

HUMAN TISSUE (SCOTLAND) BILL

SUPPLEMENTARY MEMORANDUM ON DELEGATED POWERS

PURPOSE

1. This supplementary memorandum has been prepared by the Scottish Executive in accordance with Rule 9.7.10 of the Parliament's Standing Orders, to assist consideration by the Subordinate Legislation Committee in accordance with Rule 9.7.9. It addresses changes to provisions of the Human Tissue (Scotland) Bill conferring power to make subordinate legislation and the inclusion of new powers as a result of amendments at Stage 2 of the Bill. It describes the purpose of each additional provision and explains why the matter is to be left to subordinate legislation.

2. In deciding whether to adopt negative or affirmative resolution procedure, careful consideration has been given to the degree of parliamentary scrutiny that is felt to be required for the regulations, balancing the need for the appropriate level of scrutiny with the need to avoid using up parliamentary time unnecessarily. Affirmative procedure is used where the order or regulation making powers allow for the modification of any enactment or where there is significant public interest. Negative resolution procedure is used otherwise.

Section 15 – Restrictions on transplants involving live donor

Relevant provision: Subsections (3), (3A) and (3B)
Power conferred on: The Scottish Ministers.
Power exercisable by: Regulations made by Statutory Instrument.
Parliamentary procedure: Affirmative resolution procedure of the Scottish Parliament.

3. Section 15(3) of the Bill gives the Scottish Ministers powers by regulations to provide that no offence is committed under sections 15(1)(b) or 15(2)(b) where the requirements of section 15(3) are met. The Bill, as introduced, provided that such regulations were subject to negative resolution procedure. However, following comments received from the Subordinate Legislation Committee, it was agreed that in view of the public interest in the subject matter, the regulations under this provision merited the more detailed scrutiny afforded by affirmative resolution procedure. Section 53(3) of the Bill was therefore amended at Stage 2 to provide that regulations made under this provision are subject to affirmative resolution procedure.

4. Two new subsections, (3A) and (3B), were inserted into section 15 of the Bill at stage 2. The new section 15(3A) gives Scottish Ministers powers by regulations to set out the requirements that must be satisfied in order to ensure that no offence is committed under:

- section 15(1)(a) (in relation to the removal of an organ, part of an organ or any tissue from the body of a living child intending that it be used for transplantation);

- section 15(1)(c) (in relation to the removal of any tissue from the body of a living adult with incapacity intending that it be used for transplantation);
- section 15(2)(a) (in relation to the use for transplantation of an organ, part of an organ or any tissue which has come from the body of a living child); or
- section 15(2)(c) (in relation to the use for transplantation of any tissue which has come from the body of a living adult with incapacity)

where a person removes or uses regenerative tissue.

5. The requirements are that Scottish Ministers are satisfied that no reward has been or is to be given in contravention of the provisions of section 17 (prohibition of commercial dealings in parts of a human body for transplantation) and that Scottish Ministers are satisfied that such other requirements or conditions as may be specified in the regulations are complied with.

6. The new section 15(3B) gives Scottish Ministers powers by regulations to set out the requirements that must be satisfied in order to ensure that no offence is committed under:

- section 15(1)(a) (in relation to the removal of an organ, part of an organ or any tissue from the body of a living child intending that it be used for transplantation);
- section 15(1)(b) (in relation to the removal of an organ or part of an organ from the body of a living adult intending that it be used for transplantation);
- section 15(2)(a) (in relation to the use for transplantation of an organ, part of an organ or any tissue which has come from the body of a living child); or
- section 15(2)(b) (in relation to the use for transplantation of an organ or part of an organ which has come from the body of a living adult)

where a person removes or uses an organ or part of an organ which is as described in section 15(3C) (i.e. it is necessarily removed from a child or an adult with incapacity during a domino organ transplant operation and is in turn intended to be used for transplantation in respect of another living person).

7. The requirements are that Scottish Ministers are satisfied that no reward has been or is to be given in contravention of the provisions of section 17 and that Scottish Ministers are satisfied that such other requirements or conditions as may be specified in the regulations are complied with.

8. It is considered to be more appropriate for the detailed provisions on this matter to be confined to subordinate legislation as requirements or conditions may change over time. In view of the public interest in the subject matter, the regulations made under these new subsections will be subject to affirmative procedure (by virtue of the insertion of section 53(3)(b)).

9. Section 15(4) was amended at Stage 2 so as to provide that regulations made under section 15(3), 15(3A) and 15(3B) must include provision as to appeals against decisions made in relation to matters which fall to be decided under the regulations. This provision already applied to regulations made under section 15(3), but the section was amended to include sections 15(3A) and 15(3B) as it is considered appropriate that regulations under these subsections contain

appeals against decisions, in the same way that the legislation allows for appeals in relation to subsection (3).

New section 15A – Meaning of adult with incapacity for purposes of section 15(1)(c) and (2)(c)

Relevant provision: Subsection (2).
Power conferred on: The Scottish Ministers.
Power exercisable by: Regulations made by Statutory Instrument.
Parliamentary procedure: Negative resolution procedure of the Scottish Parliament.

10. Section 15A(2) is a new provision, introduced at stage 2, which gives Scottish Ministers powers to prescribe in regulations the form in which a certificate under new section 15A(1) is to be issued.

11. Section 15A(1) provides that the meaning of “adult with incapacity” for the purposes of section 15(1)(c) and (2)(c) is a person who, in the opinion of Scottish Ministers, is an adult who is incapable in relation to a decision about the removal of regenerative tissue from the adult for transplantation and in respect of whom a certificate has been issued by Scottish Ministers in accordance with section 15A(2) that they are of this opinion.

12. Section 15A(2) also provides that the certificate is to specify the period during which it is in force, although that period must not exceed one year from the date of the certificate. This is in accordance with the timescales for certificates signed by medical practitioners under Part 5 of the Adults with Incapacity (Scotland) Act 2000.

13. Subordinate legislation is considered more appropriate for this kind of detail than primary legislation. This is especially the case in respect of this power as the forms in which a certificate is to be issued may require to be updated from time to time. It is considered appropriate to make these regulations subject to negative resolution procedure to provide a degree of flexibility for responding to changes over time.

Section 16 – Records, Information etc.: removal and use of parts of human bodies for transplantation etc.

Relevant provision: Subsections (1)(a) and (b).
Power conferred on: The Scottish Ministers.
Power exercisable by: Regulations made by Statutory Instrument.
Parliamentary procedure: Negative resolution procedure of the Scottish Parliament.

14. The powers in sections 16(1)(a) and (b) were amended at stage 2 to extend the scope of regulations made under these provisions so that they may apply to the maintenance of records and the making of specified information available in relation to the removal, use and retention for section 3(1) purposes of parts removed from the bodies of living persons, as well as deceased persons.

15. It is considered more appropriate for detailed provisions on this matter to be confined to subordinate legislation as the persons who may maintain such records or provide such

information (or any specified authority to which information is to be provided) may change over time. It is believed that the negative resolution procedure remains appropriate in respect of the extended powers in this section.

Section 36 – Notice under section 33(2) or 35(2)(a): further provision

Relevant provision: Subsection (2)(c).
Power conferred on: The Scottish Ministers.
Power exercisable by: Order made by Statutory Instrument.
Parliamentary procedure: Negative resolution procedure of the Scottish Parliament.

16. Section 36(2)(c) was amended at stage 2 to enable Scottish Ministers to specify by order the manager of a university for the purposes of sections 33(2) and 35(2)(a) in terms of receipt of fiscal notices. In terms of those provisions, the “manager of an establishment” is a person who has received written notification from the procurator fiscal that an organ or tissue removed from the body of a deceased person is no longer required for fiscal purposes and can therefore be used for specified purposes.

17. The effect of this amendment is that for the purposes of section 33(2) or 35(2)(a), the manager of an establishment which is a university (or any other establishment which is not a health service hospital) will be the person or holder of such post as Scottish Ministers may specify by order under section 36(2)(c).

18. It is considered to be more appropriate for these provisions to be confined to subordinate legislation as the establishments in which such activities may be undertaken may change over time. The use of subordinate legislation will allow changing circumstances to be taken into account. It is believed that the negative resolution procedure remains appropriate in respect of the regulation making powers under section 36(2)(c).

Section 47 – Power to prescribe forms and descriptions of persons who may act as a witness

Relevant provision: Subsection (a) and (aa).
Power conferred on: The Scottish Ministers.
Power exercisable by: Regulations made by Statutory Instrument.
Parliamentary procedure: Negative resolution procedure of the Scottish Parliament.

19. Section 47(a) was amended at stage 2 following comments from the Subordinate Legislation Committee as to whether it would be mandatory for forms to be used when they are prescribed under this provision or whether their use would be optional. Section 47(a) was amended and a new section 47(aa) inserted at stage 2 to distinguish the circumstances in which the form prescribed under this provision will or will not be mandatory.

20. Subordinate legislation is considered more appropriate for this sort of detail than primary legislation. This is especially the case here as the forms in which authorisation may be provided may require to be updated from time to time. It is believed that the negative resolution procedure remains appropriate in respect of the regulation making powers under section 47.

Section 48 – Amendment of the Anatomy Act 1984

Relevant provision: Subsection (9) – inserts new section 6A(1A) in Anatomy Act 1984.
Power conferred on: The Scottish Ministers.
Power exercisable by: Order made by Statutory Instrument.
Parliamentary procedure: Negative resolution procedure of the Scottish Parliament.

21. Section 48(9) of the legislation inserts a new section 6A(1A) into the Anatomy Act 1984. This gives Scottish Ministers the power to specify persons responsible for the operation or control of specified museums by order.

22. The effect of this new power is that sections 6A(2)(c), (2B)(e), (2D)(d) and (2E)(d) will not apply to a specified person responsible for the operation or control of a specified museum. This means that these specified persons will not be required to be authorised, through a licence granted by Scottish Ministers, for the public display of a part of a body which has been used for anatomical examination under section 6A(2), of an anatomical specimen under section 6A(2B), or of a body or part of a body which has been used outwith Scotland for anatomical examination or examination which has the characteristics of anatomical examination under section 6A(2D) or (2E).

23. The Executive considers that in order to exempt bona fide museums from the licensing requirement the best way to achieve this is by specifying the person responsible for the operation and control of each relevant museum by name in subordinate legislation. The negative resolution procedure is considered appropriate for the maintaining and amending the list, which may require to be updated periodically.

Section 48 – Amendment of the Anatomy Act 1984

Relevant provision: Subsections (12)(b) and 12(c)
Power conferred on: The Scottish Ministers.
Power exercisable by: Regulations made by Statutory Instrument.
Parliamentary procedure: Negative resolution procedure of the Scottish Parliament.

24. Section 48(12)(b) of the Bill amends the existing regulation making powers under section 8 of the 1984 Act so that it applies to parts of bodies, the possession of which is authorised under section 5(5) of the 1984 Act.

25. This provision was amended at stage 2 to include reference to bodies as well as body parts. This extends the provision to include bodies, in line with the stage 2 amendment which allows the possession of bodies, as well as parts of bodies, under section 5(5).

26. Section 48(12)(c) of the Bill amends existing regulation making powers under section 8 of the 1984 Act by extending the scope of this regulation making power to include a reference new section 6A(3), which grants the Scottish Ministers powers to grant a licence to a person to publicly display a body part if Ministers think it desirable to do so in the interests of teaching or studying, or training in or researching into, the gross structure of the human body.

27. This provision was amended at stage 2 to include reference to bodies as well as body parts. This extends the provision to include bodies, in line with the stage 2 amendment which allows the display of bodies, as well as parts of bodies.

28. It is believed that the negative resolution procedure remains appropriate in respect of these regulation making powers.

This document relates to the Human Tissue (Scotland) Bill as amended at Stage 2 (SP Bill 42A)

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