EXPLANATORY NOTES

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As required under Rule 9.3 of the Parliament’s Standing Orders, the following documents are published to accompany the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill introduced in the Scottish Parliament on 1 June 2015:

- Explanatory Notes;
- a Financial Memorandum;
- Anne McTaggart’s statement on legislative competence; and
- the Presiding Officer’s statement on legislative competence.

A Policy Memorandum is published separately as SP Bill 72–PM.
EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes have been prepared by the Non-Government Bills Unit on behalf of Anne McTaggart, the member who introduced the Bill, in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the Parliament.

2. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a section, or a part of a section, does not seem to require any explanation or comment, none is given.

THE BILL

3. The main purpose of the Bill is to amend the law on human transplantation in Scotland to provide for a move to a “soft opt-out” system. In such a system, a part of a deceased adult’s body (typically, an organ such as a heart, kidney or liver and also tissues such as skin, bones and eyes) may be removed for the purpose of transplantation without the adult having given express authorisation in advance, so long as the adult had not recorded or expressed any objection to such removal. In addition, the Bill provides for an adult to appoint a proxy (or proxies) to make decisions on the posthumous removal of parts of his or her body for the purpose of transplantation, and this serves as a further means by which such removal may be authorised.

Terminology

4. The Bill very largely consists of amendments to the Human Tissue (Scotland) Act 2006 (“the 2006 Act”), although it also makes minor and consequential amendments to the Adults with Incapacity (Scotland) Act 2000. Accordingly, the Bill generally adopts the terminology of the 2006 Act, in particular by referring to “authorisation” for the removal of “parts of the body” (rather than, for example, referring to “organ donation”). This terminology reflects the fact that the 2006 Act is of more general application than a term such as “organ donation” implies, dealing as it does (in Part 1) with the removal and use of any human tissue (which includes but is not limited to organs themselves) for a range of purposes including transplantation, but also including research, education or training, and audit. (Parts 2 and 3 of the 2006 Act make provision for post-mortem examinations, and for the use of tissue samples and organs no longer required for the procurator fiscal’s purposes.) In these Notes, in the context of removing parts of the body for the purposes of transplantation, reference is sometimes made to the removal of “organs” as a convenient shorthand.

Authorisation under the 2006 Act

5. Under Part 1 of the 2006 Act, authorisation is one of two essential pre-conditions (set out in section 3) of lawful removal of any part of the body of a deceased person (the other being compliance with certain requirements, set out in section 11, about how and by whom removal is carried out). Removal without authorisation (or without complying with the section 11
requirements) is an offence (under section 16) for which the maximum penalty (if convicted on indictment) is 3 years’ imprisonment, a fine or both.

6. At present, the following types of authorisation are provided for:
   - authorisation by an adult (section 6) – “adult” being defined as a person aged 16 or over in section 60
   - authorisation by the adult’s nearest relative (section 7) – “nearest relative” being defined in section 50
   - authorisation as respects a child aged 12 or over either by the child (section 8) or by an adult with parental rights and responsibilities for the child (section 9)
   - authorisation as respects a child aged under 12 by a person with parental rights and responsibilities for the child (section 10).

COMMENTARY ON SECTIONS

Section 1: Duties of the Scottish Ministers

7. This section imposes two new duties on the Scottish Ministers (and updates existing duties) to ensure that the new provisions added to the 2006 Act by later sections can work effectively.

8. Under the existing “opt-in” system, a principal means for people to give authorisation for the posthumous removal of their organs is by recording their wishes in the organ donor register (maintained by NHS Blood and Transplant). The existence of such a central register greatly facilitates the process of establishing the wishes of a deceased person. For this reason, subsection (1) requires the Scottish Ministers to ensure that registers are in place to allow adults resident in Scotland to record the other choices made available under the Bill – i.e. to appoint a proxy (under new section 6A of the 2006 Act) or to object to the removal of an organ or organs (thus preventing the operation of new section 6B). Subsequent choices by such adults to withdraw such appointments or objections are also to be capable of being recorded in these registers. As it is anticipated that the registers in question will be part of the existing system of registers maintained at UK level by NHSBT, the duty on Ministers is not necessarily to establish such registers themselves but merely to ensure that registers approved by them are in place before “the first appointed day” – that is, the day appointed by them (under section 19(2)) for the commencement of most of the Bill’s substantive provisions.

9. Under subsection (2), Ministers must ensure that a publicity campaign on the change to a “soft opt-out” system runs for the period between the first appointed day and the second appointed day. The latter is the day appointed by them (under section 6(2)) when it first becomes lawful to remove a deceased person’s organs for transplantation under new section 6B of the 2006 Act (inserted by section 6 of the Bill), which provides for “authorisation by operation of law”.

10. Taken together, these provisions should ensure that, during the period between the two appointed days (which must, under section 6(2), be at least 6 months) adults resident in Scotland
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are able to record any objection they have to posthumous removal of their organs, and are made aware of their right to do so.

11. Subsection (3) makes consequential changes to the existing duties of the Scottish Ministers (under section 1 of the 2006 Act) so that they reflect the expanded scope of Part 1 of that Act.

Section 2: Authorised investigating persons

12. The new provisions inserted by the Bill into the 2006 Act refer in various places to the role of the “authorised investigating person” (AIP). This section adds a new provision near the beginning of Part 1 of the 2006 Act to provide for the designation of persons as AIPs in regulations made by the Scottish Ministers. This allows designation to be by category (e.g. by reference to a role or level of experience within the NHS). By virtue of section 59(2) of the 2006 Act, regulations designating AIPs will be subject to annulment by resolution of the Parliament (“the negative procedure”).

Section 3: Use of part of body of deceased person for transplantation

13. As noted above, section 3 of the 2006 Act makes it a requirement of the lawful removal of a part of the body of a deceased person that the removal has been authorised under one of the relevant provisions of the Act (which are listed). Section 2 of the Bill updates the list to include reference to new sections 6A and 6B (inserted by sections 5 and 6 of the Bill, respectively).

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

14. At present, as noted above, the 2006 Act provides only one option to an adult who wishes to express, while alive, a preference as regards the removal of his or her organs after death – namely, authorisation under section 6. Under the 2006 Act as amended by the Bill, there are to be two additional options – to appoint a proxy (under new section 6A) or to object to the removal of some or all of his or her organs. These three options are to be mutually exclusive (at least as respects each organ), so there is always clarity about the person’s wishes. Accordingly, section 4 of the Bill amends section 6 (of the 2006 Act) to make clear that the appointment of a proxy or the registering of an objection supersedes any prior section 6 authorisation.

Section 5: Authorisation by proxy

15. This section of the Bill adds a new section 6A to the 2006 Act to enable an adult to appoint a proxy (who must also be an adult – see 6A(2)) to make decisions about the adult’s body after his or her death.

16. New section 6A(1) makes clear that a proxy’s role is limited to making decisions about the removal and use of a part of the adult’s body for the purpose of transplantation – and not for any of the other purposes for which section 6 authorisation may apply (e.g. research).
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17. Under new section 6A(4), an adult may appoint a proxy to make decisions about all of the adult’s organs or only specified organs. If the appointment only applies to specified organs, the adult may choose other options (i.e. authorising their removal under section 6, or objecting to their removal) in respect of other organs. But, under new section 6A(5) an adult may not appoint one proxy in relation to some organs, and another proxy to make decisions in relation to other organs.

18. Under new section 6A(6), the appointment of a proxy must be made in writing (as defined in subsection (17)) and either recorded in the approved register (see section 1 of the Bill) or signed. (A signature is required to help authenticate a non-registered appointment, but is not required for a registered appointment to facilitate online registration.) The appointment must give such information as could reasonably be expected to enable a proxy to be contacted should the need arise – for example, the proxy’s name and contact details (such as telephone numbers and e-mail addresses). It is not necessary, for an appointment to be valid, that the proxy must consent to, or even be aware of the appointment; but the proxy does have (under new section 6A(3)) the right to renounce the appointment at any time.

19. To maximise the chances of there being a proxy available to make a decision within a short timescale (as may sometimes be necessary if organs are to be removed quickly enough to be used for transplantation), provision is made in new section 6A(7) for up to three people to be appointed as an adult’s proxies.

20. An authorised investigating person (AIP) is a person with responsibility (by virtue of new section 2A of the 2006 Act, inserted by section 2 of the Bill) for establishing whether removal of an organ for transplantation is lawfully authorised. One of the steps an AIP must take in order to establish whether there is authorisation under new section 6B (inserted by section 6 of the Bill) is to make contact with any known proxy with a view to securing a decision by the proxy whether or not to authorise removal of the organ in question. Under new section 6A(7), the AIP must make contact with the proxies in priority order, only moving to the second (or third) proxy on the list if the first (or first and second) either do not respond in a reasonable time (e.g. by failing to reply to voicemail messages or e-mails), or do not reach a decision in a reasonable time. Under section 6A(8), it is for the AIP to judge what constitutes “a reasonable time”, taking into account how quickly the organ in question would have to be removed if it is to be used for transplantation (which means the amount of time that is reasonable may reduce the further down the proxy list the AIP goes).

21. Subsections (9) and (10) of new section 6A allow the adult to withdraw a proxy appointment at any time, subject to the same requirements as apply to the making of an appointment. Subsections (11) to (13) make special provision, in relation to either the making or withdrawal of a proxy appointment, for adults who are blind or unable to write, similar to the provision already made for such adults in section 6 of the 2006 Act. Consequential changes are made to section 51 of the 2006 Act by section 14 of the Bill (see below).

22. Under new section 6A(14), an adult’s decision either to authorise posthumous removal of an organ (under section 6 of the 2006 Act) or to register an objection to such removal supersedes any earlier proxy appointment. This matches the provision made by new section 6(7) (inserted by section 4 of the Bill, and explained in paragraph 14 above).
23. As noted above, where an adult has appointed two or more proxies, the AIP is expected to contact them in priority order, and is entitled to move on to other proxies in the list before the first has responded or made a decision. Where that happens, it is possible that a proxy higher in the list may respond with a decision either at around the same time as, or after, a proxy further down the list does so. Accordingly, there is a need for clear rules to guide the AIP as to which proxy decision is to take precedence, so that a decisive outcome can be arrived at as early as possible, without the AIP needing to wait until every proxy who has been contacted has responded.

24. Accordingly, new section 6A(15) enables the AIP to treat as decisive whichever proxy’s decision is communicated first to the AIP, and new section 6A(16) requires the AIP to treat a decision of the first proxy in the list as taking precedence over that of the second or third (and a decision of the second over that of the third) if it is unclear which of them communicated their decision earliest.

25. New section 6A(17), which corresponds to an equivalent provision in section 6 of the 2006 Act (subsection (6)), ensures that an appointment or withdrawal (unless it also requires to be signed) can be made online.

Section 6: Authorisation by operation of law

26. This section inserts a new section 6B into the 2006 Act to provide for a new means by which the removal of a part of the body of a deceased adult for transplantation may be authorised.

27. New section 6B(1) sets out the essential requirements, all of which must be satisfied before authorisation “by operation of law” is obtained. The first is that the adult was resident in Scotland at the time of death (paragraph (a)), as a result of which this form of authorisation cannot apply (for example) to someone who is in Scotland as a tourist or visitor at the time of their death. The second is that an AIP has confirmed that each of six separate pre-conditions has been met.

28. The six pre-conditions (set out in new section 6B(1)(b)(i) to (vi)) reflect the sequence of steps that an AIP would be expected to follow, in order to establish whether or not there is authorisation (by operation of law) to remove a particular organ. As all six are necessary pre-conditions, a failure to meet any one is sufficient to allow a negative conclusion to be arrived at, making it unnecessary for the AIP to initiate any subsequent step.

29. The first two pre-conditions are met if the AIP, after appropriate enquiry, is unaware of any decision by the deceased adult to “opt in” (under existing section 6 of the 2006 Act) or to “opt out” – the latter requiring the AIP to check the register that has been approved by the Scottish Ministers for any objection recorded there.

30. The third pre-condition requires the AIP to have contacted, or attempted to contact, any proxy whose appointment the AIP is aware of. If no such proxy has communicated a decision to the AIP within a reasonable time, and if no other validly-appointed proxy (of whom the AIP was
initially unaware) has communicated a decision within the same timescale, then both the third and fourth pre-conditions are met.

31. Each of the final two pre-conditions requires the AIP to ask the adult’s “nearest relative” (defined in new section 6B(5)(b) – see below) two questions – the first about whether the adult had a reasonable opportunity to record an objection, and the second about whether the adult was unwilling for the organ in question to be removed for transplantation. In relation to the first question, the AIP must apply the presumption set out in new section 6B(3) – see below. In each case, the AIP’s assessment of whether the pre-condition is met must be informed by any answer given by the nearest relative.

32. New section 6B(2) provides that an objection by the adult to the removal of an organ is not in force if the objection has either been withdrawn or superseded by a later decision by the adult either to authorise the organ’s removal or to appoint a proxy to make a decision about its removal. If, for either reason, an objection is not in force, the objection cannot affect the AIP’s ability to decide whether removal of the organ in question is authorised “by operation of law”.

33. New section 6B(3) amplifies the fifth pre-condition by creating a “rebuttable presumption” about what constitutes a “reasonable opportunity” to object. The presumption is that being habitually resident in Scotland, as an adult, for a continuous 6-month period beginning after the “first appointed day” qualifies as such a reasonable opportunity. This is because the first appointed day is the day by which (under section 1) a register must be in place in which objections may be recorded, and by which a publicity campaign lasting for at least 6 months must have begun. Accordingly, anyone who was habitually resident in Scotland, as an adult, during such a 6-month period should have been made aware how to object and what the consequences of not objecting were – making it reasonable to interpret the absence (by the end of that period) of such an objection as tacit acceptance of those consequences. However, the presumption is rebuttable – meaning that the AIP may decide that a particular adult did not have the requisite “reasonable opportunity”, despite meeting the habitual residence test, where there are specific factors that would (in the AIP’s opinion) count against the presumption. No provision is made for what those factors might be – but they might involve the adult not being physically present in Scotland or lacking capacity to act (e.g. by being in a coma or detained under mental health legislation) during substantial parts of the 6-month period.

34. New section 6B(4) provides that a proxy’s objection is ineffective if it is received after an AIP has stated a conclusion that all the pre-conditions of section 6B(1) are met and hence that there is authorisation “by operation of law” to remove the organ. This is to ensure that such a conclusion, once stated, cannot be overturned by the late communication of a proxy decision. However, this does not prevent a proxy decision being effective until that conclusion has been stated, even if the “reasonable time” allowed to that proxy by the AIP has expired.

35. New section 6B(5) defines two key terms used in this new section. The definition of “a reasonable time” makes clear it is for the AIP to determine the duration (so long as it is “reasonable”), taking into account how soon after death a particular organ needs to be removed if it is to be used for transplantation (something that may vary from one type of organ to another). Accordingly, the AIP may be justified in specifying different periods of time according to a range of factors, including the medical circumstances of the adult from whom organs are to or
may be removed, the medical circumstances of the intended recipient, and the time required to transport the organ after removal (e.g. where the intended recipient is in another part of the UK).

36. The definition of “the nearest relative” makes clear that the AIP need only use “best endeavours” to consult at least one person who qualifies under the section 50 definition. In a case where the deceased adult does not appear to have any immediate family (i.e. relatives who qualify by virtue of one of the earlier paragraphs in the section 50 list), it may not be possible for the AIP to identify (let alone consult), within a reasonable time, every person who might qualify by virtue of one of the later paragraphs.

Section 7: Rule if order of acts unclear

37. This section inserts a further new section 6C into the 2006 Act to provide a means of clarifying an uncertainty of timing that could arise. Under the system created by the Bill, adults in Scotland are to be given three specific choices in relation to their organs – to opt in by giving authorisation under section 6, to appoint a proxy under section 6A, or to opt out by recording an objection. These are to be mutually exclusive, and provision is made elsewhere in the Bill to ensure that only the most recent choice made by the adult (out of the three options) is “in force”, and that any earlier choice is ineffective. New section 6C is a fall-back provision to deal with any situation where it is not clear which decision was made most recently (and hence which option is in force), and requires that adult to be treated as having chosen none of them.

Section 8: Authorisation by adult’s nearest relative

38. This section makes amendments to existing section 7 of the 2006 to ensure it continues to work effectively alongside the new provisions for authorisation by proxy (in section 6A) and for objections (in section 6B).

39. Existing subsection (1) of section 7 allows a deceased adult’s nearest relative (defined in section 50 of the 2006 Act) to authorise the removal and use of the adult’s organs for transplantation in the absence of authorisation by the adult (under section 6).

40. The new subsection (1A) (inserted into section 7 by subsection (2)) blocks such nearest-relative authorisation where a proxy is in the process of deciding or has decided whether to give such authorisation. This ensures that where the adult appointed a proxy to make decisions about transplantation, and that proxy can be contacted, any decision made by that proxy takes precedence over any decision that the nearest relative might otherwise make under section 7.

41. Existing subsection (3) of section 7 deals with the situation where the adult gave authorisation for some organs but not others to be removed and used for transplantation, and allows the nearest relative to authorise the removal and use of those other organs for the other purposes of the 2006 Act (research, education or training, or audit) – but not for transplantation.

42. The new subsection (3A) inserted into section 7 by subsection (3) further limits the nearest relative’s role in these circumstances – partly to reflect the wider range of options that are now to be available to the adult (to opt out or appoint a proxy, as well as to opt in), and partly
to reflect the role of the AIP in investigating whether there is section 6B authorisation (to remove and use organs, for the purpose of transplantation, “by operation of law”).

43. Where the deceased adult had opted out (i.e. recorded an objection to an organ’s removal for the purpose of transplantation), that objection is to be decisive – so blocks any authorisation by the nearest relative, whether for transplantation or (by virtue of new subsection (3A)(a)) any other purpose. In a case where the adult had appointed a proxy, new subsection (3A)(b) blocks any authorisation by the nearest relative once a proxy decision has been made, or while the AIP is awaiting such a proxy decision. So the nearest relative would only be able to authorise the organ’s removal and use for a non-transplantation purpose if the AIP’s attempts to contact the known proxies have failed, or if no such proxy has communicated a decision within the time allowed by the AIP. Finally, under new subsection (3A)(c), a decision by the nearest relative is blocked if an AIP has concluded under section 6B that removal of the organ for transplantation is authorised, or while the AIP’s investigation is in progress. Accordingly, if such an investigation has not been started or has been discontinued without a conclusion being reached, or if the AIP has concluded that removal for transplantation under section 6B is not authorised, then the nearest relative would be in a position to authorise the organ’s removal and use (under section 7) for another purpose.

44. Existing section 7(4)(a) prevents the nearest relative giving authorisation (under section 7(1)) for the removal and use of any of the deceased adult’s organs for transplantation where that relative has “actual knowledge” that the adult was unwilling for his or her organs in general (or that organ in particular) to be removed and used for that purpose. Subsection (4) extends that provision so that the nearest relative is also prevented from giving section 7(1) authorisation where examination of the register reveals that an objection by the adult to the removal and use of the particular organ for transplantation was “in force” at the time of death. This helps to ensure that the adult’s most recent expressed decision always takes precedence over the later view of the nearest relative.

45. Subsection (5) clarifies what is meant in the amended section 7(4) by an objection of the adult being “in force” immediately before his or her death – and does so by applying here the same test as is introduced, for the purposes of new section 6B (inserted by section 6 of the Bill), by subsection (2) of that new section (and explained in paragraph 32 above).

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

46. Section 11 of the 2006 Act sets out a list of further requirements that must be satisfied before an organ may be removed, once authorisation has been obtained. Section 9 of the Bill amends and extends the list to take account of the new forms of authorisation added to the 2006 Act by the Bill, and to reflect the role of the AIP.

47. Existing section 11(4) requires the person who is to remove the organs to be satisfied (amongst other things) that the removal is authorised by reference to a list of the other sections of the 2006 Act under which authorisation may be given. Subsection (2) updates the list to include the two new sections (6A and 6B) added by the Bill.
48. Subsection (3) adds two new paragraphs to the list in section 11(5), each of which defines what constitutes being satisfied that the removal (of organs) is authorised under a particular provision of the 2006 Act. The two new paragraphs, (ca) and (cb), fulfil this function in relation to the two new provisions about authorisation added by the Bill (i.e. sections 6A and 6B respectively).

Section 10: Removal of tissue sample

49. Section 12 of the 2006 Act allows the person responsible for removing an organ for transplantation to remove and examine a tissue sample (in order to determine whether the transplantation would be viable). In doing so, the section lists the various provisions of the Act under which authorisation for the removal may currently be given. This section amends the list to include the two new sources of authorisation added by the Bill.

Section 11: Offences

50. Section 16 of the 2006 Act makes it an offence to remove or use part of a deceased person’s body without authorisation, and does so by reference to a list of the relevant sections of the Act. This section of the Bill amends that list to include the two new sources of authorisation added by the Bill.

Section 12: Authorisation for transplantation to have priority

51. Section 22 of the 2006 Act ensures that authorisation to remove part of a deceased person’s body for transplantation is given priority over certain other uses of the body (or part) for which separate authorisation may also exist.

52. Section 22(1) of the 2006 Act currently gives a deceased adult’s own authorisation for transplantation (under section 6) priority over:
   - authorisation by the adult in connection with a post-mortem examination (under section 29(1) of the 2006 Act)
   - a request by the adult that his or her body be used after death for anatomical examination (by virtue of section 4(1) of the Anatomy Act 1984)
   - any right of another person to give authorisation in connection with a post-mortem examination (under section 30(1) or (2) of the 2006 Act).

53. Section 22(3) of the 2006 Act makes exactly comparable provision in relation to authorisation by a deceased adult’s nearest relative (under section 7) – i.e. it gives such authorisation priority over the same list of alternative authorisations (for post-mortem or anatomical examination).

54. Subsection (2) amends section 22(1) so the authorisation that takes priority is any authorisation for transplantation of an adult’s organs under the 2006 Act – including authorisation under new sections 6A and 6B as well as under existing sections 6 and 7. As a consequence of this widening of the scope of section 22(1), 22(3) is no longer needed – so it is repealed by subsection (4). Subsection (3) removes some redundant wording from section 22(1).
Section 13: Nearest relative

55. Section 50 of the 2006 Act defines “the nearest relative” for the purposes of sections 7 and 30 of that Act. Subsection (2) extends this definition to cover new section 6B and existing section 11. (The references to a “nearest relative” in section 11 are those in new subsection (5)(cb), inserted by section 9(3) of the Bill.)

56. Section 50(5) deals with the situation where more than one person falls within one of the paragraphs in the section 50(1) definition – e.g. where a deceased adult has two children, or two parents – and makes clear that they rank equally and that authorisation may be given by either (or any) of them.

57. Subsection (3) adds a new paragraph entitling an authorised investigating person (AIP) to choose one of the equally-ranked relatives as “the nearest relative” for the purposes of investigating whether or not removal of a deceased adult’s organs is authorised under new section 6B. The new paragraph enables the AIP to obtain a single decisive answer to the questions he or she must ask of a nearest relative, even if there are two or more equally-ranked relatives to choose from, who may have differing views.

58. Section 50(6) requires a person’s relationship with the deceased adult to be disregarded if (among other things) the person does not wish or is unable to make a decision on the issue of authorisation. Subsection (4) extends this to cover the situation where the AIP, investigating whether or not removal of a deceased adult’s organs is authorised under new section 6B, has to ask questions of the nearest relative (rather than seeking their authorisation). This ensures that an AIP who is working down the list of relatives in the section 50(1) definition to find someone prepared to answer these questions is entitled to disregard anyone who either cannot or will not give the answers required.

Section 14: Witnesses

59. Section 51 of the 2006 Act makes additional provision about the witnessing of things, where this is a requirement under other provisions of the Act – for example, where the person doing that thing is blind or unable to write. Section 51(1) sets out the requirements that apply to witnessing things (authorisation, nomination or the withdrawal of either) that require to be done in writing – namely that the (or each) witness is a witness to both the signature and the content of the writing, is an adult, and signs the writing; and that, where two witnesses are required, they are present at the same time.

60. Paragraph (a) extends these requirements to new section 6A(11), which makes provision for an adult’s authorisation of a proxy (or withdrawal of such an appointment) to be signed by someone else, before a witness, when the adult is blind or unable to write. Paragraph (b) is a drafting change to simplify the existing wording (as an alternative to further complicating the list of things described).
Section 15: Adults with incapacity

61. This section of the Bill amends the Adults with Incapacity (Scotland) Act 2000 to impose restrictions on what may be done by an adult’s welfare attorney or guardian.

62. Section 16 of the 2000 Act allows a person to grant a power of attorney relating to his personal welfare (a “welfare power of attorney”) that may be exercised at such time as the granter lacks the capacity to make decisions for himself or herself. Subsection (6) of that section imposes various restrictions on what a welfare attorney may do, and this currently includes provision preventing the attorney giving authorisation for the removal or use of organs under various sections of the 2006 Act. The new restrictions added by subsection (2) prevent a welfare attorney from either appointing (or withdrawing the appointment of) a proxy, or objecting to the removal of the adult’s organs.

63. Subsection (3) amends section 64(2) of the 2000 Act to impose the same new restrictions on a guardian. A guardian is someone appointed by a court (under section 58 of the 2000 Act) to exercise certain powers on behalf of a person who lacks capacity in relation to his or her financial affairs or personal welfare.

Section 16: Regulations in relation to certain adults resident outside Scotland

64. This section empowers the Scottish Ministers to further modify the 2006 Act by regulations in relation to adults who died in Scotland when resident in another jurisdiction that operates an opt-out system for organ donation. For example, it may become possible in the future for section 6B to authorise the removal of organs for transplantation from an adult who was (immediately before dying in Scotland) a resident of Wales (which has already legislated for such a system).

65. Regulations under this section are subject to the affirmative procedure, and so require the approval of the Scottish Parliament by resolution.

Section 17: Reporting to the Scottish Parliament

66. This section requires the Scottish Ministers to lay before the Parliament and publish, no later than two years after the “second appointed day” (the day appointed under section 6(2)), a report on the effectiveness of the changes made by the Bill. The report must cover a period of at least a year from that day – i.e. the first year during which authorisation by operation of law (under section 6B) will have been in operation.

Section 19: Commencement

67. This section provides for the Bill to come into force on a staged basis. The provisions listed in subsection (1) come into force immediately after Royal Assent, for example to ensure that preliminary steps (on which the main provisions of the Bill depend) can be taken in advance of those main provisions coming into force. Subsection (2) requires the Scottish Ministers to appoint a later day (the “first appointed day”) for the commencement of the rest of the Bill’s provisions. These other provisions include section 5 (which adds new section 6B to the 2006
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Act), although it will not be until the “second appointed day”, at least 6 months later (see section 6(2)) that it becomes lawful to remove a deceased adult’s organs for transplantation under that new section. This ensures that, by the time any such removal is authorised (which requires consideration of whether the adult had a reasonable opportunity to object), a period of at least 6 months has elapsed during which an adult resident in Scotland not only had the option to object (or to appoint a proxy), but was also made aware of that option (by virtue of the publicity campaign referred to in section 1(2)).

68. Regulations appointing a day under subsection (2) are not subject to any Parliamentary procedure.
FINANCIAL MEMORANDUM

INTRODUCTION

1. This Financial Memorandum has been prepared by the Non-Government Bills Unit on behalf of Anne McTaggart MSP, the member who introduced the Bill, to satisfy Rule 9.3.2 of the Parliament’s Standing Orders. It does not form part of the Bill and has not been endorsed by the Parliament.

2. The purpose of the Bill is to amend current law (primarily, the Human Tissue (Scotland) Act 2006) to convert it to a “soft opt-out” system which allows (in certain circumstances) for the removal of parts of a deceased adult’s body (organs and tissue, in particular) for the purposes of transplantation in the absence of express authorisation. Under the Bill, it will still be possible for people to “opt in” to organ donation, but the Bill will also give adults resident in Scotland the options of appointing a proxy to make a decision about authorisation on their behalf, or to register in advance an objection to removal (i.e. to opt out). The Bill then provides a mechanism that authorises “by operation of law” the removal of parts of a deceased adult’s body in certain situations where the adult did not register such an objection (i.e. did not opt out) and where there is no appointed proxy able to make a decision on their behalf.

3. An adult for the purposes of the Bill is a person aged 16 years or over. The soft opt-out arrangements would normally only apply if the deceased person had been habitually resident in Scotland for at least a six-month period, while an adult, during which they had an opportunity to opt out.

4. The anticipated cost implications of the Bill are as follows:
   - costs on the Scottish Ministers in making preparation for the move to an opt-out system for transplantation, in particular the requirements to undertake a publicity campaign and any additional payments to NHS Blood and Transplant (see paragraph 6), in relation to updating the organ donation register and adjusting transplant procedures; and
   - costs on (and savings for) NHS health boards and NHS Scotland in undertaking a potentially larger number of transplant operations.

5. The costs on the Scottish Ministers (described in the first bullet above) would include start-up costs, liable to arise mainly in financial year 2016-17 (assuming the Bill is enacted in early 2016). The other costs would be recurring costs arising in each financial year, probably from 2017-18 or 2018-19, depending on when the Scottish Ministers bring it fully into force.

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1 The Bill (and the 2006 Act) refer throughout to “parts of the body”, which includes but is not limited to organs. Even in the context of transplantation, it is not just organs (such as hearts, kidneys and lungs) that may be removed and used, but also other material (such as pancreatic cells, retinas, and bone marrow). In this Memorandum, however, “organ” is sometimes used as convenient shorthand for “part of the body”.

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The current administrative and legislative framework

6. Organ donation and transplantation is currently delivered on a collaborative basis across the UK and is co-ordinated by NHS Blood and Transplant (NHSBT), an England and Wales Special Health Authority which operates in Scotland under a contractual arrangement with the Scottish Government. NHSBT manages certain necessary activities such as: the UK-wide NHS Organ Donor Register; the allocation of organs across the UK; management of data and information; and the training and management of specialist nurses and clinical leads.

7. Organ donation and transplantation also operates within a European and domestic regulatory framework. For Scotland, as with the rest of the UK, the Human Tissue Authority (HTA) is the regulatory body. The Scottish Transplant Group and donation and transplant services in Scotland work closely with the HTA to ensure services meet the necessary regulatory standards. Tissue donation in Scotland is managed by the Scottish National Blood Transfusion Service (SNBTS).

8. The provision of most forms of transplant surgery for Scottish patients is managed by National Services Scotland (NSS), a special health board, which works with NHS Boards to help them deliver front-line services. It funds specialist centres at the Jubilee Hospital in Glasgow and the Royal Infirmary of Edinburgh. Kidney transplants are currently undertaken at a regional level by individual NHS health boards, while lung transplants are undertaken in Newcastle via the use of a service level agreement.

9. The Human Tissue (Scotland) Act 2006 Act provides the current legislative framework for organ donation and transplantation in Scotland. The equivalent legislation for the rest of the UK is the Human Tissue Act 2004. Both Acts broadly maintain an “opt-in” system for organ donation, which requires authorisation either by the adult, their nearest relative or a nominated representative before organs (or other parts of the body) may be lawfully removed after death for the purposes of transplantation.

10. In July 2013, the National Assembly for Wales passed the Human Transplantation (Wales) Bill, and the Act (“the Wales Act”) is due to come into force on 1 December 2015. The Act introduces a new “soft opt-out” system for organ donation for Wales which would allow organs and tissues to be removed unless the deceased objected during their lifetime. The family of the deceased person must be consulted to establish whether the deceased was known to have any unregistered objections. There are exceptions for certain “excepted adults”, and there is provision allowing people to appoint a proxy (“appointed representative”) to make decisions about consent on their behalf.

11. The provisions in the draft Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill provide for a similar type of “soft opt-out” system to that in the Wales Act, and is intended to work alongside the current opt-in system for organ and tissue donation. The Bill will enable adults to register their wishes, either by opting in (as at present), opting out, or appointing a proxy to make a decision on their behalf. If none of these options apply (or no proxy is able and willing to make a decision within a reasonable time), authorisation may be achieved “by

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operation of law”, subject to establishing that the deceased adult did not have an unregistered objection and had a reasonable opportunity to opt out.

12. The Bill aims to address the significant difference between the number of people on the waiting list for transplant operations in Scotland and the number of organs available. According to the British Medical Association (BMA) up to 90% of people support organ donation but less than half of Scotland’s population is registered on the NHS Organ Donor Register. A number of surveys have suggested that more than 70% of the public supports a shift to a soft opt-out system. The BMA also estimates that there are currently around 650 people in Scotland waiting for a donor organ and found that countries that operate an opt-out model have roughly 25-30% higher donation rates than “informed consent” countries.³

COSTS ON THE SCOTTISH ADMINISTRATION

Financial implications

13. The two main areas of cost for the Scottish Ministers are the set-up and implementation costs of an opt-out system, and the costs of the publicity campaign (of at least six months duration) the Scottish Government is required to undertake to inform the public about the changes being made by the Bill.

14. The Explanatory Memorandum⁴ which accompanied the Human Transplantation (Wales) Bill⁵ provides a costs and benefits analysis of a very comparable opt-out system of organ donation.

15. That Explanatory Memorandum estimated that the total costs to be borne by the Welsh Government of implementing an opt-out system over a 10 year period would be approximately £8 million. This total cost was broken down as follows:

- £3.0 million on communications
- £0.5 million on the management of business change
- £2.5 million on IT changes
- £1.0 million to receive and process additional registrations
- £0.3 million to notify 17 year olds
- £0.2 million on evaluation, and
- £0.3 million on clinician training.

16. In written evidence to the Assembly’s Health and Social Care Committee in October 2014 on the scrutiny of the Welsh Government’s draft budget 2015-16, the Minister for Health and Social Services, Mark Drakeford AM, provided information on the actual costs incurred in implementing the Wales Act. The evidence showed that the costs incurred accurately reflected the estimates provided in the Explanatory Memorandum that had accompanied the Bill. It showed that the implementation of the Act was well under way, with a “wide-ranging communications campaign, redevelopment of the Organ Donor Register to enable the recording of opt-out decisions, and the preparation of subordinate legislation” all undertaken. It stated that the overall cost of implementation remained in the region of £7.5 million over 10 years, with £2 million allocated for 2014-15 and £2.8 million for 2015-16.6

17. In some respects (e.g. evaluation), it would be reasonable to assume that the equivalent costs in Scotland would be similar to those incurred in Wales. In some respects (e.g. publicity campaign, clinician training), it would be reasonable to assume they would be higher, roughly in proportion to Scotland’s larger population (approximately 1.7 times that of Wales). But in relation to costs for managing the business change and IT costs, it is reasonable to assume that the additional expenditure made necessary by a Scottish Act would be much less than that required for the Wales Act, given that the Organ Donor Register has already been adapted to allow for the additional information required under an opt-out system. Taking these factors together, the estimated overall cost of £7.5 million over 10 years for the Wales Act seems a reasonable overall estimate for this Bill, too.

Publicity campaign

18. The Bill requires the Scottish Government to undertake a publicity campaign to ensure public awareness of the changes being introduced by the Bill (section 1(2)). The publicity campaign is required to last throughout the period between the “first appointed day” and the “second appointed day”, which must be at least six months apart. The actual duration of the campaign will be for the Scottish Government to decide, and could be longer than the minimum required by the Bill. Should a one-year campaign be considered appropriate, for example, this may cost around £2.8 million (based on halving the £3.3 million spending by the Welsh Government over two years, and then adjusting by a factor of 1.7 to account for Scotland’s larger population size (and geographic area)).

19. The Scottish Government has an annual advertising budget, which includes marketing communications, digital, design, events, direct marketing and media. The total (gross) budget in 2012-13 was around £7.2 million. The most recent (2012-13) figure for advertising spend on health and social care campaigns was just over £1.2 million (gross) which included:

- Organ Donation, £527,000 (gross)
- Alcohol, £441,000 (gross)

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• Tobacco, £347,000 (gross).  

20. Clearly, a £2.8 million budget for organ donation would represent a very significant increase over the 2012-13 budget of just over £527,000, and would exceed total advertising expenditure in that year on all health-related topics. But the Scottish Government must already choose which campaigns to prioritise each year (meaning that some issues are not made the subject of a campaign in some years, even though underlying circumstances have not changed). The size of the Scottish Government’s advertising budget is such that it could prioritise the publicity campaign required by the Bill without necessarily increasing its overall advertising expenditure (although this would require some general re-prioritisation, for one year only, from other portfolios in favour of health).

Implementation of an opt-out system

21. NHSBT, the UK-wide organisation responsible for management of transplant services, will incur additional costs associated with the IT and business system changes necessary to maintain the organ donation register and make the necessary changes to include the opt-out system and the proxy appointment procedure, as well as costs associated with the potential increase in the number of organs available for UK-wide transplant.

22. The costs for implementing Scottish Parliament legislation which proposes a similar opt-out system to the one already enacted in Wales should be considerably lower, as the main changes required should already have been made in connection with the Welsh legislation, and should only require, at most, minor further adjustment. In particular, the IT and business system changes that NHSBT have undertaken in connection with the implementation of the opt-out system in Wales should be directly applicable in a Scottish context.

23. The Scottish Government makes an annual payment to NHSBT as a contribution towards its work in maintaining the organ donation register and co-ordinating transplant procedures. In 2013-14, this was £5.3m.

24. The central aim of the Bill is to increase the number of organs made available, in Scotland, for transplant purposes. This is not expected to lead to a corresponding reduction in Scottish transplant waiting lists (or a corresponding increase in the number of transplant operations carried out in Scotland), given that organs are matched up to patients on the basis of need on a UK-wide basis. In the Explanatory Memorandum accompanying the Welsh Bill, figures provided by NHSBT estimated that over a 4-year period (2008-2011) just over 30 per cent of organs donated by people in Wales were transplanted into people living in Wales. According to the memorandum, the activity and costs associated with an increased number of donors would be managed within current NHS resources, and the NHS should, through its arrangements to fund specialised services, similarly meet the costs of an increased number of

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8 Scottish Government: note that this figure covers a wider range of services, and not just organ and tissue transplants.
These documents relate to the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill (SP Bill 72) as introduced in the Scottish Parliament on 1 June 2015

The memorandum recognised that the Welsh Government’s own health budget would need to meet the additional infrastructure, public communication, training, delivery and evaluation costs, but that its contribution to NHSBT (which is calculated on a population basis) was not expected to change.\(^9\)

25. A similar situation applies in Scotland. Most of the specific additional costs of the Bill can be expected to fall on the Scottish Government’s health budget. To the extent that the costs associated with, or expected to result from, the Bill fall on NHSBT, it is reasonable to assume these will have no implications for the amount the Scottish Government is expected to contribute to NHSBT each year.

**Financial benefits of increased donation rates**

26. Much of the value of transplantation relates to benefits to individuals through valuing longer life expectancy and improving their quality of life, which in turn should reduce the burden on the health service.

27. When assessing the net benefits of individual operations account should be taken of the costs of transplant surgery and the medical management savings made as a result of an increase in the number of transplant surgeries undertaken. NHS National Services Scotland, as the commissioner of the national transplantation services, funds the services on fixed and variable costs, which cover assessment, diagnosis, tests, transplant operation, inpatient care costs, two weeks of immunosuppressants, and ongoing specialist follow-up care for the first year. Average cost per case was provided for the four most common types of transplantation: kidney, liver, heart and lung.

28. To give an indication of the level of economic impact of transplantation of major organs, NHS Services Scotland used the methodology for the explanatory memorandum that accompanied the draft Welsh Bill,\(^11\) and uprated it for Scotland, in order to estimate follow-up costs for subsequent years and the savings from medical management costs avoided (e.g. the costs of dialysis to patients awaiting a kidney transplant). Follow-up in subsequent years and alternate medical management are not provided by the national transplantation services, but are managed by the local NHS Boards. Cost details are as follows:

- The average cost for a kidney transplant from a deceased donor in 2013-14 was estimated at £54,364 per case (this includes the first year of follow-up costs). The follow-up costs for each subsequent year are £5,210. Each year there is an average saving in kidney dialysis avoided of £32,953.
- There were 95 liver transplants undertaken in 2013-14 at an average cost of £68,970 per case (this includes the first year of follow-up costs). In the second year, follow-up costs are £12,853 and thereafter annual follow-up costs are £5,355. Each year there is an average saving in medical management avoided of £23,563.
- There were 19 heart transplants undertaken in 2103-14 at a cost of £229,671 per case (this includes the first year of follow-up costs). There are follow-up costs each

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\(^9\) Human Transplantation (Wales) Bill. Explanatory Memorandum, paragraph 113.
\(^10\) Human Transplantation (Wales) Bill. Explanatory Memorandum, paragraphs 133, 134.
\(^11\) Human Transplantation (Wales) Bill. Explanatory Memorandum, paragraph 112.
subsequent year of £12,853. Each year there is a saving in medical management avoided of £5,355.

- There were 20 lung transplants undertaken in 2013-14 at a cost of £162,061 per case (this includes the first year of follow-up costs). The follow-up costs in years 2, 3, 4 and 5 are £23,563, £9,639, £8,568 and £4,284 respectively. In the first year there is a saving in medical management avoided of £19,279 and in the second year £16,066.\(^\text{12}\)

29. A UK Parliament briefing note on Organ Donation and Transplants\(^\text{13}\) indicates that the transplant programme delivers an annual cost saving of £316 million to the NHS, according to NHS Blood and Transplant (NHSBT). It adds that the success rate for a kidney transplant using an organ from a deceased donor is 93% and that having a successful transplant often allows patients to return to work and reduces the number of hospital visits. This not only benefits the person who has undergone the transplant operation but also benefits society as the person is able to return to work and contribute to the economy.

30. For each type of surgery, the Welsh Government considered, for a 10 year period:

- the cost of the transplant procedure and follow-up care
- the savings from reduced need for medical management of previous conditions, for example the reduced need for kidney dialysis
- the benefits resulting from increased life expectancy and improved quality of life, which is measured by “quality adjusted life years” (QALYs), with each QALY valued at £60,000, in line with the UK Department of Health guidance.

31. On the basis of the costs and benefits to the health service alone (the savings from reduced medical management set against the cost of transplants), the savings for most procedures do not offset the costs of the transplant procedure and related aftercare. (The exception to this is kidney transplants, where the savings for the health service do offset the costs of transplant procedures, due to the costs associated with dialysis and the length of time a patient is expected to survive on dialysis.)

32. Using this approach, the Welsh Government estimated the “net present value” (NPV) of one additional transplant in each of the 10 years as £12.5 million. This was broken down by each type of transplant as follows: £3.5 million – kidney; £5.8 million – liver; £2.5 million – heart; and £0.7 million – lung. It seems reasonable to assume that similar NPVs for each additional transplant would apply in Scotland.

33. The Scottish Parliament’s Financial Scrutiny Unit provided an analysis of the average numbers of transplants resulting from a given change in the number of donors based on average organ donation and transplant activity data published by NHSBT\(^\text{14}\) for the period 2008-2013.

\(^{12}\) NHS National Services Scotland, correspondence with NGBU, 7 and 20 May 2015.


Using this data, the average numbers of transplants resulting from each additional donor can be derived (a donor being a person from whom at least one organ has been removed for transplantation). It should be noted that the number of organ donors does not directly relate to the number of transplant operations or transplant recipients, as a number of organs or body parts can be taken from the same donor and transplanted into more than one person. The analysis suggested that an additional ten donors in a year could result in 17 kidney transplants, six liver transplants, one heart transplant and three lung transplants.

34. The Explanatory Memorandum that accompanied the Welsh Bill recognised that it is highly likely that a large proportion of any additional organs donated by residents of Wales as a result of introducing a soft opt-out system could be transplanted into residents living in other parts of the UK. The Welsh Government attached the same value to an additional organ transplanted irrespective of where in the UK that transplant takes place. NHSBT provided an estimate that just over 30 per cent of organs donated by people in Wales were transplanted into people living in Wales. However, the Welsh Government found that this had no material impact on the number of donors needed for an opt-out system to “break even”.

Quality of life benefits of increased donation rates

35. When undertaking a sensitivity analysis into the quality of life benefits of the proposed opt-out system in Wales, the Welsh Government used the UK Department of Health’s estimate that a year of perfect health is worth one “quality adjusted life year” (QALY) and is valued at £60,000. This covers both increased life expectancy and improved quality of life. It found that, even with a substantially lower QALY of £20,000, the number of additional donors required in order to “break even” each year would only need to increase from one to two.

36. NHS National Services Scotland provided information on the increased quality of life (QALY) for each type of transplant. The Department of Health estimated value for each QALY remains at £60,000 per year. The expected survival times for patients was taken from the impact assessment that accompanied the draft Welsh Bill. The increased QALYs were as follows: 2 years for kidney transplants from deceased donors; 13 years for liver transplants; 7 years for heart transplants; and 4 years for lung transplants.15

37. Whilst much of the value of the benefits relate to individuals through longer life expectancy and improved quality of life, a greater number of transplant procedures should reduce the use of health services of those awaiting a transplant and/or undergoing kidney dialysis. This will have an indirect financial benefit to the health service.

38. The benefits to individual transplant recipients through an improved quality of life can be mental as well as physical, as prolonged ill-health can cause anxiety and depression in individuals who then seek medical assistance for those additional health issues. Improved health enables individuals to contribute more fully to society, such as being able to work. This in turn should reduce the financial burden on the welfare system.

The most recent organ donation and transplant activity data (for Scotland) covers the period 2010-15 and is available at: https://nhsbtmediaservices.blob.core.windows.net/organ-donation-assets/pdfs/scotland.pdf

COSTS ON LOCAL AUTHORITIES

39. The Bill could have direct cost implications for local authorities with regards to the provision of social care, such as care and support in the home, for those awaiting a donor transplant. Any reduction in the number of people on the waiting list for transplant operations may reduce demand on the local authorities’ social care budgets. It is not possible at this time to quantify the financial benefits to local authorities.

COSTS ON OTHER BODIES, INDIVIDUALS AND BUSINESSES

National Health Service (NHS)

40. There will be staff and IT costs associated with setting up and maintaining the opt-out register and increasing awareness amongst medical staff of the new system and training them to implement it. There will also be costs associated with an increase in the number of transplant operations. However, these financial costs could be offset by the long-term savings of a reduction in the burden of the health service through reduced dialysis provision and associated long-term care costs.
MEMBER’S STATEMENT ON LEGISLATIVE COMPETENCE

On 1 June 2015, the member who introduced the Bill (Anne McTaggart MSP) made the following statement:

“In my view, the provisions of the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill would be within the legislative competence of the Scottish Parliament.”

PRESIDING OFFICER’S STATEMENT ON LEGISLATIVE COMPETENCE

On 1 June 2015, the Presiding Officer (Rt Hon Tricia Marwick MSP) made the following statement:

“In my view, the provisions of the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill would be within the legislative competence of the Scottish Parliament.”
These documents relate to the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill (SP Bill 72) as introduced in the Scottish Parliament on 1 June 2015

TRANSPLANTATION (AUTHORISATION OF REMOVAL OF ORGANS ETC.) (SCOTLAND) BILL

EXPLANATORY NOTES

(AND OTHER ACCOMPANYING DOCUMENTS)

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