



Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 09 December 2021

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health and Aged Care

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1 Name

This instrument is the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The later of: (a) the day on which Schedule 1 to the <i>Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021</i> commences; and (b) the day after this instrument is registered.	24 December 2021 (paragraph (a) applies)

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Narcotic Drugs Act 1967*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Narcotic Drugs Regulation 2016

1 Section 4 (paragraph (a) of the note to the heading)

Repeal the paragraph.

2 Section 4 (after paragraph (b) of the note to the heading)

Insert:

(ba) cannabis drug;

3 Section 4 (paragraph (g) of the note to the heading)

Repeal the paragraph, substitute:

(g) narcotic drug;

4 Section 4

Repeal the following definitions:

- (a) definition of *cannabis-related licence*;
- (b) definition of *cannabis-related manufacture licence*;
- (c) definition of *cannabis-related manufacture permit*;
- (d) definition of *cannabis-related permit*.

5 Section 4 (definition of certified true copy)

Omit “under regulation 4 of the *Statutory Declarations Regulations 1993*”, substitute “by section 7 of the *Statutory Declarations Regulations 2018*”.

6 Section 4

Insert:

commercial medicinal cannabis licence: see subsection 54A(4).

minor licence variation, in relation to a medicinal cannabis licence, means a variation to:

- (a) if the licence specifies a period for which the licence is in force—the period for which the licence is in force; or
- (b) remove a person specified by the licence as a person who is authorised by the licence to engage in the activities authorised by the licence; or
- (c) if the licence holder is a body corporate and the body’s name changes—update the name of the licence holder.

minor permit variation, in relation to a medicinal cannabis permit, means a variation to:

- (a) if the permit specifies the size of the cannabis crop that may be cultivated—reduce the size of the cannabis crop that may be cultivated; or
- (b) if the permit specifies the types of cannabis plants that may be cultivated—the number of each type of cannabis plant that may be cultivated provided the variation does not increase the total number of cannabis plants that:
 - (i) are of a type that has a higher level of tetrahydrocannabinol; and
 - (ii) could be cultivated under the permit before the proposed variation.

non-commercial medicinal cannabis licence: see subsection 54A(1).

7 Section 4 (definition of *starting material*)

Repeal the definition (including the note), substitute:

starting material, in relation to a cannabis or narcotic drug, means a drug used in the manufacture of the cannabis or narcotic drug.

8 Section 4 (definition of *variation application classification document*)

Repeal the definition.

9 At the end of Part 1

Add:

4B Permitted supply

For the purposes of paragraph (e) of the definition of *permitted supply* in subsection 4(1) of the Act, the following circumstances are prescribed:

- (a) the supply of a cannabis drug to a pharmacist in a public hospital for the purposes of that pharmacist dispensing the drug in accordance with the *Therapeutic Goods Act 1989*;
- (b) the supply of a cannabis drug for export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*;
- (c) the supply of a cannabis drug to a person who holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person in the manufacture of a medicine (within the meaning of that Act);
- (d) the supply of a cannabis drug that is registered goods within the meaning of the *Therapeutic Goods Act 1989*;
- (e) the supply of a cannabis drug to a person who holds a medicinal cannabis licence that authorises the manufacture of a cannabis drug.

10 Part 2 (heading)

Repeal the heading, substitute:

Part 2—Medicinal cannabis licences and permits

11 Paragraph 5(2)(f) (note)

Repeal the note.

12 Paragraphs 5(2)(g) to (o)

Repeal the paragraphs, substitute:

- (g) the following details relating to the location where the activities to be authorised by the licence will be undertaken:
 - (i) the physical address or, if there is no physical address, the location expressed in geographic coordinates;
 - (ii) the total area of land at the location and the area of that land that will be used for the activities;
 - (iii) details of the premises and facilities at the location where the activities will be undertaken;

- (iv) the zoning of the land at the location;
- (v) the applicant's legal right to use or occupy the premises at the location;
- (h) details of the measures that the applicant will take to ensure the following in relation to cannabis plants or cannabis drugs that are in the applicant's possession or control and that are obtained, cultivated, produced or manufactured under, or purportedly under, the licence:
 - (i) the physical security of the cannabis plants or cannabis drugs;
 - (ii) the safety and security of the supply, delivery and transportation of the cannabis plants or cannabis drugs;
 - (iii) the establishment of arrangements between the applicant and emergency services (including a police service or relevant local government authority) to deal with loss, theft, spoilage, disposal and destruction of the cannabis plants or cannabis drugs;
- (i) details of the measures that the applicant will take to ensure the suitability of persons employed or engaged by the applicant for the purposes of carrying out activities authorised by the licence;
- (j) if the applicant proposes to supply to a recipient cannabis plants cultivated, or cannabis or cannabis resin produced, under, or purportedly under, the licence—the purpose for which the cannabis plants, cannabis or cannabis resin are to be supplied;
- (k) if the applicant is seeking a decision of the Secretary under paragraph 54A(1)(c) that the activities that the applicant proposes to undertake under the licence will be undertaken for, or primarily for, medical or scientific research that is for a non-commercial purpose—details of the following:
 - (i) the primary purpose of the activities and research;
 - (ii) who will benefit from the activities and research;
 - (iii) how any products that may be developed as a result of the activities and research will be used;
 - (iv) the source of the funds for the activities and research;
 - (v) who owns and operates the facilities at which the activities and research are to be undertaken;
- (l) the name of each person who is to be authorised by the licence to engage in the activities authorised by the licence.

13 Paragraph 5(3)(d)

Omit “the applicant's reputation, character, honesty or professional or person integrity”, substitute “whether the applicant is a fit and proper person to hold a licence”.

14 Paragraph 5(4)(f)

Omit “the reputation, character, honesty or professional or personal integrity of such directors and officers”, substitute “whether the applicant is a fit and proper person to hold a licence”.

15 After subsection 5(4) (before the note)

Insert:

Additional information required if applicant proposes to manufacture a cannabis drug

- (5) If the applicant proposes to manufacture a cannabis drug, the application must also contain the following:
- (a) if the drug is to be supplied for use in a clinical trial that is, or is likely to be, approved under the *Therapeutic Goods Act 1989* or notified to the Secretary under that Act—information about the clinical trial in which the drug is to be used;
 - (b) if the drug is to be supplied in accordance with an approval or authority under that Act—information about that approval or authority;
 - (c) if the drug is to be supplied to a person who holds a licence under Part 3-3 of that Act for use by that person in the manufacture of a medicine (within the meaning of that Act)—information about the licence and the holder of the licence;
 - (d) if the drug is registered goods within the meaning of that Act—the number assigned to the registered goods on the Australian Register of Therapeutic Goods maintained under section 9A of that Act;
 - (e) if the drug is to be supplied to a pharmacist in a public hospital for the purposes of the pharmacist dispensing the drug in accordance with that Act—information about the hospital;
 - (f) if the drug is to be supplied for use in medical or scientific research where that research is not a clinical trial referred to in paragraph (a) and does not involve the drug being administered to humans—information about the research including the name of the entity undertaking the research;
 - (g) if the drug is to be supplied for use as a reference standard for medical or scientific testing purposes—information about the proposed use of the reference standard;
 - (h) if the drug is to be supplied for export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*—information about the licence and permission;
 - (i) if the drug is to be supplied to a person who holds a medicinal cannabis licence that authorises the manufacture of a cannabis drug—information about the licence and the holder of the licence.

16 After paragraph 6(2)(a)

Insert:

- (ab) a current and historical company extract search of the records of the Australian Securities and Investments Commission in relation to the applicant, that is carried out no more than 30 days before the application is made;

17 Paragraphs 6(2)(c) to (f)

Repeal the paragraphs, substitute:

- (c) a site plan for the location where the activities to be authorised by the licence will be undertaken showing how the land at the location will be used;
- (d) a detailed floor plan of the facilities at the location where the activities to be authorised by the licence will be undertaken;

- (e) a copy of the standard operating procedures and policies that deal with the following matters in relation to the location where the activities to be authorised by the licence will be undertaken:
 - (i) the measures to be used to prevent unauthorised access (physical and electronic);
 - (ii) the equipment to be used to prevent, monitor, detect and record unauthorised access;
 - (iii) the measures to be used for physical security at the location;
- (f) such documents as are necessary to establish the applicant's legal right to use or occupy the premises where the activities to be authorised by the licence will be undertaken.

18 Section 7A

Omit "a licence", substitute "a medicinal cannabis licence".

19 Section 7B

Repeal the section, substitute:

7B Matters to be specified in a medicinal cannabis licence—persons prescribed

For the purposes of paragraph 8M(e) of the Act, the following persons are prescribed as persons who are authorised by a medicinal cannabis licence to engage in the activities authorised by the licence:

- (a) the licence holder;
- (b) the person who holds a managerial or supervisory position that has direct control over the activities authorised by the licence;
- (c) the person responsible for controlling on a daily basis the activities authorised by the licence.

20 Paragraph 8(2)(c)

Omit ", in relation to cultivation or production, or cultivation and production,".

21 At the end of subsection 8(2)

Add:

- ; (d) the period for which the permit would need to be in force;
- (e) details of how access will be provided to the premises at which activities authorised by the licence are to be undertaken for the purposes of the Secretary, or a person authorised by the Secretary, inspecting such premises.

22 Subsection 8(3)

Omit "a licence", substitute "a medicinal cannabis licence".

23 After paragraph 8(3)(b)

Insert:

- (c) the total area of the land to be used to cultivate the proposed plants;

24 Paragraph 8(3)(g)

Omit "propagation;", substitute "propagation.".

25 Paragraph 8(3)(h)

Repeal the paragraph.

26 Subsection 8(4)

Omit “a licence”, substitute “a medicinal cannabis licence”.

27 Paragraph 8(4)(b)

Omit “, including for the lawful supply of cannabis or cannabis resin”.

28 At the end of section 8

Add:

Medicinal cannabis permits—manufacture

- (5) An application for a medicinal cannabis permit that relates to a medicinal cannabis licence that authorises the manufacture of a cannabis drug must also contain the following information:
- (a) the cannabis drug proposed to be manufactured;
 - (b) the proposed use of the manufactured cannabis drug;
 - (c) the maximum quantity of the cannabis drug that is proposed to be manufactured;
 - (d) the maximum quantity of the cannabis drug that, in the opinion of the applicant, having regard to prevailing market conditions, it will be necessary for the applicant to have in the applicant’s possession or control at any time for the normal conduct of business;
 - (e) the period during which the cannabis drug is to be manufactured;
 - (f) the starting materials to be used in the manufacture of the cannabis drug, the source of the starting materials and the amounts of the starting materials required to manufacture the cannabis drug.

29 Section 9

Repeal the section, substitute:

9 Application for medicinal cannabis permit—document requirements

For the purposes of paragraph 8P(2)(c) of the Act, the following documents are prescribed as documents that must accompany an application by the holder of a medicinal cannabis licence for a medicinal cannabis permit:

- (a) if the application is for the first permit relating to the location where the activities authorised by the licence will be undertaken—a copy of the risk management plan that will be used to manage risks associated with the activities authorised by the licence, including risks posed to the health and safety of people and risks posed to the environment;
- (b) if the application is for the first permit relating to the location where the activities authorised by the licence will be undertaken—a copy of the standard operating procedures and policies that deal with the following matters in relation to that location:
 - (i) how persons entering the location will be controlled;
 - (ii) how unauthorised access at the location will be prevented, monitored, detected and recorded;

- (iii) the physical security being used to prevent, monitor and detect the loss of cannabis plants, cannabis drugs and starting materials relating to such drugs;
- (iv) the loss and theft of cannabis plants, cannabis drugs and starting materials relating to such drugs;
- (v) the disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs;
- (vi) the supply, delivery and transportation of cannabis plants, cannabis drugs and starting materials relating to such drugs;
- (vii) the arrangements with emergency services (including a police service or relevant local government authority) to deal with loss, theft, spoilage, disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs;
- (viii) the retention of records;
- (ix) the engagement and retention of suitable staff;
- (c) if the application is for a permit that relates to a medical cannabis licence that authorises the cultivation of cannabis plants or the production of cannabis or cannabis resin but does not authorise the manufacture of a cannabis drug—copies of all contracts that are in place between the applicant for the permit and a person who is authorised by a medicinal cannabis licence to do any of the following:
 - (i) supply cannabis plants;
 - (ii) produce cannabis or cannabis resin;
 - (iii) manufacture a cannabis drug.

30 At the end of Division 1 of Part 2

Add:

11 Application for medicinal cannabis permit—particular grounds for refusal of permit

For the purposes of subparagraph 9(4)(d)(ii) of the Act, a purpose is the supply of the cannabis or cannabis resin to a person where one or more of the following apply:

- (a) the person holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person of cannabis or cannabis resin in the manufacture of a medicine (within the meaning of that Act);
- (b) the person is a pharmacist in a public hospital and the supply is for the purposes of that person dispensing the cannabis or cannabis resin in accordance with that Act;
- (c) the person holds an approval under subsection 19(1) of that Act to supply cannabis or cannabis resin for use solely for experimental purposes in humans;
- (d) the person is authorised under State or Territory legislation to obtain, possess and hold cannabis or cannabis resin for testing or research;
- (e) the person holds a licence under the *Customs (Prohibited Exports) Regulations 1958* to export cannabis or cannabis resin.

31 Division 2 of Part 2

Repeal the Division.

32 Division 3 of Part 2 (heading)

Before “cannabis”, insert “medicinal”.

33 Before section 18

Insert:

17 Condition that medicinal cannabis licence holder must only use seeds, cultivars or other genetic material of cannabis plants obtained from legitimate sources

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that the licence holder must only use seeds, cultivars or other genetic material of a cannabis plant obtained in a way that is permitted by the laws of Australia.

17A Condition that medicinal cannabis licence holder must give information relating to activities authorised by licence if requested

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that, if the licence holder receives a request, in writing, from the Secretary for information relating to the activities authorised by the licence, the licence holder must provide the requested information within the period specified in the request (which must not be less than 14 days).

17B Condition that medicinal cannabis licence holder must retain records

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that the licence holder must keep records that relate to the activities authorised by the licence for the period:

- (a) beginning when the record came into existence; and
- (b) ending 5 years after that time.

17C Condition that medicinal cannabis licence holder must notify emergency services

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that the licence holder must ensure that:

- (a) the following information is provided to the fire service and police service that have responsibility for the area in which the activity authorised by the licence is undertaken:
 - (i) the address of the premises at which the activity authorised by the licence is undertaken;
 - (ii) the name, position and contact details of a contact person from whom information may be obtained;
 - (iii) a general description of the activity authorised by the licence; and
- (b) the information provided under paragraph (a) is kept up-to-date.

17D Condition that medicinal cannabis licence holder must notify Secretary of certain information

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that the licence holder must ensure that:

- (a) the following information is provided to the Secretary, in writing, before commencing an activity authorised by the licence for the first time:
 - (i) the name, position, phone number and email address of a contact person from whom information about the activity may be obtained;
 - (ii) if the licence holder is a body corporate—the name, position with the licence holder, phone number and email address of an officer or employee of the licence holder that has authority to act, or receive notices, for the licence holder; and
- (b) any changes to the information provided under paragraph (a) is provided to the Secretary, in writing, within 72 hours of that change occurring.

17E Condition that medicinal cannabis licence holder must operate in accordance with risk management plan and standard operating procedures

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that the licence holder must, when undertaking the activities authorised by the licence, operate in accordance with:

- (a) the risk management plan that relates to the management of risks associated with the activities authorised by the licence; and
- (b) the standard operating procedures and policies that relate to the activities authorised by the licence.

17F Condition that medicinal cannabis licence holder must maintain system of security

For the purposes of paragraph 10C(b) of the Act, it is a condition of a medicinal cannabis licence that the licence holder must maintain at all times a system of security that prevents illegal or unauthorised removal of cannabis plants or cannabis drugs from the location where the activities authorised by the licence are undertaken.

34 Section 18 (heading)

Before “cannabis”, insert “medicinal”.

35 Paragraph 18(1)(a)

Repeal the paragraph.

36 Subsection 18(2)

Before “cannabis licence”, insert “medicinal”.

37 Subsection 19(2)

Omit “subsection 10J(2)”, substitute “paragraph 10J(2)(c)”.

38 Subsection 19(2)

Omit “subsection” (second occurring), substitute “paragraph”.

39 Subsection 19(3)

After “subsection (4)”, insert “of this section”.

40 Subsection 19(6)

After “subsection (7)”, insert “of this section”.

41 Subsection 19(6)

Omit “subsection 10J(2)”, substitute “paragraph 10J(2)(c)”.

42 Subparagraph 19(7)(a)(ii)

Repeal the subparagraph, substitute:

- (ii) the holder of another medicinal cannabis licence that authorises the manufacture of a cannabis drug;

43 Paragraph 19(7)(a)

Omit “licence under the Act” (last occurring), substitute “medicinal cannabis licence”.

44 Subsection 19(9)

Omit “subsection 10J(2)”, substitute “paragraph 10J(2)(c)”.

45 Section 20 (heading)

Before “cannabis”, insert “medicinal”.

46 Subsection 20(1)

Before “cannabis licence”, insert “medicinal”.

47 Paragraphs 20(1)(b) to (d)

Omit “cannabis or cannabis resin”, substitute “cannabis drugs or starting materials in relation to such drugs”.

48 Paragraph 20(1)(e)

Omit “cannabis or cannabis resin” (first occurring), substitute “cannabis drugs or starting materials in relation to such drugs”.

49 Paragraph 20(1)(e)

Omit “cannabis or cannabis resin” (last occurring), substitute “cannabis drugs or starting materials”.

50 Paragraph 20(1)(f)

Omit “cannabis or cannabis resin” (first occurring), substitute “cannabis drugs or starting materials in relation to such drugs”.

51 Paragraph 20(1)(f)

Omit “cannabis or cannabis resin” (last occurring), substitute “cannabis drugs or starting materials”.

52 Subparagraph 20(1)(h)(iii)

Before “permit”, insert “a medicinal cannabis”.

53 After paragraph 20(1)(h)

Insert:

- (ha) the licence holder commences to manufacture a cannabis drug under the licence;

54 After paragraph 20(1)(i)

Omit “cultivation, production or any other activities”, substitute “an activity”.

55 Subparagraph 20(1)(n)(ii)

Repeal the subparagraph, substitute:

- (ii) the holder of another medicinal cannabis licence that authorises the manufacture of a cannabis drug;

56 Subsection 20(2)

Repeal the subsection, substitute:

- (2) For the purposes of paragraph 10K(2)(a) of the Act, the licence holder must notify the Secretary within the following periods:
- (a) for a matter covered by paragraph (1)(a), (b), (c), (d), (e) or (f) of this section—within 24 hours starting when the matter comes to the attention of the licence holder;
 - (b) for a matter covered by paragraph (1)(g) of this section—within 20 business days starting on the day the licence holder is notified of the finding or recommendation;
 - (c) for a matter covered by paragraph (1)(l) of this section—within 20 business days starting on the day the licence holder is notified of the inquiry or investigation.

57 Division 4 of Part 2 (heading)

Before “cannabis” (wherever occurring), insert “**medicinal**”.

58 Subdivision A of Division 4 of Part 2 (heading)

Omit “cannabis licences and permits”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

59 Section 21

Repeal the section, substitute:

21 Circumstances in which medicinal cannabis licences and medicinal cannabis permits must not be varied

- (1) This section is made for the purposes of paragraph 10M(3)(b) of the Act.
- (2) A medicinal cannabis licence must not be varied on application by the licence holder if, had the proposed variation been included as part of the application for the licence, the Secretary would have been required to refuse to grant the licence under section 8G or 8J of the Act.
- (3) A medicinal cannabis permit that relates to a medicinal cannabis licence must not be varied on application by the licence holder if, had the proposed variation been included as part of the application for the permit, the Secretary would have been required to refuse to grant the permit under subsection 9(4) of the Act.

60 Section 22 (heading)

Omit “cannabis licence or permit”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

61 Section 22

Before “cannabis” (wherever occurring), insert “medicinal”.

62 Section 23 (heading)

Omit “cannabis licence or permit”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

63 Section 23

Before “cannabis” (wherever occurring), insert “medicinal”.

64 Section 24 (heading)

Omit “cannabis licence or permit”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

65 Section 24

Before “cannabis” (wherever occurring), insert “medicinal”.

66 Subdivision B of Division 4 of Part 2 (heading)

Omit “cannabis licences and permits”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

67 Section 25 (heading)

Omit “cannabis licences and permits”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

68 Section 25

Before “cannabis” (wherever occurring), insert “medicinal”.

69 Section 26 (heading)

Omit “cannabis licences and permits”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

70 Subsections 26(1) and (2)

Before “cannabis” (wherever occurring), insert “medicinal”.

71 Paragraph 26(3)(a)

Before “cannabis licence”, insert “medicinal”.

72 Paragraph 26(3)(b)

Omit “cannabis or cannabis resin”, substitute “a cannabis drug or starting material in relation to such a drug”.

73 Subsection 26(4)

Repeal the subsection.

74 Paragraph 26(5)(b)

Repeal the paragraph, substitute:

- (b) if the licence or permit ceases to be in force during the period of the suspension—the day the licence or permit ceases to be in force;

75 Subsection 26(6)

After “period of”, insert “the”.

76 Section 27

Repeal the section, substitute:

27 Secretary may permit specified activities to occur during suspension of medicinal cannabis licences

- (1) This section applies if a medicinal cannabis licence is suspended by the Secretary under subsection 26(1).
- (2) The Secretary may, in the notice given under subsection 26(1) relating to the suspension, permit the licence holder during the period of the suspension to do any of the following:
 - (a) if the suspended licence authorised the cultivation of cannabis plants—engage in specified cultivation of cannabis plants in accordance with conditions specified in the notice;
 - (b) if the suspended licence authorised the production of cannabis or cannabis resin—engage in specified production of cannabis or cannabis resin in accordance with conditions specified in the notice;
 - (c) if the suspended licence authorised the manufacture of a cannabis drug—engage in specified manufacture of a cannabis drug in accordance with conditions specified in the notice;
 - (d) if the suspended licence authorised activities relating to the cultivation of cannabis plants, the production of cannabis or cannabis resin or the manufacture of a cannabis drug—engage in specified activities relating to such cultivation, production or manufacture in accordance with conditions specified in the notice.

27A Secretary may permit specified activities to occur during suspension of medicinal cannabis permits

- (1) This section applies if a medicinal cannabis permit is suspended by the Secretary under subsection 26(1) and the permit relates to a medicinal cannabis licence that has not been suspended under that subsection.
- (2) The Secretary may, in the notice given under subsection 26(1) relating to the suspension, permit the licence holder during the period of the suspension to do any of the following:
 - (a) if the suspended permit relates to a licence that authorises the cultivation of cannabis plants—engage in specified cultivation of cannabis plants authorised by the licence in accordance with the permit in accordance with conditions specified in the notice;
 - (b) if the suspended permit relates to a licence that authorises the production of cannabis or cannabis resin—engage in specified production of cannabis or

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- cannabis resin authorised by the licence in accordance with the permit in accordance with conditions specified in the notice;
- (c) if the suspended permit relates to a licence that authorises the manufacture of a cannabis drug—engage in specified manufacture of a cannabis drug authorised by the licence in accordance with the permit in accordance with conditions specified in the notice.

77 Section 28 (heading)

Omit “**cannabis licence or permit**”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

78 Subsections 28(1), (3) and (5)

Before “cannabis” (wherever occurring), insert “medicinal”.

79 Section 29

Repeal the section, substitute:

29 Effect of suspension of medicinal cannabis licences

- (1) If a medicinal cannabis licence is suspended under subsection 26(1):
- (a) activities authorised by the licence must not be carried out during the period of the suspension; and
 - (b) any medicinal cannabis permit that relates to the licence is suspended while the licence is suspended; and
 - (c) the licence, and any permit that relates to the licence, remains in force while the licence is suspended.
- (2) Despite subsection (1), the licence holder may during the period of the suspension:
- (a) if the Secretary specified activities in the notice given to the licence holder under subsection 26(1) in relation to the suspended licence—engage in the specified activities subject to any conditions specified in the notice; and
 - (b) if the suspended licence authorised the cultivation of cannabis plants—tend, nurture, harvest or store cannabis plants in the licence holder’s possession or control as authorised by the licence at the time of the suspension of the licence; and
 - (c) if the suspended licence authorised the production of cannabis or cannabis resin—store, possess and control cannabis or cannabis resin in the licence holder’s possession or control as authorised by the licence at the time of the suspension of the licence; and
 - (d) if the suspended licence authorised the manufacture of a cannabis drug—store, possess and control:
 - (i) the cannabis drugs in the licence holder’s possession or control as authorised by the licence at the time of the suspension of the licence; and
 - (ii) starting material relating to such drugs in the licence holder’s possession or control at the time of the suspension of the licence.

29A Effect of suspension of medicinal cannabis permits

- (1) If a medicinal cannabis permit is suspended under subsection 26(1) and the permit relates to a medicinal cannabis licence that is not suspended under that subsection:
 - (a) activities authorised by the licence to be undertaken in accordance with the permit must not be carried out during the period that the permit is suspended; and
 - (b) the permit remains in force while it is suspended.
- (2) Despite subsection (1), the licence holder may during the period of the suspension:
 - (a) if the Secretary specified activities in the notice given to the licence holder under subsection 26(1) in relation to the suspended permit—engage in the specified activities subject to any conditions specified in the notice; and
 - (b) if the suspended permit relates to a licence that authorises the cultivation of cannabis plants—tend, nurture, harvest or store cannabis plants in the licence holder’s possession or control as authorised by the licence at the time of the suspension of the permit; and
 - (c) if the suspended permit relates to a licence that authorises the production of cannabis or cannabis resin—store, possess and control cannabis or cannabis resin in the licence holder’s possession or control as authorised by the licence at the time of the suspension of the permit; and
 - (d) if the suspended permit relates to a licence that authorises the manufacture of a cannabis drug—store, possess and control:
 - (i) the cannabis drugs in the licence holder’s possession or control as authorised by the licence at the time of the suspension of the permit; and
 - (ii) starting material relating to such drugs in the licence holder’s possession or control at the time of the suspension of the permit.

80 Section 30 (heading)

Omit “cannabis licence or permit”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

81 Subsection 30(1)

Before “cannabis” (wherever occurring), insert “medicinal”.

82 Section 31 (heading)

Omit “cannabis licence or permit”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

83 Subsection 31(1)

Before “cannabis” (wherever occurring), insert “medicinal”.

84 Subsection 31(2)

Omit “cannabis licence, or a”, substitute “medicinal cannabis licence, or a medicinal cannabis”.

85 Section 32 (heading)

Omit “**production during suspension**”, substitute “**activity during suspension of licence or permit**”.

86 Subsection 32(1)

Repeal the subsection, substitute:

- (1) A person contravenes this subsection if:
- (a) the person is the holder of a medicinal cannabis licence; and
 - (b) the licence, or a medicinal cannabis permit that relates to the licence, is suspended under subsection 26(1); and
 - (c) the Secretary permitted specified activities to occur during the period of the suspension in accordance with conditions specified in the notice given under subsection 26(1); and
 - (d) the person fails to comply with a condition.

87 Subsections 32(2) and (3) (note)

Repeal the note.

88 Subdivision C of Division 4 of Part 2 (heading)

Omit “**cannabis licences and permits**”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

89 Section 33 (heading)

Omit “**cannabis licences and permits**”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

90 Section 33

Before “cannabis” (wherever occurring), insert “medicinal”.

91 Section 34 (heading)

Omit “**cannabis licence or permit**”, substitute “**medicinal cannabis licences and medicinal cannabis permits**”.

92 Subsection 34(1)

Before “cannabis” (wherever occurring), insert “medicinal”.

93 Paragraph 34(2)(e)

Omit “plants, cannabis or cannabis resin”, substitute “plants or cannabis drug”.

94 Subparagraph 34(2)(e)(i)

Omit “licence under the Act”, substitute “medicinal cannabis licence”.

95 Paragraph 34(2)(f)

Omit “or production”, substitute “, production or manufacture”.

96 Part 3 (heading)

Before “**drugs**”, insert “**narcotic**”.

97 Paragraph 35(2)(fa)

Repeal the paragraph.

98 Paragraph 35(2)(g)

Omit “drugs”, substitute “narcotic drug”.

99 Paragraph 35(2)(h)

Omit “drugs” (first occurring), substitute “narcotic drug”.

100 Subparagraph 35(2)(i)(i)

Omit “drugs”, substitute “the narcotic drug”.

101 Subparagraph 35(2)(i)(vi)

Omit “land,” (wherever occurring).

102 Paragraph 35(2)(j)

Omit “drugs or starting material”, substitute “the narcotic drug or starting material in relation to such a drug”.

103 Subsection 35(8) (not including the note)

Repeal the subsection.

104 Section 36AA

Repeal the section.

105 Section 37

Repeal the section, substitute:

37 Matters to be specified in a manufacture licence—persons prescribed

For the purposes of paragraph 11N(e) of the Act, the following persons are prescribed as persons who are authorised by a manufacture licence to engage in the activities authorised by the licence:

- (a) the licence holder;
- (b) the person who holds a managerial or supervisory position that has direct control over the activities authorised by the licence;
- (c) the person responsible for controlling on a daily basis the activities authorised by the licence.

106 Paragraph 38(2)(c)

Omit “drugs”, substitute “narcotic drug”.

107 Paragraph 38(2)(e)

Omit “drugs”, substitute “narcotic drug”.

108 Paragraph 38(2)(f)

Omit “drugs that are proposed”, substitute “narcotic drug that is”.

109 Paragraph 38(2)(g)

Omit “drugs”, substitute “narcotic drug”.

110 Paragraph 38(2)(h)

Omit “drugs are”, substitute “narcotic drug is”.

111 Section 38A

Repeal the section.

112 Paragraph 39(1)(a)

Repeal the paragraph.

113 Paragraphs 40(1)(b), (c) and (d)

Omit “drugs or starting material”, substitute “narcotic drugs or starting materials in relation to such drugs”.

114 Paragraph 40(1)(e)

Omit “drugs or starting material” (first occurring), substitute “narcotic drugs or starting materials in relation to such drugs”.

115 Paragraph 40(1)(e)

Omit “drugs or starting material” (last occurring), substitute “narcotic drugs or starting materials”.

116 Paragraph 40(1)(f)

Omit “drugs or starting material” (first occurring), substitute “a narcotic drug or starting material in relation to such a drug”.

117 Paragraph 40(1)(f)

Omit “drugs or starting material” (last occurring), substitute “narcotic drugs or starting materials”.

118 Subparagraph 40(1)(h)(iii)

Before “permit”, insert “manufacture”.

119 Paragraph 40(1)(i)

Omit “drugs”, substitute “a narcotic drug”.

120 Paragraph 40(1)(j)

Repeal the paragraph, substitute:

- (j) the licence holder ceases to undertake, or proposes to cease undertaking, the manufacture of a narcotic drug or any other activities authorised by the licence;

121 Section 41

Repeal the section, substitute:

41 Circumstances in which a manufacture licence or manufacture permit must not be varied

- (1) This section is made for the purposes of paragraph 13(3)(b) of the Act.
- (2) A manufacture licence must not be varied on application by the licence holder if, had the proposed variation been included as part of the application for the licence, the Secretary would have been required to refuse to grant the licence under section 11J of the Act.
- (3) A manufacture permit that relates to a manufacture licence must not be varied on application by the licence holder if, had the proposed variation been included as part of the application for the permit, the Secretary would have been required to refuse to grant the permit under subsection 12A(4) of the Act.

122 Section 43A

Repeal the section.

123 Section 44

Before “permits”, insert “manufacture”.

124 Paragraph 45(3)(b)

Omit “drugs or narcotic preparations or starting materials”, substitute “a narcotic drug or starting material in relation to such a drug”.

125 Subsection 45(4)

Repeal the subsection.

126 Paragraph 45(5)(b)

Repeal the paragraph, substitute:

- (b) if the licence or permit ceases to be in force during the period of the suspension—the day the licence or permit ceases to be in force;

127 Subsection 45(6)

After “period of”, insert “the”.

128 Subsection 46(6)

Before “licence holder”, insert “manufacture”.

129 Section 47

Repeal the section, substitute:

47 Effect of suspension of manufacture licences

- (1) If a manufacture licence is suspended under subsection 45(1):
 - (a) activities authorised by the licence must not be carried out during the period of the suspension; and
 - (b) any manufacture permit that relates to the licence is suspended while the licence is suspended; and
 - (c) the licence, and any permit that relates to the licence, remain in force while the licence is suspended.

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- (2) Despite subsection (1), the licence holder is authorised during the period of the suspension to store, possess and control any narcotic drugs in the licence holder's possession or control as authorised by the licence at the time of the suspension.

47A Effect of suspension of manufacture permit

- (1) If a manufacture permit is suspended under subsection 45(1) and the permit relates to a manufacture licence that is not suspended under that subsection:
- (a) activities authorised by the licence to be undertaken in accordance with the permit must not be carried out during the period that the permit is suspended; and
 - (b) the permit remains in force while it is suspended.
- (2) Despite subsection (1), the licence holder is authorised during the period of the suspension to store, possess and control any narcotic drugs in the licence holder's possession or control as authorised by the permit at the time of the suspension.

130 Subsection 49(1)

Omit "(b)" (second occurring), substitute "(c)".

131 Paragraph 51(2)(e)

Omit "any drugs, narcotic preparations or starting materials", substitute "a narcotic drug".

132 Paragraph 52(a)

Before "cannabis" (wherever occurring), insert "medicinal".

133 Paragraphs 52(b) and (c)

Repeal the paragraphs, substitute:

- (b) a decision under subsection 27(2) to refuse to permit specified activities during a period of suspension of a medicinal cannabis licence;
- (c) a decision under subsection 27A(2) to refuse to permit specified activities during a period of suspension of a medicinal cannabis permit;

134 Paragraph 52(d)

Before "cannabis" (wherever occurring), insert "medicinal".

135 Paragraph 52(h)

Repeal the paragraph, substitute:

- (h) a decision under paragraph 54A(1)(c) about whether the activities an applicant proposes to undertake under a medicinal cannabis licence will be undertaken for, or primarily for, medicinal or scientific research that is for a non-commercial purpose.

136 Paragraphs 52(i) and (j)

Repeal the paragraphs.

137 Subsection 54(1)

Omit "land or".

138 Sections 54A, 54AA and 54AB

Repeal the sections, substitute:

54A Classes of medicinal cannabis licences for the purposes of charge

Non-commercial medicinal cannabis licence

- (1) For the purposes of paragraph 28(1)(e) of the Act, a medicinal cannabis licence is a **non-commercial medicinal cannabis licence** if:
 - (a) if the licence was in effect on the commencement of this section because the licence was preserved under item 2 of Schedule 2 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021*—the Secretary had, in relation to the licence, given a notice under subsection 54A(2), 54AA(3) or 54AB(3) of this instrument, as in force immediately before the commencement of this section; or
 - (b) if the licence was in effect on the commencement of this section because the licence was converted from multiple licences (the **original licences**) into a single licence under item 3 of Schedule 2 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021*—the Secretary had, in relation to one of those original licences, given a notice under subsection 54A(2), 54AA(3) or 54AB(3) of this instrument, as in force immediately before the commencement of this section; or
 - (c) when granting the licence the Secretary notifies the applicant for the licence in writing that the Secretary is reasonably satisfied that the activities the applicant proposes to undertake under the licence will be undertaken:
 - (i) for medical or scientific research that is for a non-commercial purpose; or
 - (ii) primarily for medical or scientific research that is for a non-commercial purpose.
- (2) In making a decision under paragraph (1)(c) about the activities that the applicant proposes to undertake, the Secretary must have regard to the matters mentioned in paragraph 5(2)(j).
- (3) Subsection (2) does not limit the matters to which the Secretary may have regard in making a decision under paragraph (1)(c).

Commercial medicinal cannabis licence

- (4) For the purposes of paragraph 28(1)(e) of the Act, a medicinal cannabis licence is a **commercial medicinal cannabis licence** if a notice referred to in paragraph (1)(a), (b) or (c) has not been given in relation to the licence.

139 Section 55

Omit “land or”.

140 Subparagraph 55(b)(iii)

After “the Act”, insert “or prescribed by these regulations”.

141 Paragraph 56(a)

Omit “a State or Territory”, substitute “the Commonwealth, a State or a Territory”.

142 Paragraph 56(b)

Repeal the paragraph.

143 Paragraphs 56(c) and (d)

Omit “cannabis licence is an agency of a State or Territory”, substitute “medicinal cannabis licence is an agency of the Commonwealth, a State or a Territory”.

144 Paragraphs 56(e) to (g)

Omit “a State or Territory”, substitute “the Commonwealth, a State or a Territory”.

145 At the end of Part 6

Add:

62 Application provisions relating to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*

- (1) Sections 17, 17A, 17B, 17C, 17D, 17E and 17F, as inserted by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, apply in relation to a medicinal cannabis licence held at the commencement of this section or granted on or after the commencement of this section.
- (2) The amendments of sections 20 and 40 made by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021* apply in relation to a matter that comes to the attention of a licence holder on or after the commencement of this section, whether in relation to a licence held at the commencement of this section or granted on or after the commencement of this section.
- (3) If:
 - (a) before the commencement of this section the Secretary had, under subsection 26(1) or 45(1), given to the holder of a licence notice in writing of the suspension of the licence or a permit that relates to the licence (the ***suspension notice***); and
 - (b) immediately before the commencement of this section, either of the following apply:
 - (i) the suspension had not come into effect because the day specified in the notice of suspension had not occurred;
 - (ii) the period of the suspension had started but not ended; and
 - (c) the licence or permit is preserved or converted under item 2 or 3 of Schedule 2 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021*;

then, after the commencement of this section:

- (d) the preserved or converted licence or permit is taken to be suspended under Subdivision B of Division 4 of Part 2 of this instrument as amended by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*; and
- (e) the suspension may be dealt with under that Subdivision as so amended; and
- (f) if the suspension is still to come into effect because the day specified in the notice of suspension has not occurred—the suspension takes effect in accordance with the suspension notice; and

(g) if the suspension notice permits specified activities to occur during the period of the suspension—the permitted activities can occur during the period of the suspension in accordance with the conditions specified in the suspension notice.

(4) If:

- (a) a decision was made under this instrument before the commencement of this section; and
- (b) the decision is a decision of the kind referred to in paragraph 52(b), (c), (h), (i) or (j) as in force immediately before the commencement of this section; and
- (c) immediately before the commencement of this section, the period referred to in paragraph 15G(2)(c) of the Act during which a person may apply for review of the decision has not ended;

despite the amendments of section 52 made by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, Part 4 of Chapter 5 of the Act continues to have effect in relation to the decision as if the amendments had not been made.

(5) If:

- (a) a decision (the **review decision**) was made under section 15H of the Act before the commencement of this section; and
- (b) the review decision relates to a decision of the kind referred to in paragraph (4)(b) of this section; and
- (c) immediately before the commencement of this section, both of the following apply:
 - (i) an application for review of the review decision by the Administrative Appeals Tribunal had not been made;
 - (ii) the time for a person to make such an application has not ended (including any extensions of that time under section 29 of the *Administrative Appeals Tribunal Act 1975*);

despite the amendments of section 52 made by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, sections 15L, 15M and 15N of the Act continue, after the commencement of this section, to have effect in relation to the review decision as if the amendments had not been made.

- (6) The amendments of section 56, made by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, apply in relation to:
- (a) in the case of paragraphs 56(a) and (e)—applications made on or after the commencement of this section; and
 - (b) in the case of paragraphs 56(c), (d), (f) and (g)—licences granted on or after the commencement of this section.

- (7) Clause 1 of Schedule 1, as amended by Schedule 1 to the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, applies in relation to applications made on or after the commencement of this section.

146 Schedule 1

Repeal the Schedule, substitute:

Schedule 1—Application fees

Note: See sections 7, 10 and 24

1 Table of application fees

The following table sets out the amount of the fee that is to accompany an application of a kind mentioned in an item in the table.

Application fees		
Item	Column 1 Kind of application	Column 2 Fee (\$)
1	An application under section 8E of the Act for a medicinal cannabis licence that authorises only one of the activities referred to in paragraph 8E(1)(a), (b) or (c) of the Act	8,030
2	An application under section 8E of the Act for a medicinal cannabis licence that authorises 2 of the activities referred to in paragraph 8E(1)(a), (b) or (c) of the Act	8,650
3	An application under section 8E of the Act for a medicinal cannabis licence that authorises each of the activities referred to in paragraphs 8E(1)(a), (b) and (c) of the Act	9,320
4	An application under section 8P of the Act for a medicinal cannabis permit	3,440
5	An application under section 10N of the Act for a variation of a medicinal cannabis licence that is a minor licence variation	1,100
6	An application under section 10N of the Act for a variation of a medicinal cannabis licence other than an application described in item 5	5,500
7	An application under section 10N of the Act for a variation of a medicinal cannabis permit that is a minor permit variation	120
8	An application under section 10N of the Act for a variation of a medicinal cannabis permit other than an application described in item 7	2,900

Note: For the meaning of *minor licence variation* and *minor permit variation*, see section 4.