

Off-Label Use of Medications



Chief Civil Psychiatrist Clinical Guideline 7

Provisions to Which the Guideline Relates

Mental Health Act 2013 – sections 6, 7, 8, 9, 15, 16, 38, 39, 50, 53, 55, 62 and Schedule 1 (extracted at Appendix 1).

Preamble

Under section 143 of the *Mental Health Act 2013* (the Act), the Chief Civil Psychiatrist has a general overall responsibility, under and to the Minister for Health, for ensuring that the objects of the Act are met in respect of voluntary patients and involuntary patients. This includes ensuring that everyone involved with treatment of mental illness is given clear direction as to their rights and responsibilities, and promoting the making of free and informed treatment choices.

I, Dr Aaron Robert Groves, being and as the Chief Civil Psychiatrist, pursuant to section 151 of the Act hereby issue the following guideline (clinical guideline) to controlling authorities, people in charge of community mental health premises, medical practitioners, nurses and other staff members of approved hospitals, approved assessment centres and community mental health teams in the exercise of responsibilities relating to the use of off-label medications in the treatment of patients under the Act.

Definitions

Registered medicine means a medication that has been approved by the Therapeutic Goods Administration (TGA) for marketing in Australia. All registered medicines will have registered indications for which they are approved for use.

Unregistered medicine means a medication that has not been approved by the TGA for marketing in Australia and that is only available through the TGA's Special Access Scheme (SAS).

Off-label use of a medication means the use of a registered medicine outside of the indications, dosage, route, timeframes or patient group approved by the TGA. For the purposes of this guideline, the requirements specified for the off-label use of a medication also apply to any use of an unregistered medicine.

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Summary

Off-label use of a medication in the treatment of people with mental illness should only occur:

- when the use of registered medicines do not meet the person's clinical needs
- when there is sufficient evidence to support the medication's safe and effective use
- when the benefits associated with the medication's use are likely to outweigh any harms
- when adverse events, outcomes and effectiveness associated with use of the medication can be carefully monitored
- when the reasons for the off-label use have been discussed with the patient and those reasons have been carefully documented in the patient's clinical records
- when the patient has provided informed consent or, if the patient lacks decision making capacity, when informed consent has been given by a parent (if the patient is a child) or when the off-label use is authorised by an approved medical practitioner as urgent circumstances treatment or when the off-label use is authorised by the Mental Health Tribunal via a Treatment Order
- in the knowledge that there may be clinical, safety, ethical, medico-legal and financial issues related to the off-label use of the medication.

Purpose

This Clinical Guideline is intended to provide practical assistance to controlling authorities, people in charge of community mental health premises, medical practitioners, nurses and other staff members of approved hospitals, approved assessment centres and community mental health teams in the exercise of responsibilities relating to the off-label use of medications in the treatment of patients under the Act.

Failure by an individual to comply with this Clinical Guideline may result in professional or occupational disciplinary action being instituted, particularly if the failure leads to unfavourable patient outcomes that might have been avoided had the Guideline been followed; or if there is a history of failure by the individual to comply with this Guideline, or with similar Guidelines in place at the relevant time.

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What Does Off-Label Use of Medication Mean?

Off-label use of medication occurs when a medication is used in ways other than those specified in the TGA-approved product information (PI). This includes when medication is used:

- for a different indication than that specified by the TGA
- at a different dose than that specified by the TGA
- via a different route of administration than that specified by the TGA
- for a longer or shorter period of time than that specified by the TGA
- for a different patient group than that specified by the TGA.

For a medication to be marketed in Australia it must have approval from the TGA. This is to ensure that the medication meets Australian standards for quality, safety and effectiveness.

The approval process is generally initiated by the pharmaceutical company seeking to market the medication (the “sponsor”). The company seeks approval of a medication for use with specific populations and diseases (indications), at set doses and via particular routes of administration. The TGA considers the application and grants approval for the specific indications, doses and routes of administration that have been sought. These elements of the approval are specified in product information provided with the medication or available on the TGA’s Australian Register of Therapeutic Goods. The Australian Government subsidises TGA-approved medications under the Pharmaceutical Benefit Scheme (PBS) when it is demonstrated that the use of the medication is cost-effective.

Pharmaceutical companies pay for costs associated with obtaining TGA approval and this can influence the indications for which approval is sought. As a result, TGA approval for a particular medication may not reflect the range of indications for which the medication may be effective, and safe. This may particularly be the case when medications go “off patent”, when potential markets are small and when new clinical information about a medication becomes available. Under these circumstances it may not be financially viable for the pharmaceutical company to seek approval or re-approval for different indications.

Sponsors also rarely carry out studies in children or the elderly, in pregnant or breast-feeding women, in patients with other medical conditions, and with patients who take other medications, limiting the information that a company may be able to provide to the TGA to support comprehensive approval.

Lack of TGA approval for a particular indication does not mean that a medication is ineffective for that indication.

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Off-Label Use of Medication in Treatment of People with Mental Illness

Off-label use of medication is a very common therapeutic strategy for medical practitioners in many countries including Australia, in both primary care and in specialised settings. In some cases, off-label use may represent the best level of care available. This includes circumstances where registered medicines have not been effective or tolerated, when it is thought that a higher dosage is clinically indicated, for a subgroup of patients in which the medication does not yet have an official indication, and to avoid polypharmacy by using one medication to treat two or more disorders.

Off-label use of medication occurs particularly in paediatrics, palliative care and psychiatry, and off-label use in these settings may often be the only treatment option available. Antidepressants, antipsychotics, mood-stabilisers and anti-anxiety agents are frequently used to treat a range of disorders where there is not a registered medicine, and medications in psychiatry are also frequently used in dosages above TGA-approved ranges.

Principles in Off-Label Use of Medication

There are ethical and legal issues associated with off-label use. There is often less supporting evidence associated with off-label use and lack of TGA approval means that medical practitioners must decide whether the proposed use is appropriate for particular patients rather than relying on TGA approval to this effect. In some cases the information that can be provided to patients about expected benefits and harms associated with the off-label use is limited, which has implications for patients from whom informed consent is required.

The following principles should guide off-label use of medications in the treatment of people with mental illness:

1. Off-label use should only be considered when other options, including registered medicines and non-drug treatments, do not address the patient's clinical needs and when other options have been exhausted or excluded, or are otherwise unsuitable.
2. Off-label use should only occur when the use is supported by evidence and when the benefits associated with using the medication for the particular patient outweigh the risks.
3. The decision to use a medication off-label should withstand logical analysis and meet peer expectations. Independent expert opinion on the proposed off-label use should be sought when appropriate.
4. Particular care should be taken when off-label use in the treatment of children and the elderly, women who are or may be pregnant or breast-feeding, people with other medical conditions, and careful consideration should be given to potential drug interactions when prescribing the off-label use of a medication because the evidence in these areas is often limited.
5. Dosages above the TGA-approved ranges should only be considered when standard treatment dosages have failed and dosages outside the usual range are considered appropriate and necessary.

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6. Any off-label use of medication should commence at the lowest possible dose and adverse effects, outcomes and effectiveness should be closely monitored via regular patient review and with any necessary investigations, including serum monitoring where available and appropriate.
7. Medical practitioners working in the Tasmanian Health Service need to be aware that medicines may be prescribed in hospital settings from the Tasmanian Medicines Formulary and in community settings via community pharmacies for both PBS and non-PBS medications, and that different rules and regulations apply in each circumstance. Importantly, some TGA-registered medicines in the formulary are approved for non-TGA registered indications. Some medicines listed in the Formulary are unregistered medicines (not TGA approved) and are only available via the TGA's Special Access Scheme (SAS) with application or notification to the TGA required as well as informed consent for use of an unregistered medicine.
8. Formulary-listed unregistered medicines or unregistered indications have been assessed for safety, efficacy and cost-effectiveness prior to Formulary listing and the approved indications have been endorsed by a multidisciplinary panel. As such, off-label use in that indication can be considered as "routine use". Gaining informed consent for even routine off-label use of a registered medication is still considered best practice, and informed consent is a requirement for all unregistered medicines. Particular care should be taken, however, when an inpatient moves back to the community, as community prescribers not working under the Tasmanian Medicines Formulary may need to review consent requirements for medicines that are now clearly off-label and not covered by the Formulary provisions.
9. The anticipated benefits and the potential risks, as well as any alternative treatment options, should be fully explained to the patient and, if appropriate, to the patient's family and/or support persons, and to the Mental Health Tribunal if the patient lacks decision-making capacity.
10. The patient, their family and any support persons should be closely involved in any decision involving off-label use of medication.
11. For patients with decision-making capacity, informed consent for the off-label use of medication should be obtained.
12. For children who lack decision-making capacity, informed consent for the off-label use of medication should be obtained from a parent.
13. For involuntary patients, off-label use of medication should be authorised by the Mental Health Tribunal by way of a Treatment Order, or by an approved medical practitioner as a form of urgent circumstances treatment.

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14. Off-label use of medications should only be authorised by an approved medical practitioner as a form of urgent circumstances treatment when dosages of medication outside of the PI are required and when careful monitoring for adverse effects will be undertaken. All decisions about off-label use of medications in the treatment of people with mental illnesses should be carefully documented, and the fact that off-label use has occurred should be explicitly noted. For involuntary patients, this information should be included in the patient's treatment plan, in urgent circumstances treatment documentation and in documentation provided to the Mental Health Tribunal in support of an application to make or vary a Treatment Order.
15. Treatments for which there is low or very low quality evidence should only be used where the potential benefits appear greater than the potential harms, based on the available evidence in the particular clinical circumstance under consideration.
16. Treatments for which there is low or very low quality evidence, uncertain clinical benefit or harms that are unknown or that may be significant should be considered experimental and referred to the Tasmanian Medicines Access and Advisory Committee for review and advice prior to use, unless the use is already endorsed by TMAAC through listing on the Tasmanian Medicines Formulary.

Informed Consent and Treatment that is Authorised as Urgent Circumstances Treatment or by a Treatment Order

Under the Act, a person may be given treatment for a mental illness if the patient gives informed consent, or if the treatment is authorised by an approved medical practitioner as urgent circumstances treatment or by the Mental Health Tribunal via a Treatment Order. For children, informed consent may be given by a parent of the child.

Under the Act, a medical practitioner may regard a person's consent to treatment as being informed if, amongst other matters, the practitioner is satisfied that the person has had a reasonable opportunity to make a considered decision whether or not to give consent. This requires:

- the treating medical practitioner and the person to have discussed the treatment and for the person to have been given an opportunity to disclose his or her priorities, expectations and fears about the treatment
- the person to have been given a clear and candid explanation of the advantages and disadvantages of the treatment, including information about the associated risks and common or expected side effects, and to have been given a similar explanation regarding alternative treatments
- the person to have given answers to any questions the person may have had, and a reasonable opportunity to obtain independent medical advice.

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Where off-label use is being considered the information that is given to the patient (and the patient's parent, if the patient is a child) should include information about the evidence supporting use of the medication, and any uncertainties associated with this.

For involuntary patients, treatment may only be given either with the patient's informed consent, or if the treatment is authorised by an approved medical practitioner as urgent circumstances treatment, or if the treatment is authorised by the Mental Health Tribunal via a Treatment Order. When off-label use of a medication is being considered for the treatment of an involuntary patient, information about the treatment including evidence supporting use of the medication and any uncertainties associated with it should be discussed with and provided to the patient and any representatives or support persons of the patient, and provided to the approved medical practitioner authorising the urgent circumstances treatment or to the Mental Health Tribunal, if the treatment is proposed to be authorised by a Treatment Order.

In all cases, matters relevant to the off-label use of medication in treatment of patients should be reflected in the patient's clinical notes. For involuntary patients, such matters should also be recorded in the patient's Treatment Plan.

Guidance for Controlling Authorities

Controlling authorities of approved assessment centres, approved hospitals and community mental health premises should ensure that staff members who are required, or potentially required, to exercise functions and powers relating to off-label use of medication in treatment of patients under the Act are aware of this Guideline.

Controlling authorities should consider including the following matters within the scope of quality assurance and review activities:

- the extent to which staff know about the Guideline and any local policies and procedures associated with off-label use of medication in the treatment of patients
- the reasons for off-label use of medication in treatment of patients
- the prolonged or repeated off-label use of medication in treatment of patients
- any adverse outcomes associated with the off-label use of medication in treatment of patients
- patient and support person perceptions of off-label use of medication.

Findings from activities conducted should be used to inform the development of training programs for staff.

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Guidance for Clinical Staff

Staff members working within approved assessment centres, approved hospitals and community mental health premises should ensure that they have a sound knowledge of the Act, this Guideline, relevant Chief Civil Psychiatrist Standing Orders and of any local policies and procedures relating to the off-label use of medications in treatment of patients under the Act.

Acknowledgements

This Clinical Guideline draws on the Council of Australian Therapeutic Advisory Groups (2013) *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medications*, the Royal Australian and New Zealand College of Psychiatrists (2018) *Professional Practice Guideline 4: "Off-label" Prescribing in Psychiatry* and the Royal College of Psychiatrists (2017) *Use of Licensed Medicines for Unlicensed Applications in Psychiatric Practice*.

A handwritten signature in black ink, appearing to read 'A. Groves', is positioned above the name of the Chief Civil Psychiatrist.

Dr Aaron Robert Groves

Chief Civil Psychiatrist

Dated 5th June 2019

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Appendix I: Relevant Legislative Provisions

3. Interpretation

adult means a person who has attained the age of 18 years

approved medical practitioner means a psychiatrist or a medical practitioner who is otherwise qualified or experienced in the diagnosis or treatment of mental illness who has been approved by a Chief Psychiatrist for relevant provisions of the Act.

Chief Civil Psychiatrist means the psychiatrist who has been appointed by the Governor pursuant to section 143 of the Act. The Chief Civil Psychiatrist has responsibility for ensuring that the objects of the Act are met in respect of patients other than forensic patients or persons who are subject to supervision orders, and for the running of approved facilities other than secure mental health units.

child means a person who has not attained the age of 18 years

involuntary patient means a person who is subject to an assessment order or treatment order

parent, of a child, means a person having, for the child, all of the responsibilities which, by law, a parent has in relation to his or her children

treating medical practitioner means the medical practitioner who is responsible for a patient's treatment or proposed treatment

treatment order means a treatment order made under Division 2 of Part 3 of Chapter 2 of the Act, and includes an interim treatment order made under section 38 of the Act. A treatment order is authority for a patient, without informed consent, to be given the treatment or type of treatment specified in the order and referred to or specified in the treatment plan for the patient, and for the patient to be admitted to the approved facility or type of approved facility specified in the order and referred to or specified in the treatment plan.

5. Meaning of assessment

For the purposes of the Act, **assessment** is the clinical process involved in diagnosing a condition of a person's mental health and, where necessary, identifying the most appropriate treatment.

6. Meaning of treatment

(1) For the purposes of this Act, **treatment** is the professional intervention necessary to –

- (a) prevent or remedy mental illness; or
- (b) manage and alleviate, where possible, the ill effects of mental illness; or
- (c) reduce the risks that persons with mental illness may, on that account, pose to themselves or others; or
- (d) monitor or evaluate a person's mental state.

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(2) However, this professional intervention does not extend to –

- (a) special psychiatric treatment; or
- (b) a termination of pregnancy; or
- (c) a procedure that could render a person permanently infertile; or
- (d) the removal, for transplantation, of human tissue that cannot thereafter be replaced by natural processes of growth or repair; or
- (e) general health care.

(3) For the purposes of this Act, **treatment** does not include seclusion, chemical restraint, mechanical restraint or physical restraint.

7. Capacity of adults and children to make decisions about their own assessment and treatment

(1) For the purposes of this Act, an adult is taken to have the capacity to make a decision about his or her own assessment or treatment (decision-making capacity) unless a person or body considering that capacity under this Act is satisfied that –

- (a) he or she is unable to make the decision because of an impairment of, or disturbance in, the functioning of the mind or brain; and
- (b) he or she is unable to –
 - (i) understand information relevant to the decision; or
 - (ii) retain information relevant to the decision; or
 - (iii) use or weigh information relevant to the decision; or
 - (iv) communicate the decision (whether by speech, gesture or other means).

(2) For the purposes of this Act, a child is taken to have the capacity to make a decision about his or her own assessment or treatment (decision-making capacity) only if a person or body considering that capacity under this Act is satisfied that –

- (a) the child is sufficiently mature to make the decision; and
- (b) notwithstanding any impairment of, or disturbance in, the functioning of the child's mind or brain, the child is able to –
 - (i) understand information relevant to the decision; and
 - (ii) retain information relevant to the decision; and
 - (iii) use or weigh information relevant to the decision; and
 - (iv) communicate the decision (whether by speech, gesture or other means).

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(3) For the purposes of this section –

- (a) an adult or child may be taken to understand information relevant to a decision if it reasonably appears that he or she is able to understand an explanation of the nature and consequences of the decision given in a way that is appropriate to his or her circumstances (whether by words, signs or other means); and
- (b) an adult or child may be taken to be able to retain information relevant to a decision even if he or she may only be able to retain the information briefly.

(4) In this section –

information relevant to a decision includes information on the consequences of –

- (a) making the decision one way or the other; and
- (b) deferring the making of the decision; and
- (c) failing to make the decision.

8. Meaning of informed consent to assessment or treatment

(1) For the purposes of this Act, a medical practitioner may regard a person's consent to an assessment or a treatment as being informed consent if satisfied that –

- (a) the person, at the time of giving the consent, has decision-making capacity; and
- (b) the person has had a reasonable opportunity to make a considered decision whether or not to give the consent; and
- (c) the person, having had that opportunity, has given the consent freely by some positive means, not by mere acquiescence.

(2) For the purposes of subsection (1)(b) in its application to a treatment, a person may be taken to have had the requisite reasonable opportunity if –

- (a) the treating medical practitioner and the person have discussed the treatment; and
- (b) in those discussions the person was given an opportunity to disclose his or her priorities, expectations and fears about the treatment; and
- (c) following those discussions the person was given –
 - (i) a clear and candid explanation of the advantages and disadvantages of the treatment, including information about the associated risks and common or expected side effects; and
 - (ii) where applicable, a clear and candid explanation of the alternative treatments that may be available, including information about the associated advantages and disadvantages; and
 - (iii) clear and candid answers to any questions the person may have had; and

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(iv) any other information that was considered, by the treating medical practitioner or person, to be of relevant importance and likely to influence the person's decision-making with regard to the treatment; and

(v) a reasonable opportunity to –

(A) obtain independent medical or other advice; and

(B) consider the advantages and disadvantages of giving the consent.

(3) For the purposes of subsection (1)(c), a person is taken to have given consent freely if the consent is given without coercion, pressure or undue influence, whether from another person or a medication.

(4) For the purposes of subsection (2), the information, explanations or answers must have been in a language and form that the person could understand.

(5) Nothing in this Act is to be taken to prevent a person with decision-making capacity from withdrawing his or her consent to an assessment or a treatment before the assessment or treatment is made or provided and, if he or she does so, he or she is not to be taken to have given informed consent to the assessment or treatment.

9. Informed consent for child who lacks capacity to decide on own assessment or treatment

(1) For the purposes of this Act, informed consent for the assessment or treatment of a child who lacks decision-making capacity may be given by a parent of the child.

(2) To avoid doubt, for subsection (1) the informed consent of one parent is sufficient.

(3) Informed consent for the assessment or treatment of a child who lacks decision-making capacity may be withdrawn before the assessment or treatment is made or provided, but only by each parent of the child consenting to the withdrawal of consent.

(4) Nothing in this Act is to be taken to prevent the withdrawal under subsection (3) of consent to an assessment or a treatment before the assessment or treatment is made or provided and, if the consent is withdrawn, informed consent is not to be taken to have been given to the assessment or treatment.

15. Mental health service delivery principles

All persons exercising responsibilities under this Act are to have regard to the mental health service delivery principles set out in Schedule 1.

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16. Circumstances in which treatment may be given

(1) The following policy governs the treatment of voluntary patients under this Act:

- (a) a voluntary patient may be given treatment with informed consent, either as a hospital inpatient or in the community;
- (b) a voluntary patient can never be given treatment without informed consent;
- (c) a voluntary patient may be given special psychiatric treatment if –
 - (i) the treatment is authorised by the Tribunal under Part 6; and
 - (ii) where the treatment is psychosurgery or a treatment that requires informed consent under that Part, informed consent has been given for the treatment;
- (d) a voluntary patient can never be given special psychiatric treatment except as provided by paragraph (c)

(2) The following policy governs the treatment of involuntary patients under this Act who are not forensic patients or involuntary patients to whom section 66 of the Act applies:

- (a) an involuntary patient may be given treatment –
 - (i) with informed consent; or
 - (ii) if the treatment is authorised by a treatment order; or
 - (iii) if the treatment is urgent circumstances treatment, the treatment is authorised under section 55 of the Act;
- (b) an involuntary patient can never be given treatment except as provided by paragraph (a);
- (c) an involuntary patient may be given special psychiatric treatment if –
 - (i) the special psychiatric treatment is authorised by the Tribunal under Part 6 of the Act; and
 - (ii) where the treatment is psychosurgery or a treatment that requires informed consent under that Part, informed consent has been given for the treatment;
- (d) an involuntary patient can never be given special psychiatric treatment except as provided by paragraph (c)

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(3) *The following policy governs the treatment under this Act of forensic patients or involuntary patients to whom section 66 of the Act applies:*

(a) a forensic patient, or an involuntary patient to whom section 66 of the Act applies, may be given treatment –

(i) with informed consent; or

(ii) if the treatment is authorised by the Tribunal (or a member of the Tribunal) under Division 2 of Part 5 of the Act; or

(iii) if the patient is also an involuntary patient, if the treatment is authorised by a treatment order; or

(iv) if the treatment is urgent circumstances treatment, if the treatment is authorised under section 87 of the Act;

(b) a forensic patient, or an involuntary patient to whom section 66 of the Act applies, can never be given treatment except as provided by paragraph (a);

(c) a forensic patient, or an involuntary patient to whom section 66 of the Act applies, may be given special psychiatric treatment if –

(i) the special psychiatric treatment is authorised by the Tribunal under Part 6 of the Act; and

(ii) if the treatment is psychosurgery or a treatment that requires informed consent under that Part, informed consent has been given for the treatment;

(d) a forensic patient, or an involuntary patient to whom section 66 of the Act applies, can never be given special psychiatric treatment except as provided by paragraph (c).

38. Interim treatment order

(1) Despite section 36, a single member of the Tribunal may make an interim treatment order in respect of a person if, but only if, the member is satisfied that –

(a) an approved medical practitioner has applied for a treatment order in respect of the person; and

(b) the requirements of section 37 appear to have been met in respect of the application; and

(c) the person meets the treatment criteria; and

(d) the Tribunal cannot immediately determine the application; and

(e) the delay that would be involved in awaiting a decision of the Tribunal under section 39 should the interim treatment order not be made would, or is likely to, seriously harm –

(i) the person's health or safety; or

(ii) the safety of other persons.

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- (2) An interim treatment order may include a requirement –
- (a) that the treatment setting for a patient be –
 - (i) an approved facility (other than an SMHU), or a premises or place, specified in the order; or
 - (ii) a type of approved facility (other than an SMHU), or a type of premises or place, specified in the order; and
 - (b) that, for the purposes of receiving treatment, a patient may be admitted to and, if necessary, detained in –
 - (i) an approved facility (other than an SMHU) specified in the order; or
 - (ii) a type of approved facility (other than an SMHU) specified in the order.
- (2A) An interim treatment order may provide for a combination of treatment settings and for the admission and re-admission of the patient to those settings.
- (3) Despite subsection (2) , the Tribunal member is not to make an interim treatment order requiring a patient who is a child to be admitted to and, if necessary, detained in an approved hospital for the purposes of receiving treatment unless the member is satisfied that the hospital –
- (a) has facilities and staff for the treatment and care of the patient; and
 - (b) is, in the circumstances, the most appropriate place available to accommodate the patient.
- (4) The Tribunal member may make the interim treatment order on the basis of the application alone, without any hearing or further investigation.
- (5) Section 41 applies in relation to the making of an interim treatment order.
- (6) If an interim treatment order is made, the order is, for all purposes, taken to be a treatment order made by the Tribunal except that sections 43 , 44 and 48 do not apply in relation to the order.
- (7) The interim treatment order –
- (a) takes effect as soon as it is made; and
 - (b) continues in effect, subject to subsection (8) , until the application is determined by the Tribunal.
- (8) Any Tribunal member may revoke or amend the interim treatment order at any time.
- (9) The interim treatment order lapses after 10 days (calculated from the precise time it is made) if, by then, the Tribunal has not determined the application.

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39. Determination of application for treatment order

- (1) *The Tribunal may make a treatment order in respect of a person if, and only if, it is satisfied that –*
- (a) *an approved medical practitioner has applied for a treatment order in respect of the person; and*
 - (b) *the requirements of section 37 have been met in respect of the application; and*
 - (c) *the person meets the treatment criteria; and*
 - (d) *a treatment plan has been prepared for the person; and*
 - (e) *the requirements of section 53(2) appear to have been met with respect to the treatment plan.*
- (2) *A treatment order may include a requirement –*
- (a) *that the treatment setting for a patient be –*
 - (i) *an approved facility (other than an SMHU), or a premises or place, specified in the order; or*
 - (ii) *a type of approved facility (other than an SMHU), or a type of premises or place, specified in the order; and*
 - (b) *that, for the purposes of receiving treatment, a patient may be admitted to and, if necessary, detained in –*
 - (i) *an approved facility (other than an SMHU) specified in the order; or*
 - (ii) *a type of approved facility (other than an SMHU) specified in the order.*
- (2A) *A treatment order may provide for a combination of treatment settings and for the admission and re-admission of the patient to those settings.*
- (3) *Despite subsection (2), the Tribunal is not to make a treatment order requiring a patient who is a child to be admitted to and, if necessary, detained in an approved hospital for the purposes of receiving treatment unless it is satisfied that the hospital –*
- (a) *has facilities and staff for the treatment and care of the patient; and*
 - (b) *is, in the circumstances, the most appropriate place available to accommodate the patient.*
- (4) *The Tribunal is to determine an application for a treatment order as soon as practicable after it is received and must do so by way of a hearing.*
- (5) *An application for a treatment order lapses and is rendered invalid if the Tribunal for any reason fails to determine the application within 10 days after it is lodged.*
- (6) *The President of the Tribunal is to ensure that a hearing for the purposes of this section is before a division of the Tribunal constituted by 3 members.*

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50. Nature of treatment plan

The treatment plan for a patient is an instrument that sets out an outline of the treatment the patient is to receive.

53. Preparation of treatment plan

- (1) A patient's treatment plan may be prepared by any medical practitioner involved in the patient's treatment or care.*
- (2) In preparing a treatment plan, a medical practitioner –*
 - (a) is to consult the patient; and*
 - (b) may, after consulting the patient, consult such other persons as the medical practitioner thinks fit in the circumstances.*
- (3) A medical practitioner who prepares a treatment plan is to –*
 - (a) give a copy of the treatment plan to –*
 - (i) the patient; and*
 - (ii) the CCP; and*
 - (b) place a copy of the treatment plan on the patient's clinical record.*

55. Urgent circumstances treatment

- (1) An involuntary patient may be given treatment (urgent circumstances treatment) without informed consent or Tribunal authorisation if an approved medical practitioner authorises the treatment as being urgently needed in the patient's best interests.*
- (2) An approved medical practitioner may, under subsection (1), authorise treatment as being urgently needed in the patient's best interests only if the approved medical practitioner is of the opinion that achieving the necessary treatment outcome would be compromised by waiting for the urgent circumstances treatment to be authorised by the Tribunal (or by a member thereof on an interim basis).*
- (3) An approved medical practitioner may give the authorisation if, and only if, he or she has concluded from an examination that –*
 - (a) the patient has a mental illness that is generally in need of treatment; and*
 - (b) the urgent circumstances treatment is necessary for –*
 - (i) the patient's health or safety; or*
 - (ii) the safety of other persons; and*
 - (c) the urgent circumstances treatment is likely to be effective and appropriate in terms of the outcomes referred to in section 6(1); and*
 - (d) achieving the necessary treatment outcome would be compromised by waiting for the urgent circumstances treatment to be authorised by the Tribunal (or by a member thereof on an interim basis).*

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(4)

(5)

(6)

(7) *The advice under subsection (6) may be given by any means of communication the approved medical practitioner considers appropriate in the circumstances but, if it is given orally, the approved medical practitioner is to confirm it in writing by means of a CCP approved form.*

(8) *If the authorisation is given, the approved medical practitioner has the following obligations:*

- (a) *to ensure that the patient is advised of the authorisation as soon as possible after it is given;*
- (ab) *to give a copy of the authorisation to the CCP and the Tribunal;*
- (ac) *to give a copy of the authorisation to the patient (together with a statement of rights in a CCP approved form);*
- (b) *to place a copy of the authorisation on the patient's clinical record.*

(9) *If the authorisation is given, the patient may be given the urgent circumstances treatment until whichever of the following first occurs:*

- (a) *the treatment is completed;*
- (b)
- (c) *an approved medical practitioner, for any reason he or she considers sufficient, stops the treatment;*
- (d) *the 96-hour period immediately following the giving of the authorisation expires;*
- (da) *the assessment order, treatment order or interim treatment order ceases or is discharged;*
- (e) *the authorisation is set aside by the Tribunal.*

(10)

62. Rights of involuntary patients

Every involuntary patient has the following rights:

- (a) *the right to have the restrictions on, and interference with, his or her dignity, rights and freedoms kept to a minimum consistent with his or her health or safety and the safety of other persons;*
- (b) *the right to have his or her decision-making capacity promoted, and his or her wishes respected, to the maximum extent consistent with his or her health or safety and the safety of other persons;*
- (c) *the right, while in an approved hospital, to have access to current information about local, national and world events;*
- (d) *the right to be given clear, accurate and timely information about –*
 - (i) *his or her rights as an involuntary patient; and*

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- (ii) the rules and conditions governing his or her conduct in the hospital; and*
 - (iii) his or her diagnosis and treatment;*
- (e) the right, while in an approved hospital, to apply for leave of absence in accordance with this Act;*
- (f) the right to have contact with, and to correspond privately with, his or her representatives and support persons and with Official Visitors;*
- (g) the right, while in an approved hospital, to be provided with general health care;*
- (h) the right, while in an approved hospital, to wear his or her own clothing (where appropriate to the treatment setting);*
- (i) the right, while in an approved hospital, not to be unreasonably deprived of any necessary physical aids;*
- (ia) the right, while in an approved hospital, not to be unreasonably deprived of any communication aid;*
- (j) the right, while in an approved hospital, to be detained in a manner befitting his or her assessment, treatment or care requirements;*
- (k) the right, while in an approved hospital, to practise a religion of the patient's choice, to join with other patients in practising that religion and to possess such articles as are reasonably necessary for the practice of that religion (to such extent as is consistent with his or her health or safety, the safety of other persons and the management, good order and security of the hospital);*
- (l) the right, while in an approved hospital –*
 - (i) to practise customs in accordance with the patient's cultural beliefs or cultural background; and*
 - (ii) to join with other patients in practising those customs; and*
 - (iii) to possess articles that are reasonably necessary for the practice of those customs –*
to the extent that the practice of those customs is not contrary to any law and is consistent with the health and safety of the patient and other patients and the management, good order and security of the hospital;
- (m) the right, while in an approved hospital, to ask for and be given such reasonable help from hospital staff as will enable the patient to enjoy these rights.*

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Schedule 1

1. The mental health service delivery principles are as follows:

- (a) to respect, observe and promote the inherent rights, liberty, dignity, autonomy and self-respect of persons with mental illness;
- (b) to interfere with or restrict the rights of persons with mental illness in the least restrictive way and to the least extent consistent with the protection of those persons, the protection of the public and the proper delivery of the relevant service;
- (c) to provide a service that is comprehensive, accessible, inclusive, equitable and free from stigma;
- (d) to be sensitive and responsive to individual needs (whether as to culture, language, age, religion, gender or other factors);
- (e) to emphasise and value promotion, prevention and early detection and intervention;
- (f) to seek to bring about the best therapeutic outcomes and promote patient recovery;
- (g) to provide services that are consistent with patient treatment plans;
- (h) to recognise the difficulty, importance and value of the role played by families, and support persons, of persons with mental illness;
- (i) to recognise, observe and promote the rights, welfare and safety of the children and other dependants of persons with mental illness;
- (j) to promote the ability of persons with mental illness to make their own choices;
- (k) to involve persons receiving services, and where appropriate their families and support persons, in decision-making;
- (l) to recognise families, and support persons, of persons with mental illness as partners, with mental health service providers, in the provision of their treatment and care to the extent that this is appropriate and consistent with their own wishes;
- (m) to respect the wishes of persons receiving services, and the wishes of their families and support persons, to the maximum extent consistent with the health and safety of those persons and the safety of others;
- (n) to promote and enable persons with mental illness to live, work and participate in their own community;
- (o) to operate so as to raise community awareness and understanding of mental illness and to foster community-wide respect for the inherent rights, liberty, dignity, autonomy and self-respect of persons with mental illness;
- (p) to be accountable;
- (q) to recognise and be responsive to national and international clinical, technical and human rights trends, developments and advances.