

Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill

[AS INTRODUCED]

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ACCOMPANYING DOCUMENTS

Explanatory Notes, together with other accompanying documents, are printed separately as SP Bill 72-EN. A Policy Memorandum is printed separately as SP Bill 72-PM.

Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill

[AS INTRODUCED]

An Act of the Scottish Parliament to amend the law on the removal of parts of the human body for transplantation by providing for decisions to be made on behalf of a deceased adult by a proxy and by authorising removal and use in certain cases where the deceased adult has not recorded an objection; and for connected purposes.

- 5 **1 Duties of the Scottish Ministers**
- (1) The Scottish Ministers must ensure that before the first appointed day registers approved by them are in place to enable an adult resident in Scotland to record free of charge—
- 10 (a) an appointment of a proxy for the making of decisions relating to the removal and use of a part of the adult’s body after death for transplantation,
- (b) an objection by the adult to the removal and use of a part of the adult’s body after death for transplantation,
- (c) a withdrawal of any such appointment or objection.
- (2) The Scottish Ministers must ensure that a publicity campaign on the principal changes introduced by this Act runs for the period between the first appointed day and the
- 15 second appointed day.
- (3) In section 1 of the Human Tissue (Scotland) Act 2006 (duties of the Scottish Ministers as respects transplantation, donation of body parts etc.)—
- 20 (a) in paragraph (b), for the words from “donation” to “body” substitute “methods by which the removal of parts of a human body for transplantation may be authorised or objected to”,
- (b) in paragraph (c), for “donated” substitute “removed”.
- 2 Authorised investigating persons**
- After section 2 of the 2006 Act, insert—

“2A Authorised investigating persons

The Scottish Ministers may by regulations provide for certain persons or categories of persons to be designated as authorised investigating persons for the purposes of this Act.”

5 **3 Use of part of body of deceased person for transplantation**

In section 3(2)(a) of the 2006 Act, after “6,” insert “6A, 6B,”.

4 Authorisation by adult superseded by appointment of proxy or recorded objection

In section 6 of the 2006 Act (authorisation: adult), insert at the end—

- 10 “(7) An authorisation by virtue of subsection (1) is to be regarded as withdrawn if, in relation to the same part of the adult’s body, the adult subsequently—
- (a) appoints a proxy under section 6A; or
 - (b) records an objection in a register approved by the Scottish Ministers for the purposes of sections 6A and 6B.”.

5 Authorisation by proxy

15 After section 6 of the 2006 Act, insert—

“6A Authorisation by proxy: transplantation

- (1) The removal and use of a part of a deceased adult’s body for transplantation may be authorised by a proxy appointed by the adult to make decisions relating to such removal and use.
- 20 (2) Only an adult may be appointed as a proxy.
- (3) A proxy may renounce the appointment at any time.
- (4) The appointment may be general or limited to one or more parts of the body.
- (5) Different proxies may not be appointed for different parts of the body and accordingly if a proxy has been appointed for one part of the body a proxy
- 25 nominated for another part is not validly appointed.
- (6) The appointment is valid only if—
 - (a) it is in writing and is either signed by the adult or recorded in a register approved by the Scottish Ministers for the purposes of this section and section 6B; and
 - 30 (b) it gives such information as could reasonably be expected to enable the proxy and any nominated alternate proxy to be contacted after the adult’s death by an authorised investigating person.
- (7) The appointment may nominate an alternate proxy who may act if the first-named proxy cannot be contacted within a reasonable time or is unable or
- 35 unwilling to make a decision within a reasonable time and, if so desired, a second alternate proxy who may act if neither the first-named proxy nor the first-named alternate proxy can be contacted within a reasonable time or is able and willing to make a decision within a reasonable time.

- 5
- (8) An authorised investigating person may determine what is a reasonable time under subsection (7), taking into account the time within which a part will have to be removed if it is to be used for transplantation.
- (9) An appointment of a proxy or alternate proxy may be withdrawn by the adult at any time.
- (10) The withdrawal must be in writing and either signed by the adult or recorded in a register approved by the Scottish Ministers for the purposes of this section and section 6B.
- 10 (11) Where the adult is blind or unable to write, an appointment or a withdrawal of an appointment may be signed by another adult (the signatory) on the adult's behalf before a witness.
- (12) Nothing in subsection (11) prevents an adult who is blind from recording an appointment or withdrawal, or signing an appointment or withdrawal himself or herself.
- 15 (13) A document which is signed by a signatory on behalf of an adult under subsection (11) must contain a statement signed by both the signatory and the witness in the presence of the adult and of each other that the adult, in the presence of them both, expressed the intention to make or withdraw the appointment, as the case may be, and requested the signatory to sign the document on behalf of the adult.
- 20 (14) An appointment of a proxy is to be regarded as withdrawn if, in relation to the same part of the body, the adult subsequently grants an express authorisation of removal and use under section 6 or records an objection to removal and use in a register approved by the Scottish Ministers for the purposes of this section and section 6B.
- 25 (15) Where a proxy with power to decide on removal and use of a part of the body has communicated a decision relating to that part to an authorised investigating person, the decision may be regarded by the authorised investigating person as decisive and as not affected by a decision communicated later to the authorised investigating person by that or any other proxy.
- 30 (16) Where the order of communications by two or more proxies is unclear the decision of the first-named proxy prevails over the decision of an alternate proxy and the decision of the first-named alternate proxy prevails over that of the second-named alternate proxy.
- 35 (17) In this section, “writing” includes representation of a character in visible form.”.

6 Authorisation by operation of law

- (1) After section 6A of the 2006 Act (as inserted by section 5 of this Act), insert—

“6B Authorisation by operation of law: transplantation

- 40 (1) The removal and use of a part of a deceased adult's body for transplantation are authorised by operation of law if the following requirements are satisfied—
- (a) the adult was resident in Scotland at the time of death;
 - (b) an authorised investigating person has confirmed—

- (i) that he or she is not aware of any authorisation of such removal and use by the adult under section 6 which was in force immediately before the adult's death;
- 5 (ii) that he or she, having examined any register approved by the Scottish Ministers for the purposes of section 6A and this section, is not aware of any objection by the adult to such removal and use which was in force immediately before the adult's death;
- 10 (iii) that he or she has contacted or attempted to contact all known proxies appointed by the adult under section 6A with power to decide on the removal and use and has not, within a reasonable time, received a decision from any such proxy;
- 15 (iv) that he or she has not, before the end of the time referred to in subparagraph (iii), received a decision from any proxy with power to decide on the removal and use who was unknown prior to the receipt of the decision;
- (v) that in his or her opinion, after consulting the nearest relative of the adult, if any, and after applying the presumption in subsection (3), the adult had a reasonable opportunity to record an objection to such removal and use; and
- 20 (vi) that he or she has asked the adult's nearest relative, if any, whether the relative has actual knowledge that the adult was unwilling for the part to be removed and used for transplantation and has concluded, in the light of any answer given, that the relative has no such knowledge.
- 25 (2) An objection by the adult is not in force immediately before the adult's death if it has been withdrawn by the adult or if, in relation to the same part of the body, the adult has subsequently granted an express authorisation under section 6 or appointed a proxy under section 6A.
- 30 (3) There is a rebuttable presumption that an adult had a reasonable opportunity to record an objection if he or she, since attaining the age of 16, had been habitually resident in Scotland for any continuous period of 6 months beginning after the day appointed under section 19(2) of the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Act 2015.
- 35 (4) An objection by a proxy is ineffective if it is received by an authorised investigating person after he or she has issued a statement under section 11(5)(cb) that in his or her opinion the requirements of this section are satisfied.
- (5) In this section—
- 40 (a) "a reasonable time" is such time as the authorised investigating person considers reasonable, taking into account the time within which a part of the body will have to be removed if it is to be used for transplantation;
- (b) "the nearest relative" is any such relative, as defined in section 50, who can be consulted by the authorised investigating person, using his or her best endeavours, within a reasonable time after the adult's death."
- 45 (2) No removal for transplantation is authorised by virtue of this section before such day, being a day at least 6 months after the first appointed day, as the Scottish Ministers may by regulations appoint.

7 Rule if order of acts unclear

After section 6B of the 2006 Act (as inserted by section 6 of this Act), insert—

“6C Rule if order of acts unclear

Where it is uncertain which of the following acts by an adult came last, the adult is to be treated as having done none of them—

- (a) an authorisation under section 6,
- (b) an appointment of a proxy under section 6A,
- (c) a recording of an objection in a register approved by the Scottish Ministers for the purposes of sections 6A and 6B.”

8 Authorisation by adult’s nearest relative

(1) Section 7 of the 2006 Act (authorisation by adult’s nearest relative) is amended as follows.

(2) After subsection (1), insert—

“(1A) Subsection (1) does not apply to removal for transplantation if a proxy appointed by the adult is known to be in the process of deciding, or has decided, for or against the removal.”

(3) After subsection (3), insert—

“(3A) The nearest relative may not authorise removal and use of a part of the body under subsection (3) if—

- (a) there is in force immediately before the adult’s death an objection to the removal and use for transplantation of that part by the adult which is recorded by the adult in a register approved by the Scottish Ministers for the purposes of sections 6A and 6B;
- (b) an authorised investigating person is awaiting, or has received, a decision by a proxy relating to removal and use of that part for transplantation; or
- (c) an authorised investigating person is investigating whether, or has concluded that, such removal and use is authorised by operation of law under section 6B.”

(4) In subsection (4)(a), after “transplantation” insert “or if there is in force immediately before the adult’s death an objection by the adult to the removal and use for transplantation of the part in question which was recorded in a register approved by the Scottish Ministers for the purposes of sections 6A and 6B”.

(5) After subsection (4), insert—

“(4A) Section 6B(2) applies for the purpose of determining whether an objection by the adult is in force immediately before the adult’s death.”

9 Further requirements relating to authorisation under section 6A or 6B

(1) Section 11 of the 2006 Act (removal of part of body of deceased person: further requirements) is amended as follows.

(2) In subsection (4)(c), after “6,” insert “6A, 6B,”.

(3) After subsection (5)(c), insert—

“(ca) in the case of authorisation by a proxy by virtue of section 6A, an authorised investigating person has recorded the dates, times and results of the communications with all known proxies with power to decide on the removal and has stated that—

- 5 (i) there bears to be a valid appointment of the authorising proxy under that section;
- (ii) there is no reason to believe that the appointment was withdrawn;
- (iii) the appointment bears to confer power to authorise removal of the relevant part for transplantation;
- 10 (iv) where the authorising proxy is an alternate proxy, any proxy named earlier in the appointment could not be contacted within a reasonable time or was unable or unwilling to give a decision within a reasonable time, as determined by the authorised investigating person under section 6A(8);
- 15 (v) the authorisation bears to be in writing signed by the proxy or was given in some other way which is described and recorded by the authorised investigating person; and
- (vi) the authorisation bears to be as respects the deceased adult and to authorise removal of the part for transplantation;
- 20 (cb) in the case of authorisation by operation of law by virtue of section 6B, an authorised investigating person—
- (i) has recorded the dates, times and results of the examinations of the records and communications with any known proxy or nearest relative for the purpose of section 6B; and
- 25 (ii) has stated that in his or her opinion the requirements of section 6B are satisfied;”.

10 Removal of tissue sample

In section 12 of the 2006 Act (removal of tissue sample to determine viability of transplantation), after “6(1),” insert “6A(1), 6B(1),”.

30 11 Offences

In section 16(1)(a) of the 2006 Act, after “6,” insert “6A, 6B,”.

12 Authorisation for transplantation to have priority

- (1) Section 22 of the 2006 Act (authorisation by virtue of Part 1 for transplantation to have priority) is amended as follows.
- 35 (2) In subsection (1), for the words from “If” to “the authorisation” substitute “An authorisation under this Act of removal and use of a part of an adult’s body for transplantation”.
- (3) In subsection (1)(a), the words “, which is also in force at that time” are repealed.
- (4) Subsection (3) is repealed.

13 Nearest relative

- (1) Section 50 of the 2006 Act (nearest relative) is amended as follows.
- (2) In subsection (1), for “7 and 30” substitute “6B, 7, 11 and 30”.
- (3) In subsection (5), insert “(a)” before “authorisation” so that the words from there to the end become paragraph (a), and after that paragraph insert—
- “(b) for the purposes of section 6B an authorised investigating person may decide which of them to regard as the nearest relative”.
- (4) In subsection (6)(b), after “authorisation” insert “or, in relation to section 6B, to respond to any questions required by that section to be put by the authorised investigating person”.

14 Witnesses

In section 51(1) of the 2006 Act—

- (a) after “6(3),” insert “6A(11),”,
- (b) for the words from “authorisation”, where first occurring, to “in writing,” substitute “a writing”.

15 Adults with incapacity

- (1) The Adults with Incapacity (Scotland) Act 2000 is amended as follows.
- (2) In section 16(6), at the end of paragraph (d) omit “or” and insert—
- “(da) make or withdraw an appointment of a proxy under section 6A of that Act;
- (db) record an objection in a register approved by the Scottish Ministers for the purposes of sections 6A and 6B of that Act or withdraw an objection recorded in the register; or”.
- (3) In section 64(2), at the end of paragraph (d) omit “or” and insert—
- “(da) make or withdraw an appointment of a proxy under section 6A of that Act;
- (db) record an objection in a register approved by the Scottish Ministers for the purposes of sections 6A and 6B of that Act or withdraw an objection recorded in the register; or”.

16 Regulations in relation to certain adults resident outside Scotland

- (1) The Scottish Ministers may by regulations further modify the 2006 Act in relation to the removal of parts of the body for transplantation from a deceased adult who meets the requirements of subsection (2).
- (2) The requirements are that the adult died in Scotland but was resident, immediately before death, in a jurisdiction other than Scotland the laws of which authorise the removal of parts of the body from a deceased adult for transplantation, either generally or in particular circumstances, in the absence of a prior objection by the adult.
- (3) Regulations made under subsection (1) are subject to the affirmative procedure.

17 Reporting to the Scottish Parliament

- (1) The Scottish Ministers must report to the Scottish Parliament on the effectiveness of the changes made by this Act.
- (2) The report is to cover a period of at least a year beginning on the second appointed day.
- 5 (3) It is to be laid before the Parliament not later than two years after that day and published.

18 Interpretation

- (1) In this Act—

“the 2006 Act” means the Human Tissue (Scotland) Act 2006,

10 “the first appointed day” means the day appointed under section 19(2),

“the second appointed day” means the day appointed under section 6(2),

“adult” means a person who is 16 years of age or over,

“transplantation” means transplantation into a human body.

- (2) In section 60 of the 2006 Act (interpretation), insert at the end—

15 “(3) In this Act references to an authorised investigating person are to a person designated as such in accordance with regulations made by the Scottish Ministers under section 2A.”.

19 Commencement

- 20 (1) This section and sections 1(1) and (2), 2, 6(2), 16, 17, 18(1) and 20 come into force on the day after Royal Assent.
- (2) The remaining provisions of this Act come into force on such day as the Scottish Ministers may by regulations appoint.

20 Short title

25 The short title of this Act is the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Act 2015.

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