Delegated Powers and Law Reform Committee

Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill at Stage 1
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Delegated Powers and Law Reform Committee

The remit of the Delegated Powers and Law Reform Committee is to consider and report on—

a. any—
   i. subordinate legislation laid before the Parliament or requiring the consent of the Parliament under section 9 of the Public Bodies Act 2011;
   ii. [deleted]
   iii. pension or grants motion as described in Rule 8.11A.1; and, in particular, to determine whether the attention of the Parliament should be drawn to any of the matters mentioned in Rule 10.3.1;

b. proposed powers to make subordinate legislation in particular Bills or other proposed legislation;

c. general questions relating to powers to make subordinate legislation;

d. whether any proposed delegated powers in particular Bills or other legislation should be expressed as a power to make subordinate legislation;

e. any failure to lay an instrument in accordance with section 28(2), 30(2) or 31 of the 2010 Act; and

f. proposed changes to the procedure to which subordinate legislation laid before the Parliament is subject.

g. any Scottish Law Commission Bill as defined in Rule 9.17A.1; and

h. any draft proposal for a Scottish Law Commission Bill as defined in that Rule; and

i. any Consolidation Bill as defined in Rule 9.18.1 referred to it by the Parliamentary Bureau in accordance with Rule 9.18.3.

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Introduction

1. At its meetings on 3 November and 1 December 2015 the Delegated Powers and Law Reform Committee considered the delegated powers provisions in the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill at Stage 1 (“the Bill”)\(^1\). The Committee submits this report to the lead committee for the Bill under Rule 9.6.2 of Standing Orders.

2. The Bill was introduced by Anne McTaggart MSP (“the Member”) on 1 June 2015. The Bill seeks 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.

3. The Non-Government Bills Unit on behalf of the Member has produced a Delegated Powers Memorandum (“DPM”) on the delegated powers provisions in the Bill\(^2\).
Overview of the Bill

4. The main purpose of the Bill is to provide for a “soft opt-out” system for organ donation in Scotland. Under this system, a part of a deceased adult’s body may be removed for the purpose of transplantation without the adult having given express authorisation in advance, provided that the adult had not recorded or expressed any objection to the removal, and subject to meeting a number of criteria. The Bill also provides a system by which adults may appoint a proxy or proxies to make decisions on the posthumous removal of parts of the adult’s body for transplantation.

5. The Bill mostly amends the Human Tissue (Scotland) Act 2006 (“the 2006 Act”). That Act currently sets out the legal basis on which organs and human tissue can be removed from a deceased person for use in transplantation. In summary at present, the removal of organs can be authorised as follows:
   - By the adult having given express authorisation prior to death;
   - By the adult’s nearest relative giving express authorisation after the adult’s death;
   - By a child aged 12 or over giving express authorisation prior to the child’s death;
   - By a person with parental rights and responsibilities as respects a child (of any age) giving express authorisation after the child’s death.

6. Removal of organs without authorisation, or without complying with the statutory requirements, is a criminal offence. The maximum penalty on conviction on indictment is 3 years’ imprisonment or a fine, or both.

7. Section 1 of the Bill requires the Scottish Ministers to establish a register of proxies—who may make decisions relating to the removal of body parts after an adult’s death. It also requires the Scottish Ministers to establish a register in which adults can register an objection to the removal and use of any body parts after their death. Registration in the register of objections will mean that an adult’s body parts will not be permitted to be used for transplantation after their death. Ministers are also obliged to run a publicity campaign about the changes made by the Bill between specified dates.

8. Section 2 confers a power on the Scottish Ministers to make regulations about which persons may exercise the functions of “authorised investigating persons”. These persons are to investigate whether or not removal of a deceased person’s body parts is authorised, in accordance with the requirements stated in the Bill.

9. Sections 3 to 7 give effect to the central elements of the Bill. Sections 8 to 15 make changes consequential on those elements. New section 6A of the 2006 Act, inserted by section 5 of the Bill, makes provision for the appointment of proxies who may take the decision on whether to authorise removal of body parts of a
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(Session 4)

deceased adult. New section 6B, inserted by section 6 of the Bill, makes provision for the authorisation of removal of body parts by what the Bill calls “operation of law”. Section 6B sets out a list of conditions which, if satisfied, will permit the removal of parts of a deceased adult’s body by operation of law.

10. The conditions are:

- That the adult was resident in Scotland at the time of death;
- An authorised investigating person has confirmed that –
  - (s)he is not aware of an existing express authorisation of removal of body parts;
  - having examined the register of objections (s)he is not aware of any objection by the adult to removal;
  - having consulted any known proxy and having given that proxy a reasonable time to respond, (s)he has not received a decision from the proxy;
  - (s)he has not received any decision from any other proxy within the time given to known proxies;
  - after consulting the nearest relative, (s)he is of the opinion that the adult had a reasonable opportunity to record an objection to removal and use of body parts;
  - (s)he has established that the nearest relative has no actual knowledge that the adult was unwilling for body parts to be removed and used for transplantation.

11. A number of further provisions expand on how this system will operate in practice. For example, for the purposes of the proposed new section 6B of the 2006 Act, there is a rebuttable presumption that an adult who had been habitually resident in Scotland for a continuous period of 6 months after the Bill comes into force had a reasonable opportunity to record an objection to the removal of their organs.

12. Section 16 confers power on the Scottish Ministers to modify the 2006 Act by means of regulations, with regard to the removal of parts of the body for transplantation from a deceased adult who died in Scotland, but was not resident there immediately before death. Regulations may only modify the 2006 Act if the laws of the country of the person’s residence 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.

13. Section 17 requires the Scottish Ministers to report to the Scottish Parliament on the effectiveness of the Bill, covering a period of not less than a year after commencement. The report must be laid before the Parliament not later than two years after commencement. Section 18 defines terms used in the Bill. Section 19 has the commencement provisions, and section 20 confirms the short title.
14. Sections 1(1) and (2), 2, 6(2), 16, 17, 18(1), 19 and 20 would come into force on the day after Royal Assent. The remaining provisions would come into force on a day appointed by regulations.
Delegated Powers Provisions

15. The Committee considered the delegated powers in the Bill. At its first consideration of the Bill, the Committee determined that it did not need to draw the attention of the Parliament to the delegated powers in the following provisions:

- Section 6(2) – Prescription of second appointed day
- Section 19(2) – Commencement

16. At its meeting on 3 November, the Committee agreed to write to the Member to raise questions on the remaining delegated powers in the Bill. This correspondence is reproduced at the Annexe.
Recommendations

17. The Committee’s comments and recommendations on the remaining delegated powers in the Bill are detailed below.

Section 2 – Designation of authorised investigating persons

Power conferred on: the Scottish Ministers
Power exercisable by: regulations
Parliamentary procedure: negative procedure

Provision

18. Section 2A of the 2006 Act, as inserted by section 2 of the Bill, enables the Ministers to provide by regulations for the designation of persons, or categories of person, as authorised investigating persons for the purposes of the 2006 Act (as amended by the Bill).

19. The authorised investigating person has a key role in assessing and determining whether there is proxy authorisation, or authorisation by operation of law, for the removal of organs under the proposed new sections 6A and 6B of the 2006 Act. Paragraph 10 above sets out the conditions about which an authorised investigating person must be satisfied, before the removal of body parts would be authorised by operation of law, under the proposed “soft opt out” system.

20. The DPM states that the Member envisages that the designation of authorised investigating persons by regulations is likely to be done by reference to certain job descriptions and/or clinical grades within the NHS. Under section 59(2) of the 2006 Act, the negative procedure would apply to the regulations.

Comment

21. The Committee asked the Member certain questions in relation to this power, as set out at paragraph 3 of the Annex. In particular, the Committee queried that the Delegated Powers Memorandum states it is anticipated that the persons to be designated as authorised investigating persons would be in clinical and administrative roles in the NHS, expressed in terms of NHS grading and staffing arrangements. However the power is drawn to permit any certain persons, or categories of persons, to be so designated for the purposes of the Bill.

22. The Member’s written response to the Committee is set out in the Annexe. It acknowledges that this power is drawn in a way that would allow the Scottish Ministers to designate persons from outwith the NHS as authorised investigating persons. This is not the intention which underlies the proposed new section 2A of the 2006 Act. The Member will therefore consider lodging an amendment at
Stage 2 of the Bill, to draw the scope more narrowly, to apply to relevant health professionals within the NHS.

23. The Member also confirms in the response that her understanding is that (within the present system of organ donation for transplantation) both specialist nurses for organ donation and clinician leads for organ donation currently carry out many of the tasks that an authorised investigating person would be expected to do. As such, the Member considers that they would be the most appropriate roles and grades to take on any additional tasks that result from the Bill.

24. The Committee notes that the Member is considering an amendment which would be lodged at Stage 2 of the Bill, which would draw the scope of the power in section 2 more narrowly so that only relevant health professionals within the NHS could be designated as authorised investigating persons.

25. The Committee would return to consider the terms of the power in section 2, after Stage 2 of the Bill.

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

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**Provision**

26. The proposed new section 6B(1)(a) of the 2006 Act (as inserted by section 6(1) of the Bill) excludes any adult who was not resident in Scotland at the time of death from the proposed new opt-out system “by operation of law”. This aims to ensure that adults from countries operating “opt-in” systems of organ donation (such as England) who die in Scotland cannot have their organs removed for transplantation under the proposed new section 6B. Such adults would not have had the opportunity to record any objection to removal.

27. There are however a number of other countries around the world which have “opt-out” systems of different types, and subject to different conditions. The DPM states that Wales has recently legislated for a system similar to the one contained in the Bill, which is scheduled to come into force in December 2015. The DPM also states that it might be thought unreasonable that a person dying in Scotland, who met the requirements for authorisation by operation of law under their “home system”, should be excluded from the “opt out” provisions in the proposed new section 6B.

28. Section 16 would enable the making of regulations to modify the 2006 Act (as amended by the Bill), to make provision for these circumstances. Regulations could only modify the 2006 Act if the laws of the country of the person’s residence 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.

Comment
29. In corresponding with the Member on this power, the Committee noted that section 16(1) would enable, by regulations subject to the affirmative procedure, any further modification of the 2006 Act to cater for the circumstances explained above. The Parliament would be asked to either approve or reject any further modifications of the 2006 Act which might be proposed in the regulations (without an ability to propose amendments to the proposed modification).

30. The Committee asked the Member to consider whether this power might more suitably be exercised by a “super-affirmative” form of scrutiny procedure in the Parliament. Such a procedure would enable the Parliament to consider an initial draft of the regulations, before the regulations would be laid for final approval. The Committee sought an explanation of what the advantages and disadvantages of applying such procedure would be (for the Parliament and others), in comparison with the affirmative procedure.

31. In her response, the Member has confirmed that this regulation-making power will require some careful exercises of judgment. An assessment of any other jurisdiction’s “opt-out” system of organ donation would be needed, to determine whether it is sufficiently similar to the proposed system in the Bill, to make it reasonable for people who are normally resident in that jurisdiction to be made subject to the proposed Scottish “soft opt-out” system.

32. The Member also contends that, should England and Northern Ireland join Wales in implementing a “soft opt-out” system, the Organ Donor Register “could easily be used to gain authorisation or make a decision on organ donation for an adult resident anywhere in the UK.”

33. Despite the Member’s explanation of how this power might be used by the Scottish Ministers, the Committee is concerned that the scope of this power is drawn widely, to permit any further modification of the Human Tissue (Scotland) Act 2006 in relation to the removal of body parts for transplantation from a deceased adult where the requirements specified in section 16(2) are met. Those requirements define the persons who would be subject to this power, rather than defining the system of organ donation which might be applied to them in future.

34. The Member’s intention, as expressed in the DPM read with her written response to the Committee, is that the circumstances might possibly arise in future when it is considered that a person (“a relevant person”) who dies in Scotland but who meets the requirements for authorisation by operation of law under the opt-out system applying in their home country should have the provisions in the proposed new section 6B of the 2006 Act applied to them. In particular in the view of the Member, this might possibly arise
should all the jurisdictions in the remainder of the UK operate a “soft opt-out system” in future.

35. The Committee is concerned that, in principle, the scope of this power enables any further modification of the 2006 Act in relation to relevant persons. The power is therefore capable of being used by the Scottish Ministers to apply to relevant persons a system of organ donation which differs from that proposed in the Bill.

36. The Committee therefore recommends that, should the Bill proceed to Stage 2, the Member gives consideration to amending this power so that it is drawn more narrowly to enable the application of the pertinent provisions of the 2006 Act (as amended by the Bill) to relevant persons, rather than permitting any further modification of the 2006 Act in relation to those persons.

37. The Committee also recommends that the Member consider whether this power should be more narrowly drawn in a further respect, to accord with her policy intentions as to the use of the power in the event that all the jurisdictions in the remainder of the UK were to operate a “soft opt-out system” in future. The Member could consider amending the requirements in section 16(2), so that the adult must be resident immediately before death in a jurisdiction in the remainder of the UK, rather than any jurisdiction other than Scotland. While it relates to policy matters, as part of this consideration the Member could consider further how practicable it would be to apply the Bill provisions to an adult who was resident outwith the UK.

38. The Committee would return to consider this power after Stage 2.
Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill [as introduced] is available at the following website:
http://www.scottish.parliament.uk/S4_Bills/(1)Transplantation%20(Authorisation%20of%20Removal%20of%20Organs%20etc.)%20(Scotland)%20Bill/b72s4-introd.pdf [accessed December 2015]

Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill Delegated Powers Memorandum is available at the following website:
Correspondence with the Member

On 3 November 2015, the Committee wrote to the Member as follows:

1. The Delegated Powers and Law Reform Committee considered the above Bill on Tuesday 3 November and seeks an explanation of the following matters:

Section 2 – Designation of authorised investigating persons

Power conferred on: the Scottish Ministers
Power exercisable by: regulations
Parliamentary procedure: negative procedure

2. Section 2A of the 2006 Act, as inserted by section 2, enables the Ministers to provide by regulations for the designation of persons, or categories of person, as authorised investigating persons for the purposes of the Human Tissue (Scotland) 2006 Act (“the 2006 Act”) (as amended by the Bill).

3. The Committee asks the Member in relation to the power in section 2:

(a) The Delegated Powers Memorandum (“DPM”) states it is anticipated that the persons which would be designated as authorised investigating persons would be in clinical and administrative roles in the NHS, expressed in terms of NHS grading and staffing arrangements. However the power is drawn to permit any certain persons, or categories of persons, to be so designated for the purposes of the Bill.

To assist the Committee to understand how this power is capable of being exercised, could the Member explain what other persons, or categories of persons, might be designated as authorised investigating persons, apart from NHS staff? Is the Member in a position to explain what NHS clinical or administrative roles or grades might be appropriate for designation?

(b) The DPM justifies the application of the negative procedure for scrutiny of the regulations on the ground that they are likely to have largely technical content, expressed in terms of NHS grading and staffing arrangements. However the power is capable of being exercised to designate persons, or categories of persons, beyond persons in an NHS role. The exercise of the power would also be highly significant to the proper operation of the opt-out system proposed by the Bill.
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The Member is therefore asked to explain further why the negative procedure is considered to be more suitable than the affirmative procedure for scrutiny of the regulations.

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

Power conferred on: the Scottish Ministers
Power exercisable by: regulations
Parliamentary procedure: affirmative procedure

4. New section 6B(1)(a) of the 2006 Act (as inserted by section 6(1) of the Bill) excludes any adult who was not resident in Scotland on death from the new opt-out system “by operation of law”. This ensures that adults from countries operating “opt-in” systems of organ donation (such as England) who die in Scotland cannot have their organs removed for transplantation under new section 6B. Such adults would not have had the opportunity to record any objection to removal.

5. There are however a number of other countries around the world which have “opt-out” systems of different types, and subject to different conditions. The DPM states that Wales has recently legislated for a system similar to the one contained in the Bill, which is scheduled to come into force in December. The number of these countries may increase in future. The DPM also states that it might be thought unreasonable that a person dying in Scotland, who met the requirements for authorisation by operation of law under their “home system”, should be excluded from the “opt out” provisions in the proposed new section 6B.

6. Section 16 would enable the making of regulations to modify the 2006 Act (as amended by the Bill), to make particular provision for these circumstances.

7. The Committee asks the Member in relation to the power in section 16:

The Delegated Powers Memorandum explains that the objective underlying this power is that, at the judgment of the Scottish Ministers, there may in future be circumstances where a person dying in Scotland but who met the requirements for an “opt-out” system of transplantation under their “home system” should be included within the opt-out provisions in the new section 6B of the 2006 Act (inserted by section 6 of the Bill).

The Committee notes that section 16(1) of the Bill would enable, by regulations subject to the affirmative procedure, any further modification of the 2006 Act to cater for those circumstances. The Parliament would be asked to either approve or reject the further modifications of the 2006 Act which would be proposed in the regulations.

The Member is asked to consider whether this power could more suitably be exercised by a “super-affirmative” form of procedure, which would enable the Parliament to consider an initial draft of the regulations. What in this context would the advantages and disadvantages of applying such procedure be (for the Parliament and others), in comparison with the affirmative procedure?
On 19 November 2015 the Member responded as follows:

I refer to the letter of 3 November 2015 sent by the Assistant Clerk to your Committee, in which she sought, on behalf of the Committee, an explanation of a number of matters in relation to the above Bill.

My responses to the Committee’s queries are set out below.

Section 2 – designation of authorised investigating persons

The Committee asked for an explanation of what other persons, or categories of persons, might be designated as authorised investigating persons, apart from NHS staff.

The term ‘authorised investigating persons’ (or AIPs) refers to those individuals who would be tasked with establishing whether organs may be removed from a deceased adult.

Paragraph 41 of the policy memorandum makes clear that the authorised investigating persons are to be health professionals (appointed under regulations made by Ministers).

The Bill is drafted in this way to allow Scottish Ministers to decide which health professionals would be best placed to take on any additional tasks resulting from the Bill. Given the particular skill and expertise that these tasks will require it is anticipated that Ministers would only designate NHS staff.

The Committee is correct that the power is drawn in a way that would allow Scottish Ministers to designate people from outwith the NHS as AIPs. This is not the intention of section 2A and I would therefore be happy to consider a stage 2 amendment to the Bill to draw the scope more narrowly to apply to relevant health professionals within the NHS.

The Committee asked for an explanation of the NHS clinical or administrative roles or grades that might be appropriate for designation.

My understanding is that both specialist nurses for organ donation and clinician leads for organ donation currently carry out many of the tasks that an authorised investigating person would be expected to do, and as such they would be the most appropriate roles and grades to take on any additional tasks that result from the Bill. This would be similar to the recent implementation of the Human Transplantation (Wales) Act 2013, where NHSBT updated the policies and processes applicable to those roles.

The Committee asked for an explanation of why the negative procedure is considered to be more suitable than the affirmative procedure for scrutiny of the regulations to designate authorised investigating persons.
The scope of this power is narrow and specific, as it can only be used to designate persons (or classes of persons) as authorised investigating persons (AIPs), and cannot, for example, be used to further define their powers or duties, create rules or guidance, or amend existing legislation. The content of the regulations is therefore likely to be uncontroversial and the negative procedure should be sufficient.

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

The Committee asked the Member to consider whether this power could more suitably be exercised by a “super-affirmative” form of procedure which would enable the Parliament to consider an initial draft of the regulations. What in this context would the advantages and disadvantages of applying such procedure be (for the Parliament and others), in comparison with the affirmative procedure?

As section 16 provides Scottish Ministers with the power to amend the parent Act (the Human Tissue (Scotland) Act 2006) I thought it appropriate that any proposed regulations should require the Parliament’s express approval. This regulation-making power will require some careful exercises of judgement, for example in assessing any other jurisdiction’s opt-out organ donation system to determine whether it is sufficiently similar to the one proposed in the Bill to make it reasonable for people normally resident in that jurisdiction to be made subject to a Scottish soft opt-out system.

The recent changes to the UK Organ Donor Register mean that people can now opt in, opt-out, and nominate and provide contact details for up to two appointed representatives to make a decision on their behalf. It is not difficult to see that in the future, should England and Northern Ireland (who have just agreed Stage 1 of an opt-out Bill) join Wales in implementing a soft opt-out system of organ donation, the Register could easily be used to gain authorisation or make a decision on organ donation for an adult resident anywhere in the UK.

The super-affirmative procedure would provide the Parliament with two scrutiny opportunities, enabling committees to take evidence from people who may be affected by the changes and those who are to implement them and to propose modifications to the regulations. This level of scrutiny would seem appropriate in areas where there may be conflicting views or where there are controversial issues to consider. However, this level of scrutiny may not be necessary for all proposed changes, for example adding an area within the UK as an opt-out jurisdiction. In this case the affirmative procedure may be adequate.

The super-affirmative procedure is a more time consuming and onerous approach to considering regulations. The Parliament would need to be satisfied that this was the necessary approach to considering all regulations to include adults, who were not resident in Scotland, in the soft opt-out system of organ donation.

I trust that the above is sufficient to respond to the Committee’s questions.