



Human Tissue (Scotland) Act 2006

2006 asp 4

PART 1

TRANSPLANTATION ETC.

[^{F1}Pre-death procedures relating to transplantation

Textual Amendments

- F1** S. 16A-16G and cross-heading inserted (11.10.2019 for specified purposes, 26.3.2021 in so far as not already in force) by [Human Tissue \(Authorisation\) \(Scotland\) Act 2019 \(asp 11\)](#), **ss. 23(1), 29(2)**; [S.S.I. 2019/305](#), reg. 2(c); [S.S.I. 2021/108](#), reg. 2

16A **Meaning of “pre-death procedure”, “Type A procedure” and “Type B procedure”**

- (1) In this Part, a “pre-death procedure” means a medical procedure—
- (a) which is carried out on a person for the purpose of increasing the likelihood of successful transplantation of a part of the person's body after the person's death, and
 - (b) which is not for the primary purpose of safeguarding or promoting the physical or mental health of the person.
- (2) In this Part, a pre-death procedure is—
- (a) a “Type A procedure” if it is a pre-death procedure or category of pre-death procedure specified in regulations made by the Scottish Ministers under section 16B(1),
 - (b) a “Type B procedure” if it is a pre-death procedure or category of pre-death procedure specified in regulations made by the Scottish Ministers under section 16C(1).

16B **Type A procedures**

- (1) The Scottish Ministers may by regulations specify a pre-death procedure or category of pre-death procedure as a Type A procedure for the purposes of sections 16D to 16F.

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- (2) Regulations under subsection (1) may make different provision for different procedures or categories of procedure and in particular may specify that a pre-death procedure or category of pre-death procedure is a Type A procedure only where that procedure is carried out in a particular way.
- (3) Regulations under subsection (1) may specify a pre-death procedure (or category of pre-death procedure) as a Type A procedure only if the Scottish Ministers consider that it is appropriate that the carrying out of the procedure or, as the case may be, the category of procedure should be in accordance with section 16E.
- (4) Before laying draft regulations under subsection (1) before the Scottish Parliament, the Scottish Ministers must consult such persons as they consider appropriate.

16C Type B procedures

- (1) The Scottish Ministers may by regulations specify a pre-death procedure or category of pre-death procedure (other than one specified in regulations under section 16B(1)) as a Type B procedure for the purposes of section 16D and 16E.
- (2) Regulations under subsection (1)—
 - (a) may also make provision about—
 - (i) the circumstances in which Type B procedures may be carried out,
 - (ii) the way in which the carrying out of Type B procedures may be authorised,
 - (iii) the process for authorisation of Type B procedures, and
 - (iv) the carrying out of Type B procedures, and
 - (b) may make different provision for different procedures or categories of procedure.
- (3) Regulations under subsection (1) may specify a pre-death procedure (or category of pre-death procedure) as a Type B procedure only if the Scottish Ministers consider that it is appropriate that the procedure or, as the case may be, the category of procedure should be subject to provision mentioned in subsection (2)(a)(i) to (iv).
- (4) Before laying draft regulations under subsection (1) before the Scottish Parliament, the Scottish Ministers must consult such persons as they consider appropriate.

16D Restrictions on carrying out of pre-death procedures

- (1) A pre-death procedure may be carried out only if it is a Type A procedure or Type B procedure.
- (2) A Type A procedure may be carried out only in accordance with section 16E.
- (3) A Type B procedure may be carried out only in accordance with—
 - (a) section 16E, and
 - (b) any provision made in regulations under section 16C(1) in relation to that procedure (or category of procedure).

16E Carrying out of Type A and Type B procedures

- (1) A Type A procedure or Type B procedure may be carried out only if—

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- (a) the health worker who is to carry out the procedure or who has authorised a person to carry out the procedure considers that the requirements of subsection (2) are met,
 - (b) that health worker—
 - (i) has no actual knowledge that the person was unwilling for the procedure to be carried out,
 - (ii) has had regard to the person's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence referred to in section 16H(6)(c) or 16I(4)(c)), and
 - (iii) is satisfied that if the person were capable of making a decision about authorisation of the procedure, the person would not be unwilling for the procedure to be carried out,
 - (c) the use of a part of the person's body for transplantation is authorised by virtue of section 6, 6D, 6E, 6F, 6G, 8, 9, 10 or, as the case may be, 10A,
 - (d) in the case of a Type A procedure, the carrying out of the procedure is authorised under section 16F, and
 - (e) in the case of a Type B procedure, the carrying out of the procedure is authorised in accordance with any provision made under section 16C(1) in relation to that procedure (or category of procedure).
- (2) The requirements mentioned in subsection (1)(a) are met if—
- (a) in the view of the health worker primarily responsible for the person's medical treatment, the person is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment),
 - (b) where the person is receiving life-sustaining treatment, the decision to withdraw that treatment has been taken by that health worker,
 - (c) the carrying out of the procedure is necessary (see subsection (3)),
 - (d) the carrying out of the procedure is not likely to cause more than minimal discomfort to the person, and
 - (e) the carrying out of the procedure is not likely to harm the person.
- (3) For the purposes of subsection (2)(c), the carrying out of a procedure is necessary if either of the following apply—
- (a) it is necessary to carry it out for the purpose of ascertaining whether a part of the person's body is suitable for transplantation,
 - (b) it is necessary to carry it out for the purpose of increasing the likelihood of successful transplantation of a part of the person's body.

16F Authorisation of Type A procedures

- (1) For the purposes of section 16E(1)(d), the carrying out of a Type A procedure is authorised in relation to a person if—
- (a) the person has expressly authorised the carrying out of the procedure,
 - (b) in the case of an adult who, at the relevant time, has not expressly authorised the carrying out of any procedure, if the adult's nearest relative is, at the relevant time, entitled to authorise the removal and use of a part of the adult's body by virtue of section 6E or 6F and the adult's nearest relative authorises the carrying out of the procedure,
 - (c) in the case of a child who, at the relevant time, has not expressly authorised the carrying out of any procedure—

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- (i) if a person who has parental rights and parental responsibilities in relation to the child is, at the relevant time, entitled to authorise the removal and use of a part of the child's body by virtue of section 8D or 10 and that person authorises the carrying out of the procedure,
 - (ii) if a person is, at the relevant time, entitled to authorise the removal and use of a part of the child's body by virtue of section 10A and that person authorises the carrying out of the procedure,
 - (d) in the case of an adult who, at the relevant time, has not expressly authorised the carrying out of any procedure, there is in force an express authorisation by the adult of removal and use of a part of the adult's body for transplantation,
 - (e) in the case of a child who, at the relevant time, has not expressly authorised the carrying out of any procedure, there is in force an authorisation by virtue of section 8 by the child of removal and use of a part of the child's body for transplantation, or
 - (f) in the case of an adult, the adult is deemed by virtue of section 6D to have authorised the removal and use of a part of the adult's body for transplantation.
- (2) For the purposes of subsection (1)(b), the nearest relative of an adult may not give authorisation—
- (a) if the relative has actual knowledge that the adult was unwilling for the procedure to be carried out, or
 - (b) unless the relative—
 - (i) has had regard to the adult's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence referred to in section 16H(6)(c)), and
 - (ii) is satisfied that if the adult were capable of making a decision about authorisation of the procedure, the adult would not be unwilling for the procedure to be carried out.
- (3) For the purposes of subsection (1)(c), a person may not give authorisation—
- (a) if the person has actual knowledge that the child was unwilling for the procedure to be carried out, or
 - (b) unless the person—
 - (i) has had regard to the child's past wishes and feelings so far as reasonably ascertainable (having had regard to any evidence referred to in section 16I(4)(c)), and
 - (ii) is satisfied that if the child were capable of making a decision about authorisation of the procedure, the child would not be unwilling for the procedure to be carried out.
- (4) Where a person has expressly authorised the carrying out of one or more Type A procedures under subsection (1)(a), subsection (1)(f) does not authorise the carrying out of a Type A procedure not mentioned in that authorisation.
- (5) An authorisation under subsection (1)(a), (b) or (c) must be—
- (a) in writing, or
 - (b) given orally to a health worker.

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16G Authorisation of Type A procedures: transitory provision

- (1) Until section 6D comes into force, section 16E(1)(b)(ii) applies as if the words “(having had regard to any evidence referred to in section 16H(6)(c) or 16I(4)(c))” were omitted.
- (2) Until section 6D comes into force, section 16F applies as if—
 - (a) in subsection (1)—
 - (i) for paragraph (b) there were substituted—

“(b) in the case of an adult, a person who is entitled to authorise the removal and use of a part of the adult's body by virtue of section 7(1), (2) or (3) authorises the carrying out of the Type A procedure,”
 - (ii) for paragraph (c) there were substituted—

“(c) in the case of a child, a person who is entitled to authorise the removal and use of a part of the child's body by virtue of section 9(1), (2) or (3) or 10(1) authorises the carrying out of the Type A procedure,”
 - (iii) paragraphs (d) to (f) were omitted,
 - (b) in subsection (2)(b)(i), the words “(having had regard to any evidence referred to in section 16H(6)(c))” were omitted,
 - (c) in subsection (3)(b)(i), the words “(having had regard to any evidence referred to in section 16I(4)(c))” were omitted,
 - (d) subsection (4) were omitted.]

[^{F2}16H Duty to inquire: adult

- (1) A health worker must act in accordance with subsection (2) before the earlier of—
 - (a) the carrying out of a pre-death procedure in relation to an adult, or
 - (b) the removal of part of the body of a deceased adult for any of the purposes referred to in section 3(1).
- (2) The health worker must—
 - (a) take reasonable steps to inquire into whether there is in force—
 - (i) an express authorisation by the adult,
 - (ii) an opt-out declaration by the adult,
 - (b) if subsection (3) applies, inquire into whether the adult—
 - (i) is a non-resident adult (within the meaning given by section 6D(2)(a)),
 - (ii) is an adult who is incapable of understanding the nature and consequences of deemed authorisation (within the meaning given by section 6D(3)),
 - (c) in the case of an adult who is incapable of understanding the nature and consequences of deemed authorisation, inquire into the adult's past wishes and feelings so far as reasonably ascertainable, and
 - (d) in any case inquire, by consulting (so far as is reasonably practicable) the persons referred to in subsection (5), into the adult's most recent views in relation to—
 - (i) the carrying out of pre-death procedures in relation to the adult, and

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- (ii) the removal and use of a part of the adult's body for a purpose referred to in section 3(1).
- (3) This subsection applies in relation to an adult if there is in force at the relevant time—
 - (a) no express authorisation by the adult of removal and use of any part of the adult's body for transplantation, and
 - (b) no opt-out declaration by the adult as respects removal and use of the part of the adult's body for transplantation.
- (4) When acting in accordance with subsection (2)(b)(ii), the health worker must consult (so far as is reasonably practicable) any person who has indicated a wish to provide evidence that the adult is an adult who is incapable of understanding the nature and consequences of deemed authorisation.
- (5) The persons referred to in subsection (2)(d) are—
 - (a) the nearest relative of the adult,
 - (b) any person who has indicated to a health worker a wish to provide evidence mentioned in subsection (6), and
 - (c) such other persons as the health worker considers appropriate.
- (6) The evidence referred to in subsection (5)(b) is evidence—
 - (a) that the adult's most recent view was that the adult was willing or, as the case may be, unwilling for a part of the adult's body to be removed and used for a purpose referred to in section 3(1),
 - (b) that if the adult were capable of making a decision about removal and use of a part, the adult would be willing or, as the case may be, unwilling in the circumstances for part of the adult's body to be removed and used for a purpose referred to in section 3(1),
 - (c) about the adult's views in relation to the carrying out of a pre-death procedure in relation to the adult.

Textual Amendments

F2 Ss. 16H, 16I inserted (26.3.2021) by [Human Tissue \(Authorisation\) \(Scotland\) Act 2019 \(asp 11\)](#), ss. 24, 29(2); S.S.I. 2021/108, reg. 2

16I Duty to inquire: child

- (1) A health worker must act in accordance with subsection (2) before the earlier of—
 - (a) the carrying out of a pre-death procedure in relation to a child, or
 - (b) the removal of part of the body of a deceased child for any of the purposes referred to in section 3(1).
- (2) The health worker must—
 - (a) take reasonable steps to inquire into whether there is in force—
 - (i) an authorisation by virtue of section 8(1) by the child,
 - (ii) a declaration by virtue of section 8B(1) by the child, and
 - (b) inquire, by consulting (so far as is reasonably practicable) the persons referred to in subsection (3), into the child's most recent views in relation to—
 - (i) the carrying out of pre-death procedures in relation to the child, and

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- (ii) the removal and use of a part of the child's body for a purpose referred to in section 3(1).
- (3) The persons referred to in subsection (2)(b) are—
- (a) a person who, at the relevant time, has parental rights and parental responsibilities in relation to the child,
 - (b) if a person is entitled to authorise removal and use of a part of the child's body by virtue of section 10A, that person,
 - (c) any person who has indicated to a health worker a wish to provide evidence mentioned in subsection (4), and
 - (d) such other persons as the health worker considers appropriate.
- (4) The evidence referred to in subsection (3)(c) is evidence—
- (a) that the child's most recent view was that the child was willing or, as the case may be, unwilling for a part of the child's body to be removed and used for a purpose referred to in section 3(1),
 - (b) that if the child were capable of making a decision about removal and use of a part, the child would be willing or, as the case may be, unwilling in the circumstances for a part of the child's body to be removed and used for a purpose referred to in section 3(1),
 - (c) about the child's views in relation to the carrying out of a pre-death procedure in relation to the child.]

Textual Amendments

F2 Ss. 16H, 16I inserted (26.3.2021) by [Human Tissue \(Authorisation\) \(Scotland\) Act 2019 \(asp 11\)](#), ss. 24, 29(2); S.S.I. 2021/108, reg. 2

[^{F3}16J Meaning of “health worker”

- (1) In sections 1 to 16K, “health worker” means—
- (a) a registered medical practitioner,
 - (b) a registered nurse,
 - (c) a person (or person within a description) in so far as that person is (or persons of that description are) authorised by a person listed in subsection (2) to exercise the functions of a health worker under sections 6A to 16I.
- (2) The persons are—
- (a) a registered medical practitioner,
 - (b) a registered nurse,
 - (c) a Health Board,
 - (d) a Special Health Board,
 - (e) the Common Services Agency for the Scottish Health Service.
- (3) An authorisation under subsection (1)(c) may, in particular—
- (a) authorise a person (or description of person) to exercise some or all of the functions of a health worker under sections 6A to 16I,
 - (b) authorise a person (or description of person) to exercise functions in relation to particular cases or classes of case,

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- (c) authorise different persons (or descriptions of person) to exercise different functions.
- (4) An authorisation under subsection (1)(c) may be given only if the person listed in subsection (2) considers that the person (or the description of person) has the appropriate skills, qualifications or experience to carry out the functions in respect of which the authorisation is given.
- (5) An authorisation under subsection (1)(c) may be revoked—
 - (a) in the case of an authorisation given to a description of person by a person other than a registered medical practitioner or a registered nurse, by the person who gave that authorisation, and
 - (b) in any other case, by any person listed in subsection (2).
- (6) The Scottish Ministers may give directions (of a general or specific nature) to persons listed in subsection (2) in relation to authorisations under subsection (1)(c).
- (7) A person listed in subsection (2) must comply with any direction given to the person under subsection (6) when authorising a person (or description of person) under subsection (1)(c).
- (8) The Scottish Ministers may by regulations—
 - (a) modify the list in subsection (1),
 - (b) modify the list in subsection (2),
 so as to add to, amend or remove any entry on the list.]

Textual Amendments

F3 S. 16J inserted (26.3.2021) by [Human Tissue \(Authorisation\) \(Scotland\) Act 2019 \(asp 11\), ss. 27\(2\), 29\(2\); S.S.I. 2021/108, reg. 2](#)

[^{F4}16K Interpretation and meaning of “relevant time”

- (1) In sections 1 to 16J and this section—
 - “excepted body part” has the meaning given in section 6D(5),
 - “express authorisation” has the meaning given in section 6(1),
 - “Health Board” means a board constituted by order under section 2(1)(a) of the National Health Service (Scotland) Act 1978,
 - “health worker” has the meaning given in section 16J(1),
 - “incapable of understanding the nature and consequences of deemed authorisation” has the meaning given in section 6D(3),
 - “medical treatment”, in relation to a person, means any procedure or treatment that has the purpose of safeguarding or promoting the person's physical or mental health,
 - “non-resident adult” has the meaning given in section 6D(2)(a),
 - “opt-out declaration” has the meaning given in section 6B(1),
 - “pre-death procedure” has the meaning given in section 16A,
 - “register organisation” has the meaning given in section 2B(2),
 - “Special Health Board” means a board constituted by order under section 2(1) (b) of the National Health Service (Scotland) Act 1978,

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“writing” includes representation of a character in visible form.

(2) For the purposes of sections 1 to 16J, this section and section 50, “relevant time” means—

(a) in relation to a living person, when—

- (i) in the view of the health worker primarily responsible for the person's medical treatment, the person is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment),
- (ii) where the person is receiving life-sustaining treatment, the decision to withdraw that treatment has been taken by that health worker, and
- (iii) in the case of a person who is 12 years of age or over, that health worker is of the view that the person is incapable by reason of ill health of making a decision about the removal and use of a part of the person's body for a purpose referred to in section 3(1),

(b) in relation to a deceased person, immediately before the person's death.]

Textual Amendments

F4 S. 16K inserted (26.3.2021) by [Human Tissue \(Authorisation\) \(Scotland\) Act 2019 \(asp 11\)](#), ss. 27(4), 29(2); S.S.I. 2021/108, reg. 2

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