

Guidance note for Commissioners on consent to treatment and the Mental Health Act 1983

This guidance relates to England only

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CONTENTS

i.	Introduction	<i>page 2</i>
THE LEGAL & PROCEDURAL FRAMEWORK		
1.	The legal framework	<i>page 3</i>
2.	Patients to whom Part 4 applies	<i>page 3</i>
3.	The provisions of section 58	<i>page 4</i>
4.	The three-month rule	<i>page 4</i>
5.	Treatment after the three-month period	<i>page 5</i>
6.	Purpose and duration of Forms T2	<i>page 6</i>
7.	Procedure for Second Opinions	<i>page 7</i>
8.	Purpose and duration of Forms T3	<i>page 7</i>
9.	Concurrent Forms T2 or T3	<i>page 8</i>
10.	Section 61 and section 61 Review Of Treatment	<i>page 8</i>
11.	Urgent treatment under section 62	<i>page 9</i>
12.	Part 4A and SCT patients	<i>page 10</i>
DEFINING & DESCRIBING TREATMENT FOR MENTAL DISORDER		
13.	Defining medication for mental disorder	<i>page 14</i>
14.	Describing medication on Forms T2 and T3	<i>page 16</i>
	- Describing drugs by BNF category	
	- Describing drugs by name	
	- Doses above BNF limits	
15.	Describing ECT	<i>page 17</i>
CHECKLISTS		
16.	Issues for Commissioners if there is a Form T2	<i>page 18</i>
17.	Issues for Commissioners if there is a Form T3	<i>page 19</i>
ANNEX A – BNF categories		
		<i>page 20</i>
ANNEX B – Abbreviations as they should appear on Forms T2 and T3		
		<i>page 21</i>
ANNEX C – Certification of adult / child detained / SCT patients matrix		
		<i>page 22</i>
ANNEX D – Certification of all detained / SCT patients flowchart		
		<i>page 23</i>
ANNEX E – Certification of adult detained / SCT patients flowchart		
		<i>page 24</i>
ANNEX F – Certification of child/adolescent detained / SCT pts flowchart		
		<i>page 25</i>
ANNEX G – Treatment with meds of detained patients flowchart		
		<i>page 26</i>
ANNEX H – Treatment with meds of SCT patients flowchart		
		<i>page 27</i>
ANNEX I – Treatment with meds of recalled SCT patients flowchart		
		<i>page 28</i>

(i) introduction

This guidance is intended for Mental Health Act Commissioners to use when reviewing consent documentation. It gives a brief definition of medication for mental disorder and information on the completion of statutory forms that Commissioners will see in relation to Consent to Treatment during the course of their visits. Guidance is also given on the action Commissioners should take in relation to issues raised by the review of these forms.

This guidance should be read in conjunction with

- Chapters 23 and 24 of the *Code of Practice*;
- Chapters 16 of the *Reference Guide to the Mental Health Act 1983*;
- Sections 56 - 64 (especially section 58, 58A and 62) of the 1983 Mental Health Act (see figure 1 below).

Commissioners should also be aware of the publication entitled the *British National Formulary* (BNF), which is the official guide to prescribing medicines that is used in England and Wales. The British Medical Association and the Royal Pharmaceutical Society of Britain jointly produce this publication, which is updated twice a year.

Other helpful guidelines are the *Maudsley Hospital Prescription Guidelines* (2001; Martin Dunitz Ltd) and the *Guidelines for the Administration of Medicines* (2000; United Kingdom Central Council for Nursing and Midwifery (UKCC)).

Part I

The legal and procedural framework relating to parts 4 & 4A

1 The legal framework

- 1.1. Part 4 of the Mental Health Act 1983 (sections 56 -64) sets out the powers and duties provided by the Act in relation to the administration of medical treatment for mental disorder to certain detained patients. An outline of Part 4 of the Act is given below (Fig 1).

PART 4 OF THE MENTAL HEALTH ACT 1983	
S56	Definition as to the patients to whom Part 4 applies
S57	Treatment requiring consent and a Second Opinion (NMD)
S58	Treatment requiring consent or a Second Opinion (medication)
S58A	ECT
S59	Plan of treatment
S60	Withdrawal of treatment
S61	Review of treatment
S62	Urgent treatment
62A	Treatment on recall of community patient or revocation of order
S63	Treatment not requiring consent
S64	Supplementary provisions and definition of Responsible Medical Officer (RMO)

Figure 1: Outline content of Part 4 of the Mental Health Act 1983

- 1.2. This guidance focuses on section 58 and s58A of the Act, which applies to the administration of medicine beyond three months from the date of first administration during a continuous period of detention under the Mental Health Act, and to treatment with ECT at any time.

2. **Patients to whom part 4 applies** (see section 56, MHA 1983)

- 2.1. Part 4 of the Act is applicable to patients who are “liable to be detained” in hospital for treatment. This means that patients detained under sections 2, 3, 17A, 36, 37 (except as indicated in Paragraph 2.2), 38, 44, 45A, 46, 47, 48, 49 of the Mental Health Act 1983. Part 4 also encompasses SCT patients who have been recalled to hospital and patients who are subject to a hospital order under the Criminal Procedure (Insanity and Unfitness to Plead) Act 1991.

2.2. Part 4 of the Act does not apply to patients:

- who are liable to be detained under section 4 prior to the receipt of the second recommendation for a section 2;
- who are liable to be detained under holding powers (sections 5(2), 5(4), 35, 135, 136);
- who have been conditionally discharged under section 42(2) or sections 73 or 74 and have not been recalled to hospital; or
- who are in hospital on the sole authority of directions under either section 35 or 37(4).

2.3. Patients to whom Part 4 of the Act does not apply retain the same rights to refuse treatment as informal patients.

3 the provisions of section 58 and section 58A (See Annexes C – G)

3.1 **Section 58** directs that, except in an emergency and after the initial three months from its first administration (see 4.1 below), medicine for mental disorder cannot be given without either the capable consent of the patient or, in the absence of such consent, the authorisation of a Second Opinion Appointed Doctor (SOAD). To certify the former, the patient's Approved clinician (or in rare circumstances, a SOAD¹) must state on Form T2 that the patient has the capacity to consent and does so. SOADs authorise treatment on Form T3 when the patient refuses to give consent or is not capable of giving consent.

3.2 **Section 58A** directs that, except in an emergency, ECT cannot be given without either the capable consent of the patient or, in the absence of such consent, the authorisation of a Second Opinion Appointed Doctor (SOAD). To certify the former (in the case of **patients aged over 18**), the patient's Approved clinician (or in rare circumstances, a SOAD²) must state on Form T4 that the patient has the capacity to consent and does so. SOADs authorise treatment on Form T6 when the patient is not capable of giving consent, but are not empowered to authorise treatment in the face of a capable refusal of consent. For these purposes, a capable refusal of consent includes an advance directive, or a decision by a deputy, donee or the Court of Protection. A patient's capacitous refusal of consent to ECT may, however, be overridden using emergency powers.

Section 58A establishes slightly different procedures for the approval of ECT in the case of **children and adolescents**. In brief, these are that s.58A applies to

¹ Occasionally, a SOAD who has been asked to undertake a Second Opinion finds the patient to be both competent and consenting to treatment when interviewed. In such circumstances the SOAD may complete a Form T2 (see also para 6.6 below).

² See note 1 above.

all patients under 18, whether they are detained or not, and ECT may not be given to such patients without certification that the treatment is appropriate. This applies whether or not the patient is incapable of giving consent (in which case Form T6 is used) or is both capable and consenting to the treatment (in which case Form T5 is used). As with adult patients, the capable refusal of consent to ECT by a patient aged under 18 can only be overridden using emergency powers.

4 The three-month rule

- 4.1 For three months from its first administration to a patient who has been detained under a section of the Act to which Part 4 applies, medication for mental disorder may be administered on the authority of the approved clinician in charge of that treatment, whether or not the patient has capacity and consents. However, consent should still be sought and medical records should show evidence of assessment of capacity and consent during this time (see Code of Practice 24.10).
- 4.2 Once medication for mental disorder has been administered for the first time to a detained patient, and the three-month period begins, the clock will only stop if the patient's detention comes to an end. The three-month period is unaffected by interruptions in or changes to treatment, transfers to other hospitals or renewals of the power of detention or to changes in the section under which the patient is detained, provided that no break in detention takes place (see *Code of Practice*, 24.10; *Reference Guide*, 16.25).
- 4.3 The following example (Fig 2) conflates a number of queries received by the Commission on the definition of the three-month period:

A sample patient history

A patient is detained under section 2 on the 1 January, having been brought into hospital under section 136 on New Year's Eve. Medication for mental disorder is first administered on the 2 January, although there is a days gap in treatment whilst a physical health problem is attended to later in the month. On the 24 January the patient's detention is regraded to section 3. A week's leave is granted at the start of March. During this week the patient stops taking any medication and goes AWOL, and is eventually arrested following an incident. In late March the patient is returned to the hospital where he is detained but, on the 31 March, a court orders the patient to be detained in another hospital under section 37.

The three-month period nevertheless expires on the 2 April. None of the circumstances described affected its running from the second day of January.

Figure 2: A sample patient history

- 4.3 Any break in detention cancels the three-month period. A patient who is taken off section to become informal and then is placed on a new section would begin a new three-month period from the first time medication is administered under the new section. Similarly, any patient who is found to be unlawfully detained and re-detained under the Act will have to start another three-month period from the date of re-detention.
- 4.4 The three-month period applies to medication for mental disorder but not to ECT where consent or a second opinion is required if the treatment is to be given at any time.

5 Treatment after the three month period for hospital patients

- 5.1 If an approved clinician wishes a detained patient to receive medication for mental disorder beyond three months he or she must first establish whether the patient has the capacity to consent (see *Code of Practice, 23.27 et seq* on capacity: the Code states that the capacity test applicable to Part 4 of the MHA 1983 is “defined by the Mental Capacity Act 2005. This is technically untrue – the MHA contains its own separate definition of capacity – but there should be no practical differences between the two definitions as applied).
- 5.2 If the patient has capacity to consent, the approved clinician responsible for the treatment will personally seek the patient's consent to that treatment having explained the reason for treatment, the beneficial effects, side effects, alternatives to the treatment and the likely consequence of not continuing with the treatment (see *Code of Practice, 23.31 et seq*). If the patient understands and agrees to the proposed treatment, the approved clinician will complete a Form T2 (see Annexes C – G to this guidance).
- 5.3 If the patient lacks capacity to consent, or has capacity but refuses consent, the approved clinician will request a Second Opinion to consider authorising the proposed treatment.
- 5.4 The approved clinician should make a record of the discussion with the patient in the medical notes, with reference to the patient's capacity to consent (*Code of Practice, 24.16*). The discussion should take place before the expiry of the three-month period, so that arrangements can be made for a Second Opinion if necessary. It can take up to five working days to obtain a Second Opinion, although approved clinicians should be encouraged to allow for more time than this where practicable.

6 Purpose and duration of forms T2

- 6.1 Form T2 is a statutory form set out by the Mental Health (Hospital, Guardianship and Treatment) Regulations 2008. Its wording is therefore set by statute and cannot be changed or altered (although this does not mean that only the Government contracted printed versions are acceptable in law: hospitals are at liberty to produce their own form so long as they follow the statutory wording exactly. SOADs have been issued with electronic versions of forms to use should they wish to do so). All parts of the form must be completed as directed in the notes on the form.
- 6.2 The form is used for certifying that the patient is capable of understanding the nature, purpose and likely effects of a specific treatment described on the form, and has consented to it.
- 6.3 It will usually be the approved clinician in charge of the patient's treatment who completes the form, although SOADs may do so on occasion³. Where the approved clinician completes a Form T2, that form is only valid whilst that clinician retains responsibility for the treatment: if responsibility is passed to another clinician, that clinician should issue a further form before further treatment is given. This limitation does not apply where a SOAD completes the form.
- 6.4 Although the act does not require the validity of certificates authorising treatment to be reviewed after any particular period, it is good practice for the clinician in charge of the treatment to review them at regular intervals (Code of Practice, para 24.72). Regardless of whether it has been completed by an approved clinician in charge of the treatment or a SOAD, Form T2 should be reviewed and a new form completed as appropriate:
- following a change in treatment plan from that recorded;
 - following the re-establishment of consent after this has been withdrawn, and
 - when detention is renewed (or annually, whichever is earlier).
- 6.6 All patients for whom a Form T2 has been completed should be aware that they may withdraw their consent at any time: certification of consent in no sense acts as a binding contract on the patient.

³ For example, a SOAD may complete Form T2 if, having been asked to visit a patient who is deemed to be refusing consent, s/he finds on the SOAD visit that the patient is consenting, or reaches a compromise treatment plan with the approved clinician in charge to which the patient consents.

7 Procedure for second opinions

- 7.1 Where a patient either refuses or is incapable of giving consent to treatment falling within section 58, the approved clinician must contact the Commission to request a Second Opinion.
- 7.2 The Commission administers the “Second Opinion Appointed Doctor” (SOAD) service. For second opinions involving medication proposals, the Commission aims to arrange for the SOAD to visit within five working days from the request. For ECT Second Opinions the Commission will try to arrange the visit to take place within two working days. The SOAD will talk with the patient, the approved clinician, the two “statutory consultees” (a nurse and another person who is neither a nurse nor a doctor but who has been professionally concerned with the patient’s treatment). The Code of Practice (24.54) requires statutory consultees to make a record of their consultation in the patient’s narrative clinical notes. The SOAD may authorise that specified treatment can be given to the patient without their consent by completing Form T3. In some cases the SOAD may instead complete a Form T2 to indicate that the patient has now consented to the treatment plan.
- 7.3 SOADs must provide a statement of the reasons for their decision on the statutory form T3. The approved clinician should have given the patient an opportunity to see those reasons unless one or other doctor feels it would be inappropriate to do so. See the Commission Guidance Notes⁴ for further details.

8 Purpose and duration of forms T3

- 8.1 Form T3, like Form T2, is a statutory Form. The Form is used by the SOAD to certify either that a patient is incapable of giving consent or has refused to give consent to a plan of treatment which should nevertheless be given. Only a SOAD – a doctor who is appointed by the Care Quality Commission - can sign a Form T3.
- 8.2 The validity of a Form T3 is unaffected by changes in approved clinician or even detaining hospital. If a patient is transferred to another hospital under s.19 the Form T3 from their originating hospital remains valid.
- 8.3 Whilst SOADs have the right to authorise time-limited authorisations Forms T3

⁴ Mental Health Act Commission (2002) *Guidance for SOADs: R (on the application of Wooder) v Dr Feggetter and the Mental Health Act Commission (GN 1A/02)* and *Guidance for Responsible Medical Officers: R (on the application of Wooder) v Dr Feggetter and the Mental Health Act Commission (GN 1B/02)*.

are not time-limited, and the Code of Practice gives no guidance on when they should be reviewed. However, the Commission has taken the general view that Forms T3 should not normally be extant for more than two years.

Commissioners who encounter Forms T3 that are more than two years old should pass the details of the form to the Commission Secretariat so that further investigation can take place.

- 8.4 If a patient gives genuine and consistent consent to the treatment authorised on a Form T3, the approved clinician should complete a Form T2 to replace that authority. Where consent fluctuates, it may be appropriate to continue treating under the authority of Form T3. However, **it is now clearly stated in the Code of Practice (24.79) that any certificate issued on the basis that a patient is incapable of consent will cease to authorise treatment upon that patient regaining capacity.** Similarly, where T3 states that the patient is capable but refusing consent, but subsequently the patient loses capacity, that certificate must no longer be deemed to authorise treatment and a further second opinion is required. The same approach should, of course, be applied where patients cease to consent and a Form T2 is extant.
- 8.5 If the approved clinician wishes to change the medication given to the patient and the new medicine is not authorised by the Form T3 a further Second Opinion should be requested.

9 CONCURRENT FORMS T2 AND T3

- 9.1 Treatment plans for medication for mental disorder must be considered as a whole, covering all of the medication which is relevant to s.58. In most cases we would expect a SOAD to have intended to authorise the parameters of treatment that it is appropriate to impose upon a patient, and not to leave such an authorisation open to be added to, should the patient be persuaded to consent to additional medication on top of that which for which they refuse consent. However, whereas, in past guidance, the Mental Health Act Commission has stated that “there should never be concurrent Forms [T2] and [T3]”, we recognise the legal opinions of others who argue that this is untenable where a patient genuinely consents to a part of a treatment plan but refuses consent to the remainder⁵, Where it is considered appropriate, in such circumstances, to enforce that remainder, we accept that the SOAD should complete both Form T2 (certifying the part to which the patient consents) and T3 (certifying that part to which the patient refuses consent). Each form should clearly state its interdependence with the other, by the SOAD stating that either

⁵ See, for example, Jones R (2008) *Mental Health Act Manual*, 11th edition, para 1-667

form should be deemed cancelled should the other cease to authorise treatment (i.e. either because consent is withdrawn to the treatment certified on Form T2, or because a new Form T2 or T3 is issued to authorise an amended treatment plan).

- 9.2 The CQC will encourage SOADs to include a similar statement on all Forms T3, to the effect that it ceases to authorise treatment and a further second opinion will be needed upon the concurrent issue of any Form T2.

10 section 61 and section 61 review of treatment form (previously MHAC1)

10.1 Section 61 directs the Responsible Clinician to complete a report (section 61 Review Of Treatment Form) on the current treatment being given to a patient and the patient's condition.

10.2 The report should be sent by the approved clinician to the Commission:

- when the section is renewed (for restricted patients, this translates as at the end of the first six months of their detention and then on subsequent occasions that a report is furnished on the patient to the Secretary of State);
- at any other time if so required by the Commission.

10.3 The Commission has designed the section 61 Review of Treatment Form to assist the approved clinician in detailing the information required under this section of the Mental Health Act. Unlike Forms T2 or T3, this is not a statutory form, its wording is not set by statute and it provides no authority for treatment in its own right.

11 Urgent treatment under section 62

11.1 Treatments falling within section 58 or s.58A may be given in emergency situations without having been authorised on either Form T2 or T3. The fact that a treatment has been given under the emergency treatment provisions of s.62 should be recorded in the patient's clinical notes. Hospitals are encouraged to devise and use local forms for Approved clinicians to complete. For further details see the *Code of Practice, 24.32 et seq.*

11.2 There are no statutory limitations to the number of treatments (whether these are ECT or medication) that can be given under section 62(1). Each treatment must be justified against the criteria set for emergency treatment in section 62(1) and details should be fully recorded by the approved clinician. Whenever it is necessary to administer emergency treatment consideration should be given to requesting a Second Opinion for any future treatments that may be needed.

11.3 An urgent or emergency treatment is not necessarily one that is life-saving, as urgent treatment is allowed in situations other than when failure to treat would be life-threatening. The threshold for justifying urgent treatment increases proportionally with the invasiveness of that treatment (see MHA s62(1) and Code of Practice para 24.33). The criteria for emergency treatment listed in s.62 are that treatment is immediately necessary either:

- (a) To save a patient's life; or
- (b) To prevent a serious deterioration in the patient's condition, where the treatment does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail a significant physical hazard; or
- (c) To alleviate serious suffering by the patient, where the treatment does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail a significant physical hazard; or
- (d) To prevent patients behaving violently or being a danger to themselves or others, where the treatment is the minimum interference necessary for that purpose, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail a significant physical hazard;

The criteria (a) to (d) above are applicable justifications for emergency treatment with medication under s.62, but only (a) and (b) are applicable criteria for the administration of ECT.

11.4 Section 62(2) of the Act allows for "the continuation of any treatment or of treatment under any plan pending compliance with section...58...if... discontinuance...would cause serious suffering to the patient". This power might be used, for example, to provide authority for a plan of treatment to be continued whilst a Second Opinion visit is pending, following the patient's withdrawal of consent or loss of capacity. The reference in this subsection to "treatment under any plan" allows in these circumstances that the approved clinician may make a single record in the patient's notes evoking the powers of this section, without having to record the use of section 62 powers at every administration of medication.

12. Supervised community treatment & part 4a of the MHA

12.1 The limits of coercive power on SCT

Whilst an SCT patient is in the community (i.e. excepting such times as they might be recalled to hospital, or their SCT status is revoked, which are dealt

with below at 12.5 and 12.6), consent to treatment falls under the new Part 4A of the Act. Patients who are made subject to Supervised Community Treatment cannot, whilst they are in the community, be compelled to take medication for mental disorder to which they have given a capacitated refusal of consent. Patients who lack capacity to consent but do not object to taking such medication may be given it under Part 4A and, in an emergency only, medication may also be imposed upon an incapacitated patient who resists it. SCT patients may, of course, also give capacitated consent to taking medication.

12.2 *The one-month (and three-month) periods*

Patients are discharged onto SCT from sections 3, or unrestricted Part 3 hospital orders. For the initial month of an SCT, medication for mental disorder may be given to a patient without certification (provided that the patient either consents to it or, if incapacitated, does not resist taking it). In certain circumstances that 'one-month period' may be extended. If a patient is discharged onto SCT with more than one month of his or her three-month period (as discussed at 4 above) still to run (i.e. the patient is discharged less than two months after first being treated with medication as a detained patient in hospital to whom Part 4 applies), the patient will not need to have treatment certified until the three-month period expires.

12.3 *Treatment following the initial month of SCT (or after the three-month period ends, whichever is the later) (annexes C, D, E, F, H)*

After the initial months of SCT (or at the end of the three-month period if this is later), treatment with medication for mental disorder must be certified as appropriate by a SOAD if its administration is to be continued, whether the patient is consenting or incapable of consenting. A SOAD will certify that the treatment is appropriate on Form CTO11. The SOAD cannot certify that treatment is appropriate if the patient has capacity and refuses consent to it, or has refused consent through an advance directive, or if treatment would conflict with a decision made by a deputy, donee or the Court of Protection in relation to an incapacitated patient.

Before authorising that treatment is appropriate, a SOAD must interview the patient, discuss the treatment plan with the approved clinician in charge of the treatment, and consult two other persons who have been professionally concerned with the patient's medical treatment. At least one of these 'statutory consultees' must not be a doctor, and neither can be the patient's Responsible Clinician or the approved clinician in charge of the patient's treatment, although of course the SOAD will wish to discuss the case with the approved clinician in

charge of the patient's treatment and may wish to see the Responsible Clinician.

SOADs do not have to certify on Form CTO11 whether the patient is consenting or incapacitated, but they may make it a condition of the certificate that particular treatments are given only in certain circumstances (Code of Practice, 24.27). This might include, for example, that a treatment is only appropriate so long as the patient consents to it. Nurses should be clear that such conditions are met if they are dispensing the medication to the patient.

SOADs completing a Part 4A certificate may also authorise, on that certificate, the administration of medication for mental disorder upon an SCT patient's recall to hospital (see 12.5 below), and may set conditions on such authorisation. Unless it specifies otherwise, any such advance authority to treat upon recall will allow for treatment to be given by force against the patient's capacitous refusal (as well as to an incapacitated or consenting patient).

12.4 *Urgent treatment*

Under Part 4A, there are some circumstances in which the approved clinician may authorise an SCT patient's urgent treatment without certification. However, it is only the requirement to have a certificate authorising such treatment that is lifted in emergency situations *in the community*, and treatment must otherwise have a legal basis in either the patient's consent or under the Mental Incapacity Act. Under such circumstances treatment can be enforced against an incapacitated patient's resistance (s.64G), but emergency powers do not authorise treatment against a patient's capacitated refusal of consent.

"Urgent treatment" is defined as treatment:

- i. That is immediately necessary to save the patient's life; or
- ii. That (not being irreversible) is immediately necessary to prevent a serious deterioration of the patient's condition; or
- iii. That (not being irreversible or hazardous) is immediately necessary to alleviate serious suffering by the patient; or
- iv. That (not being irreversible or hazardous) is immediately necessary and represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to himself or others.

The MHA 1983 Code of Practice (paragraph 24.37) requires managers to devise a form for completion by the clinician in charge of the treatment *every time* urgent treatment is given under Part 4A.

12.5 *Supervised community treatment patients upon recall to hospital (see annex H)*

Patients who are recalled to hospital whilst on Supervised Community Treatment may be held there for up to 72 hours. During this period in hospital they are subject to the provisions of Part 4 of the Act, and as such require certification under section 58 for medication for mental disorder to be lawfully given, EXCEPT in the following circumstances:

- If the three-month period under Part 4 has yet to expire, or it is not yet a month since the SCT was implemented, no certification is needed;
- If the SOAD explicitly authorised the administration of medication upon recall on Form CTO11, and any conditions placed by the SOAD on doing so are met, then no further certification is needed.
- Treatment that was already being given on the basis of a Part 4A certificate may be continued pending compliance with section 58, even if the SOAD has not certified for continuation upon recall, if the approved clinician in charge of the treatment in question considers that discontinuing it would cause the patient serious suffering.
- The approved clinician otherwise uses emergency treatment powers (section 62) to authorise treatment.

If none of the above exceptions can be claimed by the approved clinician in charge of the patient's treatment, a new SOAD visit should be arranged to authorise treatment. The Code of Practice (24.81) explicitly condemns as bad practice using the last s.58 certificate that was issued to the patient before his or her discharge from detention in hospital onto SCT status to authorise treatment upon recall from SCT, although it acknowledges that such certificates may be technically valid. It would appear that this technical validity may be an unforeseen consequence of the drafting of Parts 4 and 4A. The Commission takes the view that it would indeed be very poor practice to take the authority to impose treatment upon a patient from such a certificate.

12.6 *Supervised community treatment patients upon revocation of SCT*

If the patient's SCT status is revoked, they return to detained status. Although in most respects the law treats such patients as if they have been newly admitted on the section 3 or hospital order from which they were previously discharged onto SCT, there is no new three-month period for medication.

The exceptions to the need for certification listed in the bullet-point list at paragraph 12.5 above may also authorise treatment upon recall, but only for so long as it takes to arrange a further second opinion. No 'old' certificate from the patient's detention in hospital prior to release from SCT should be used to authorise treatment, as discussed also at paragraph 12.5 above.

PART II

DEFINING AND DESCRIBING DRUGS USED FOR MENTAL DISORDER

13.1 Defining medication for mental disorder

The powers of compulsion and associated safeguards provided by s.58 of the Act apply only to “medication for treatment of mental disorder”. Guidance on defining “medication for mental disorder” is given at Figure 3 below.

MEDICATION FOR MENTAL DISORDER SHOULD INCLUDE:

- i) Medication used to alleviate the symptoms of mental disorder included under BNF categories 4.1, 4.2, 4.3 and 4.11.
- ii) Medication that is not included in BNF categories 4.1, 4.2 or 4.3 or is not licensed for such use but is used to alleviate the symptoms of mental disorder. This includes, for example, antiepileptic drugs (BNF category 4.8.1) used as “antimanic drugs” (“mood stabilisers”) in bipolar disorder.
- iii) For homeopathic, herbal and alternative medicines, see para 13.2 *et seq* below.
- iv) Adjuvant medication without which the therapeutic objectives of alleviation of the symptoms of mental disorder set out in i) and ii) could not be achieved. Such medication may include, for example:
 - a) Drugs used to alleviate the parkinsonian and other motor side effects of antipsychotic agents, such as the antimuscarinic drug, procyclidine (BNF Category 4.9.2) or tetrabenazine (BNF Category 4.9.3), used to alleviate dyskinesia such as tremor, chorea or tardive dyskinesia. Dyskinesia may lead to reduced compliance with treatment for mental disorder and may mask or prevent assessment of the underlying symptoms of mental disorder.
 - b) Antisialogogic agents (i.e. inhibitors of salivation) such as hyoscine (BNF category 1.2). Excessive salivary secretion, caused by antipsychotic drugs such as clozapine, may reduce the ability of the patient to communicate effectively and / or reduce compliance with treatment.
 - c) Antiepileptic drugs, in BNF category 4.8.1 may also be used to ameliorate or prevent seizure induction by atypical antipsychotic drugs (clozapine): seizures might otherwise preclude the use of such medication.

continues overleaf...

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MEDICATION FOR MENTAL DISORDER SHOULD NOT INCLUDE:

- i) Laxatives, which are not considered to be treatment for mental disorder, even when the antipsychotic medication contributes to the constipation. Similarly, medication to treat general side effects of medication for mental disorder should not be authorised under s.58, unless it can be shown that not giving such treatment would seriously compromise attaining the therapeutic objective of ameliorating the symptoms of mental disorder.
- ii) Medication used to treat epilepsy: epilepsy is not considered to be a mental disorder.
- iii) Some treatments, such as feeding by naso-gastric tube, which may be considered to be treatments for mental disorder but do not involve medicine. The authority for such treatments *may* be had from s.63 of the Act (see Richard Jones *Mental Health Act Manual* 11th Ed paragraph 1-718 *et seq*).

Fig 3: Defining medication for mental disorder

13.2 *Herbal remedies and certification under the Act*

The MHAC is occasionally asked whether herbal remedies, such as St John's Wort, need to be certified under s.58 of the Act if they are to be taken by detained patients to whom that section applies. In our Tenth Biennial Report (2003) we stated that, in general, we would not consider herbal remedies to be 'medicines for mental disorder' falling within s.58. This position is open to the criticism that it adopts a rather arbitrarily restrictive definition of 'medicine' compared to the dictionary definition of the term⁶, and so we have now revised our view and accept that herbal preparations may be considered as 'medicines for mental disorder'.

In general, the use of alternative medicines usually stems from the patient or carer, rather than being suggested or even imposed by the clinical team. As such, the practical question is most likely to be whether such medication should be included in the certification of medication to which the patient consents (i.e. on Form T2), although it is conceivable that family members might wish for such medication to be administered to an incapacitated detained patient, or a SOAD might be asked to allow for the continuance of such medication after a patient who has been using such medication has lost capacity, and as such included on Form T3. We take the view that, at least insofar as any herbal remedy is prescribed or supplied by the patient's doctor to a patient subject to Part 4 of the Act who is no longer subject to the three-month rule, it should be certified on either Form T2 or T3 .

⁶ See, for example, Jones R (2006) *Mental Health Act Manual*, Tenth edition, paragraph 1-721, where Jones argues against the MHAC's rejection of placebo (in our Eighth Biennial Report of 1999) as 'medicine' on the grounds that 'placebo' is defined in the Shorter OED as, *inter alia*, "a medicine ... prescribed more for psychological effect than for any physiological effect".

If a patient is using herbal preparations having bought them over the counter (or having them brought into hospital by relatives or friends), it would not appear to be necessary in law for his or her doctor to certify the treatments on a Form T2, as the clinical team is playing no part in the administration of such medication and therefore needs no authority to do so. However, some herbal preparations can produce side effects or interactions with prescription drugs. Of all herbal remedies, the strongest claims for efficacy are made for St John's Wort, albeit only for mild to moderate depression⁷, although this herbal preparation appears to have important and potentially dangerous interactions with many prescription drugs, reducing their efficacy through lowered plasma levels⁸. It is also reported that it is suspected of triggering psychoses in patients who concomitantly take SSRI antidepressants⁹. That a patient may be choosing to take such preparations is therefore clearly relevant to a prescribing doctor, if only on grounds of safety.

It is therefore important that clinical and nursing staff are in a position to advise patients (and if necessary intervene) where patients are supplementing, or plan to supplement, their medication regime with herbal remedies. We recognise, of course, the limitations of the evidence upon which any such advice would have to be based. If a patient wishes to self-medicate with certain herbal remedies known to have potential interactions or side-effects, his or her doctor may wish to agree a particular dose (or even agree to provide and dispense the preparation). Whether or not any brought-in and self-administered preparation is recorded on a patient's Form T2, it is important that a record of what the patient is taking is made in the clinical notes, in the event of any side effects or drug interactions requiring intervention.

13.3 *Fish oils and certification under the Act*

Although commonly thought of as an 'alternative' medicinal approach to the treatment of psychosis (perhaps because of their over-the-counter availability as a nutritional supplement), omega-3 fish-oils have a licensed prescription form used for lipid regulation in treating hyperlipidaemia (BNF 2.12). Omega-3 Fish-oil has also been reported to enhance the efficacy of antipsychotic drugs (especially Clozapine) in poorly responding patients, and we understand that it is currently undergoing clinical trials for this purpose. We have been asked whether fish-oils used in these circumstances fall within the definition of medication for mental disorder.

⁷ Ernst E (2007) 'Herbal remedies for depression and anxiety' *Advances in Psychiatric Treatment* 13, 312-6

⁸ Ernst E (2007) *ibid.*, p.315: see Box 2.

⁹ Izzo A A & Ernst E (2001) 'Interactions between herbal medicines and prescribed drugs: a systematic review'. *Drugs* 15; 2163-2175

It is the MHAC view that fish-oil used in this way as an adjunctive treatment of psychosis *does* fall within the definition of medication for mental disorder and should be certified on Forms T2 or T3 if it is to be administered to a patient to whom s.58 is applicable. We have advised SOADs that the treatment should be certified as “one omega 3 marine triglyceride orally BNF 2.12 for adjunct treatment of psychosis”.

13.3 *Unlicensed use of medication*

Products listed in the BNF (see **Annex A** for BNF categories commonly employed in mental disorder) may be considered as licensed for the use indicated. However, Commissioners should be aware that the BNF is updated every 6 months and that significant changes do occur. Medication for mental disorder may include medication that does not have a product licence or is not licensed for the particular use for which it is employed. It is the Approved clinician’s responsibility to make such choices.

If medication is to be administered for a different purpose than that for which it has a licence, then the Form T2 should indicate the medication by generic name (see para 13.8 below), specific dosage and the purpose for which it is to be administered. Alternatively, if it is listed in the BNF for a different use than that intended, it could be indicated on Form T2 by BNF category and limits with a comment summarising the purpose for which it is to be administered (for example, “One oral 4.81.1 anti-epileptic drug used as a mood stabilizer, within BNF limits”).

14 **DESCRIBING MEDICATION ON FORMS T2 AND T3**

Forms T2 or T3 should indicate all drugs proposed, including p.r.n. (as required) medication. P.r.n. medication does not need to be separately designated as such. Medicines for mental disorder may be identified on statutory forms by either name (i.e. “chlorpromazine 100mg t.d.s. orally”) or by the categories as listed in the BNF (i.e. “4.2.1 antipsychotic drugs oral or i/m, within BNF limits”).

14.1 *Describing drugs by BNF category.*

A brief guide to BNF categories commonly used in the treatment of mental disorder is given at **Annex A**. When a treatment plan is described in terms of BNF categories, it should look something like the example shown at figure 4 below. The advantage of this way of describing a treatment plan is that it

allows for the substitution of one type of drug from within a specified BNF category with any other from that category without having to complete another form. For this reason, SOADs are specifically encouraged to use this form of notation for Forms T3. Approved clinicians may choose to do so for Forms T2, although it is perhaps questionable that most patients can give valid informed consent to any drug in a BNF category, as opposed to a particular drug whose effects and possible side effects they are more likely to understand.

Up to two oral / i/m antipsychotic drugs (excluding clozapine) BNF 4.2.1
One depot antipsychotic drug BNF 4.2.2
One oral antimuscarinic drug BNF 4.9.2

All medicines to be given within BNF Limits

Figure 4: treatment plan described by BNF category (see Annex B for abbreviations)

The description must show the maximum number of drugs allowed in any one category, the route of administration and the dose range. The latter will usually be described with reference to BNF Limits (see also Code of Practice Chapter 24.17

When BNF 4.2.1 is authorised, it should have been stated whether clozapine is included or excluded from the authorisation (see the Commission's *Guidance on the Administration of Clozapine and other Treatments Requiring Blood-tests under the Provisions of the Mental Health Act* for details).

Even where only one drug in a particular category is actually being prescribed, the treatment plan written on the Form will often allow for up to two such drugs: this is usually to allow for titrated changeovers from one drug to another or to give another drug in the same category for a specific purpose, e.g. in emergency situations.

14.2 Describing drugs by name

You are most likely to encounter treatment plans described in terms of named drugs on Forms T2. SOADs are generally discouraged from using this form of annotation for Forms T3, as changing from one medication to another in the same BNF category requires a further review and new form. This would be inconvenient in the case of a Form T2, where the approved clinician will have to formally ascertain the patient's capacity and consent status and issue a fresh

Form, but it would be both impractical and expensive for the SOAD service. However, there are good reasons to use it to certify treatments to which patients consent, or where a SOAD feels that it is appropriate to impose one named drug to the exclusion of others in its BNF category.

Specific doses and the frequency of administration can also be written on the form (see figure 5 below). The disadvantage of this is that the prescribing doctor cannot make minor adjustments to treatments (such as moving from one named drug to another of the same type) without the approved clinician renewing the form. Nevertheless, Forms T2 that have specific medicines mentioned by name are acceptable. In certain circumstances (such as when a patient has expressed a preference for a specific named drug and will not accept any other) it will be good practice to complete the form in this way.

chlorpromazine oral 200 mg t.d.s. zuclopenthixol decanoate i/m 400 mg fortnightly procyclidine hydrochloride oral 5 mg t.d.s
--

Figure 5– Treatment plan described by named drug (see Annex B for abbreviations).

Medication should be referred to by its generic name, rather than its proprietary name. Thus one uses ‘chlorpromazine’ rather than ‘Largactil’.

14.3 *Doses above BNF limits*

Doses above BNF limits should be referred to either as multiples of the BNF limit or as a specific maximum dose expressed in mg. If you have concerns about high-dose antipsychotic medication or polypharmacy, refer to Commission *Guidance on RCPsych consensus statement on high-dose medication*

15 *Describing ECT*

Descriptions of ECT must specify the maximum number of treatments authorised. (Twelve treatments is the usual number for a “course” of ECT, although the number of treatments authorised may be more or less than this).

16 ISSUES FOR COMMISSIONERS IF THERE IS A FORM T2

The following table is intended as a guide to action on visits. If a Commissioner is in doubt as to what action to take or has a query regarding medication on a visit this should be referred to the Chair of the visit or to the Secretariat for clarification.

Question	Action if answer is “no”
Is the Form T2 signed by the current approved clinician?	The certificate is not a valid authority for treatment, and the current approved clinician should be advised to complete a new form before further treatment is given.
Was a new Form T2 completed at the last renewal of detention or in the last year?	Advise of the Commission view that consent status should be reviewed & a new FT2 completed if appropriate.
Was a new Form T2 completed if and when the patient was transferred from another hospital?	Advise of the Commission view that consent status should be reviewed & a new FT2 completed if appropriate.
Is there written, dated and signed evidence of the consent interview in the clinical notes?	Refer to ward staff for them to locate. If no evidence located, raise issue of documentation. <i>(Code of Practice, 24.16)</i>
Is there a copy of the Form T2 with the prescription card?	Suggest that this should be remedied (recommendation 23, Ninth Biennial Report)
Is the medication on the Form T2 treatment <i>for mental disorder</i> ? (If unsure, raise with your RD or the Commission Secretariat).	Advise that the issue be brought to the approved clinician’s attention as soon as it is practicable to do so.
Question	Action if the answer is “yes”
Is antipsychotic medication significantly above BNF limits?	Refer to Commission <i>Guidance on RCPsych consensus statement on high-dose medication.</i>

General

If the patient during an interview with a Commissioner expresses a wish to refuse medication, this should be written on the letter given to the patient and with his or her agreement passed to the ward manager to bring to the attention of the approved clinician in charge of that treatment.

If a Commissioner is unsure of the patient’s ability to consent, this again should be raised with the ward manager to bring to the attention of the approved clinician in charge of that treatment. Commissioners should be particularly careful not to pass on personal clinical judgements.

Whilst Commissioners may occasionally identify a need for a Second Opinion for an individual case, it is the responsibility of the patient’s approved clinician to request a second opinion. Any action to be taken should be discussed with the visit Chair.

17 ISSUES FOR COMMISSIONERS IF THERE IS A FORM T3

The following table is intended as a guide to action on visits. If a Commissioner is in doubt as to what action to take or has a query regarding medication on a visit this should be referred to the Chair of the visit or to the Secretariat for clarification.

Question	Action if the answer is “no”
Is there a copy of the Form T3 with the prescription card? (So that the person administering the medication can check what is actually authorized)	Suggest that this should be remedied (recommendation 23, Ninth Biennial Report)
Is the medication for mental disorder currently being administered authorized on the Form T3?	Raise with ward staff to bring to the attention of the approved clinician as a matter of urgency
Is the Form T3 over two years old?	Contact the Secretariat to pass on the details of the Form. Do not ask the hospital to arrange a new second opinion.
If Form T3 was completed, was either (i) The patient supplied with the SOAD’s reasons for authorising medication; or (ii) A note made by the approved clinician as to why it was not appropriate to do this?	Raise with ward staff to bring to the attention of approved clinician. Suggest reference made to Commission publication <i>Guidance for SOADs: on giving reasons when certifying that treatment is appropriate.</i>
If the patient's detention has been renewed, was an section 61 Review Of Treatment Form completed and sent to the Commission? (see para 10 of this guidance).	Raise with ward staff to bring to the attention of the approved clinician
If so, has the patient received a copy of the section 61 Review Of Treatment Form	Raise with ward staff to bring to the attention of the approved clinician
Have the statutory consultees made a record of their consultation with the SOAD in the patient’s records? (Code of Practice 24.54)	Raise with ward staff and/or ward manager to note for future practice.
Question	Action if the answer is “yes”
Do you have other concerns about Form T3 or SOADs	Refer them to the visit Chair and to the Commission for action. Do not ask the hospital to do so.
Is antipsychotic medication significantly above BNF limits?	Refer to CQC <i>Guidance on RCPsych consensus statement on high-dose medication.</i>

BNF CATEGORIES**Commonly used in treatment of mental disorder****4.1 Hypnotics and Anxiolytics** (sleeping and anxiety-reducing drugs)

- 4.1.1. Hypnotics
- 4.1.2 Anxiolytics

4.2 Drugs used in psychoses and related disorders

- 4.2.1 Antipsychotic drugs given orally or by intramuscular or rarely by intravenous injection (e.g. chlorpromazine, haloperidol or clozapine). This category includes both typical and atypical antipsychotic drugs
- 4.2.2 Depot antipsychotic drugs administered as an intramuscular depot injection (e.g. flupentixol decanoate)
- 4.2.3 Antimanic drugs (e.g. lithium). Other drugs commonly used to treat manic episodes are not listed in detail in this category, and therefore you may see “4.8.1 antiepileptic medication used to treat mood disorders” or “used as antimanic drugs” where sodium valproate or carbamazepine is being used for this purpose.

4.3 Antidepressants (orally administered)

- 4.3.1 Tricyclic and related antidepressants (e.g. amitriptyline)
- 4.3.2 MAOIs (e.g. phenelzine) – rarely used
- 4.3.3 Selective serotonin re-uptake inhibitors (e.g. fluoxetine)
- 4.3.4 Other antidepressants (e.g. venlafaxine)

4.9.2 Antimuscarinic drugs (e.g. procyclidine, used to control side effects of antipsychotic drugs, administered orally or by injection)**4.11 Drugs for dementia** (e.g. donepezil, galantamine and rivastigmine) administered orally.

**ABBREVIATIONS
AS THEY SHOULD APPEAR ON FORM 38 OR 39.**

Dose to be administered:

The units of dosage to be administered should be stated in lower case.

g	=	grams
mg	=	milligrams (10^{-3} g)
μ cg or mcgm	=	microgram (10^{-6} g)*
max.	=	maximal dose given in the BNF
within BNF limits	=	within the dose range quoted in the BNF

** Note: It is better to state "micrograms" in full to avoid legibility errors (the difference between "mg" and " μ cg" is one thousand fold)*

The number or frequency of administration:

o.d.	=	omni die (daily)
b.d.	=	bis die (twice daily)
t.d.s.	=	ter die sumendus (three times daily)
q.d.s.	=	quater die sumendus (four times daily)
o.m. (or mane)	=	omni mane (in the morning)
o.n. (or nocte)	=	omni nocte (at night)
p.r.n.	=	pro re nata (when or as required)

Route of administration:

oral	=	administered by mouth
i/m (or imi)	=	intramuscular injection
i/v (or 4i)	=	intravenous injection
rectal	=	administered via the rectum

Certification of adult and child detained & SCT patients

The form to be used in certification is indicated in brackets. “AC in charge” = Approved clinician in charge of the treatment in question

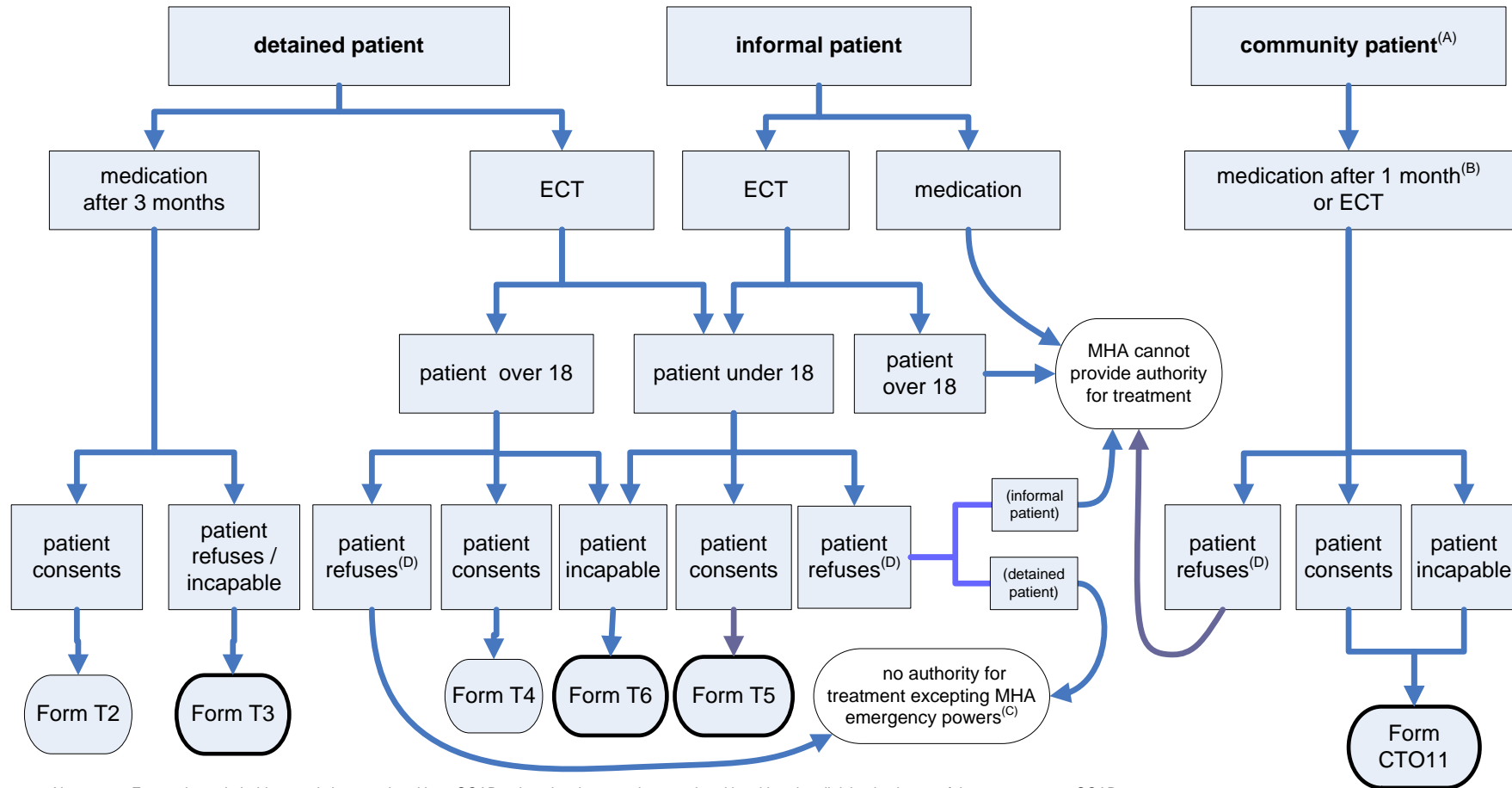
Adult (Patient aged over 18 years)		Consenting	Incapable	Refusing
Detained in hospital	ECT	AC in charge usually certifies (T4) SOAD may also certify (T4)	SOAD certifies (T6)	Emergency treatment only (s.62)
	Meds	AC in charge usually certifies (T2) SOAD may also certify (T2)	SOAD certifies (T3)	SOAD certifies (T3)
SCT in community	ECT	SOAD certifies (CTO11)	SOAD certifies (CTO11)	Cannot be given
	Meds	SOAD certifies (CTO11)	SOAD certifies (CTO11)	Emergency treatment only (s.64G)

Child / Adolescent (Patient aged under 18 yrs)		Consenting	Incapable	Refusing
Detained in Hospital	ECT	SOAD certifies (T5)	SOAD certifies (T6)	Emergency treatment only (s.62)
	Meds	AC in charge usually certifies (T2) SOAD may also certify (T2)	SOAD certifies (T3)	SOAD certifies (T3)
SCT in Community	ECT	SOAD certifies (CTO11)	SOAD certifies (CTO11)	Cannot be given
	Meds	SOAD certifies (CTO11)	SOAD certifies (CTO11)	Emergency treatment only (s.64G)
Informal	ECT	SOAD certifies (T5)	SOAD certifies (T6)	Cannot be given

Questions or concerns about this guidance should be addressed to the
 Care Quality Commission, The Belgrave Centre , Stanley Place, Talbot Street, Nottingham
 ,NG1 5GG, Telephone: 0115 8736250
 e-mail.mat.kinton@cqc.org.uk

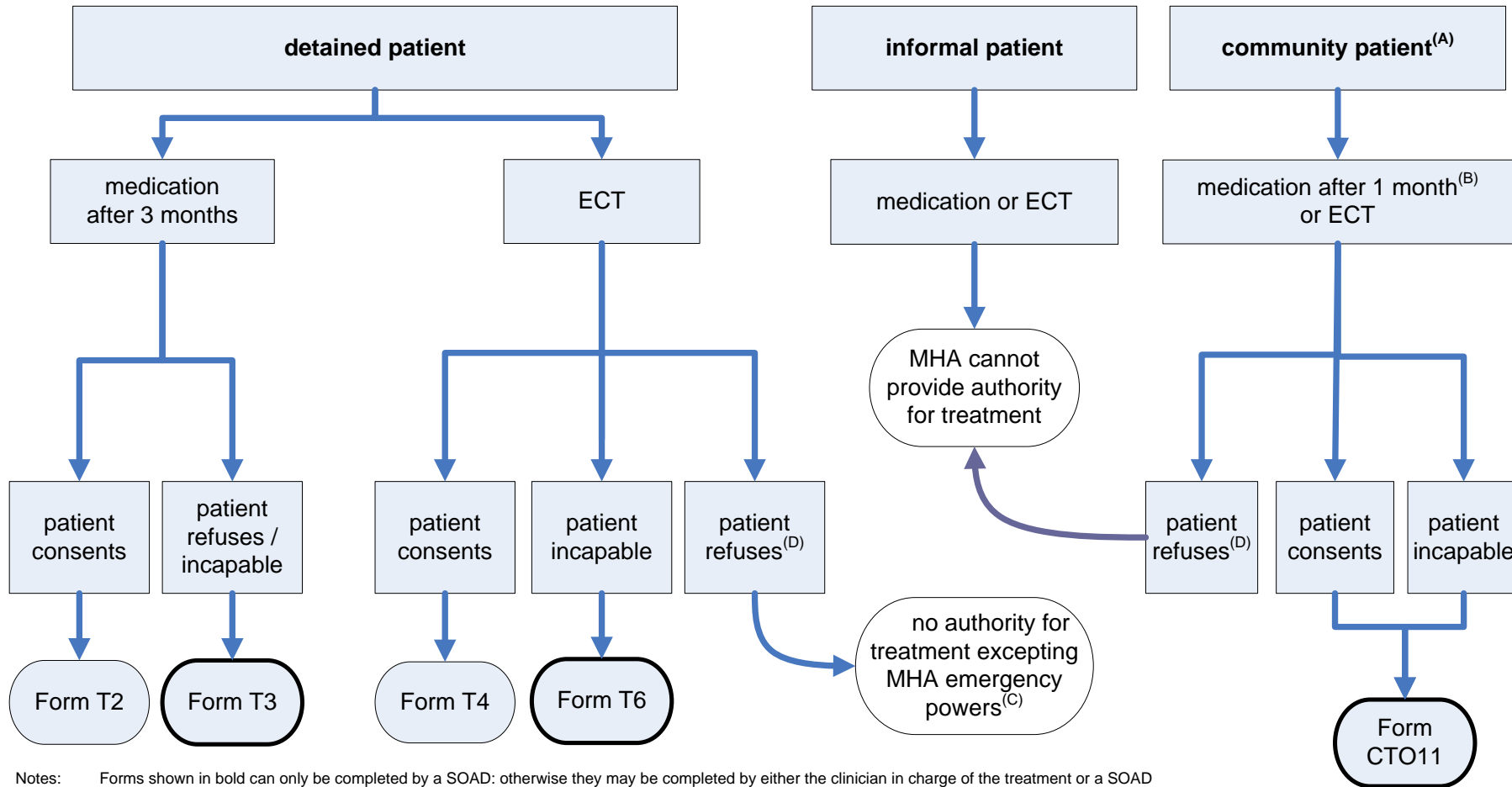
Certification of treatment under the revised Mental Health Act 1983 - all patients

Annex D



Notes: Forms shown in bold can only be completed by a SOAD: otherwise they may be completed by either the clinician in charge of the treatment or a SOAD
 (A) i.e. patients subject to a Community Treatment Order (Supervised Community Treatment) who have not been recalled to hospital
 (B) After one month, or the end of the three-month period relevant to s.58(3), whichever is later
 (C) See s.62.
 (D) Refusal in these circumstances includes, for patients aged over 16, refusal by advance directive, or conflict with a decision by a deputy, donee or the Court of Protection.

Certification of treatment *of adults* under the revised Mental Health Act 1983



Notes: Forms shown in bold can only be completed by a SOAD: otherwise they may be completed by either the clinician in charge of the treatment or a SOAD

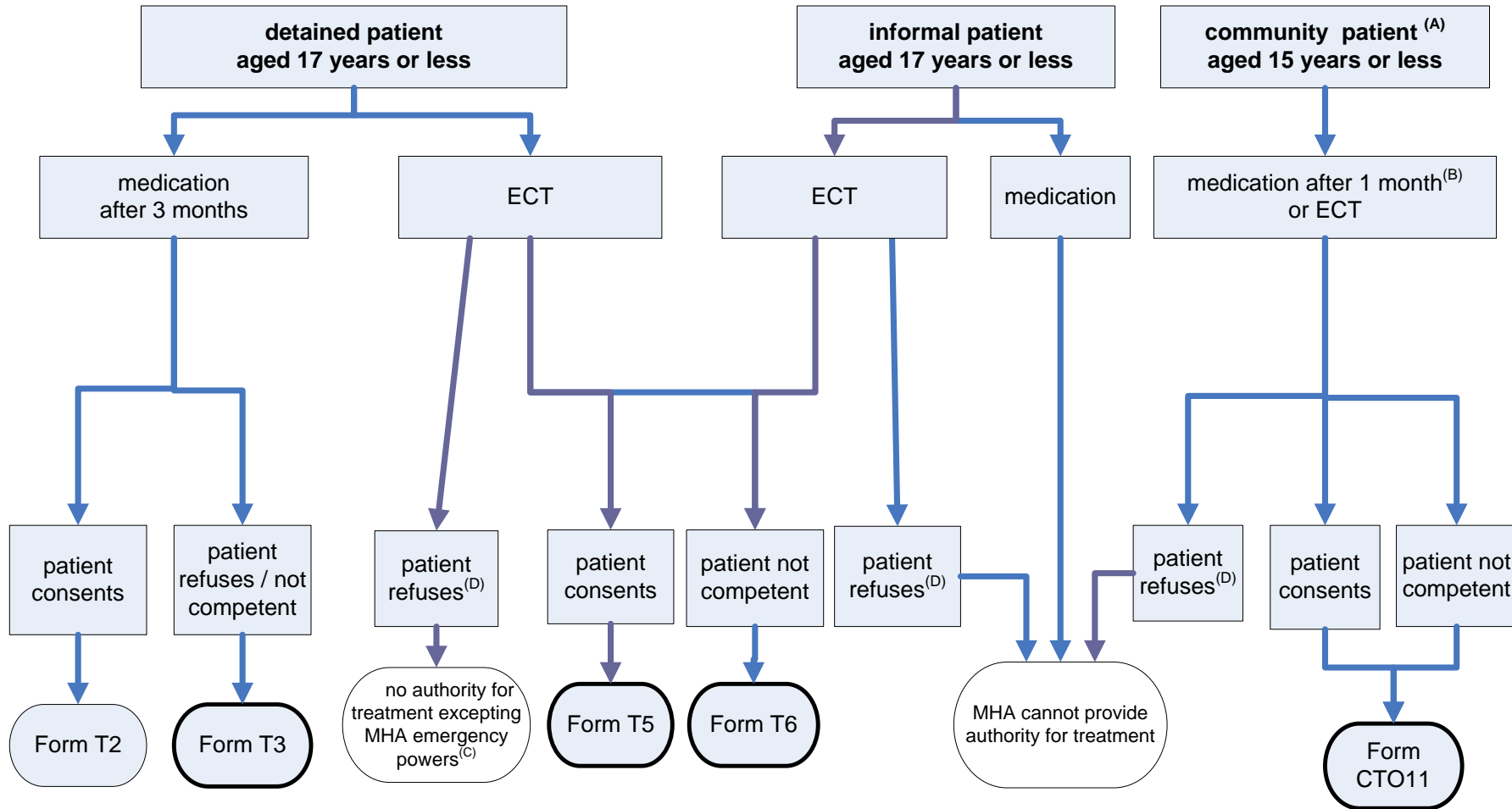
^(A) i.e. patients subject to a Community Treatment Order (Supervised Community Treatment) who have not been recalled to hospital

^(B) After one month, or the end of the three-month period relevant to s.58(3), whichever is later

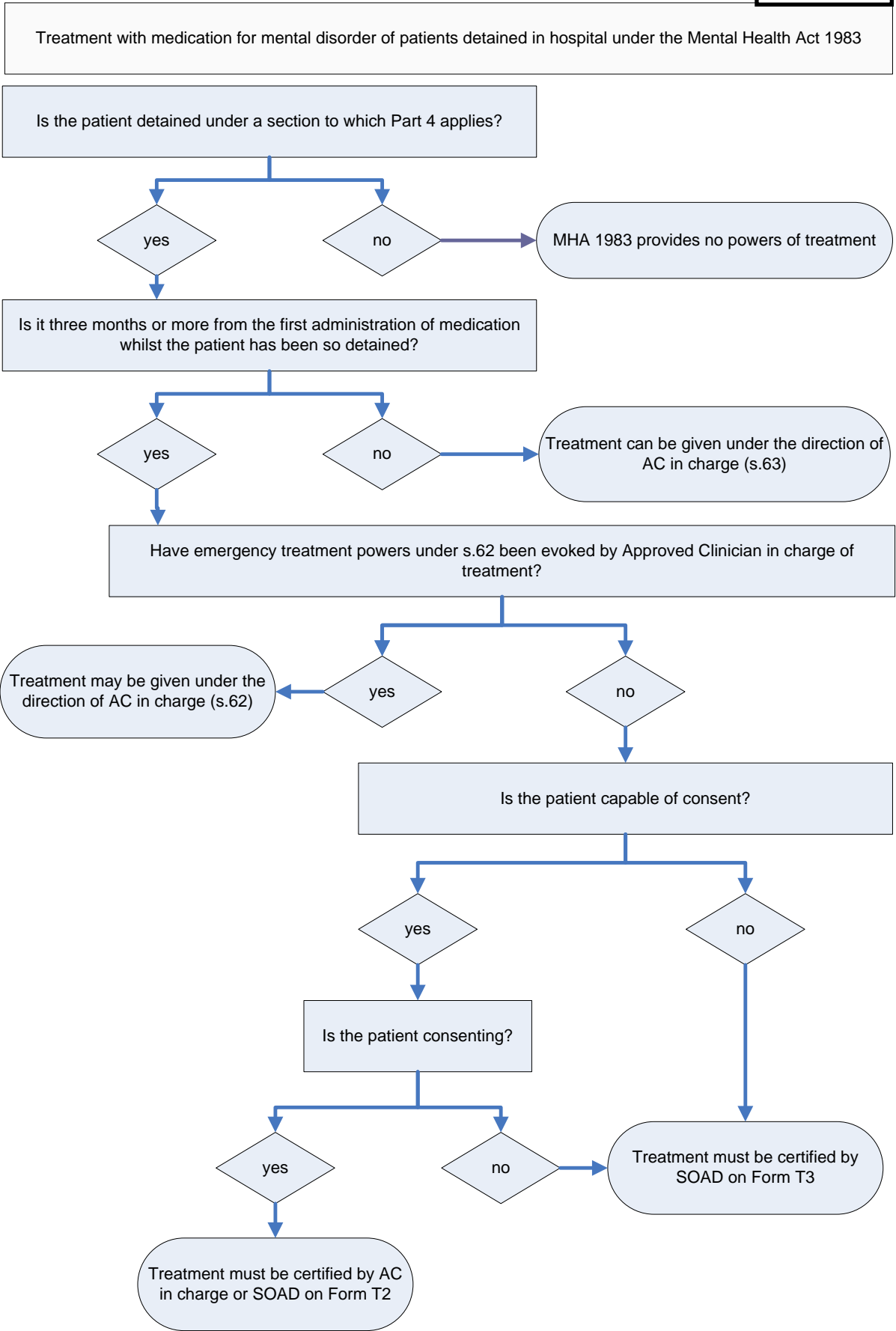
^(C) See s.62.

^(D) Refusal in these circumstances includes refusal by advance directive, or conflict with a decision by a deputy, donee or the Court of Protection.

Certification of treatment of *child / adolescent patients* under the revised MHA 1983

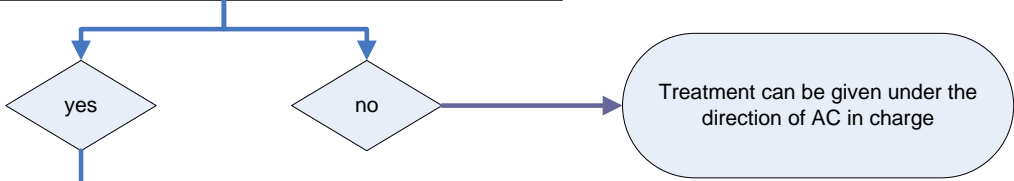


Notes: Forms shown in bold can only be completed by a SOAD: otherwise they may be completed by either the clinician in charge of the treatment or a SOAD
 (A) i.e. patients subject to a Community Treatment Order (Supervised Community Treatment) who have not been recalled to hospital
 (B) After one month, or the end of the three-month period relevant to s.58(3), whichever is later
 (C) See s.62.
 (D) Refusal in these circumstances includes, for patients over the age of 16, refusal by advance directive, or conflict with a decision by a deputy, donee or the Court of Protection.

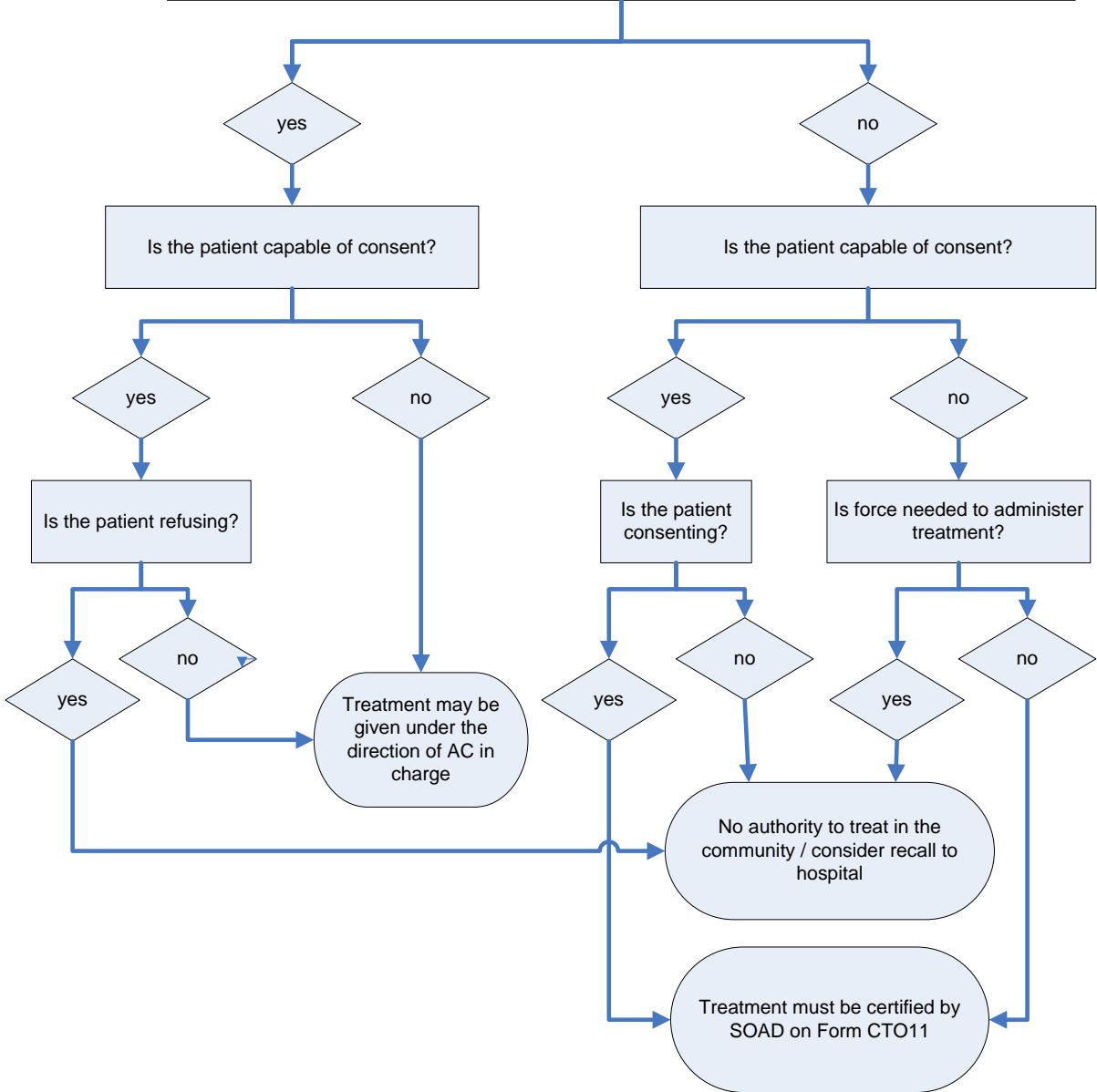


Treatment with medication for mental disorder under the Mental Health Act 1983 of Supervised Community Treatment patients not recalled to hospital

Is it three months or more from the first administration of medication when the patient was detained / one month or more since the start of SCT status?



Have emergency treatment powers been evoked by Approved Clinician in charge of treatment?



Treatment with medication for mental disorder under the Mental Health Act 1983 of Supervised Community Treatment patients **upon recall to hospital**

