	12. Product start date (dd/mm/yyyy)
	13. Product end date (dd/mm/yyyy)
	At the time of the adverse reaction, specify:
	14. Dosage 15. Frequency
B. Suspected Adverse Reaction	16. Did you stop the product after the adverse reaction?
6. Event/Reaction start date (dd/mm/yyyy)	❑ Yes ❑ No
7. Event/Reaction stop date (dd/mm/yyyy)	
8. Describe Event/Reaction	17. If the product was stopped, did the adverse reaction stop?
	❑ Yes ❑ No
	18. Was the product restarted after the adverse reaction stopped?
	❑ Yes ❑ No
	19. If the product was restarted, did the adverse reaction return?
	❑ Yes ❑ No
9. How long the the adverse reaction last?	**E. Additional Information**
D. Current Medications	20. Please provide any additonaly information deem relevant
10. Please list the all medications that you are currently on	to this report.
	21. Date of this report (dd/mm/yyyy)
	22. Signature and Name of Receiving Personnel:
	Signature:
	Name:

Appendix 6.

PATIENT TREATMENT AGREEMENT/INFORMED CONSENT
MEDICINAL CANNABIS

I _____understand that I will be receiving a medical document from Dr._____which will authorize me to purchase cannabis for a medicinal purpose.

I hereby acknowledge that I have been provided with information regarding possible risks and benefits of this treatment. I understand that my participation is voluntary and that I have the right to withdraw at any time.

I agree to the following:

a) I will not seek to obtain a medical document to authorize me to purchase cannabis form any other physician during the period for which the cannabis is authorized;

b) I will utilize the cannabis as authorized in the medical document and I will not use the cannabis in larger amounts or more frequently than is authorized in the document;

c) I will not give or sell the prescribed cannabis to anyone else, including friends and family members;

d) I will store the cannabis in a safe place;

e) I understand that if I break any of these conditions, Dr._____may refuse to provide any future medical authorization to purchase cannabis.

Patient's signature	Date