

Human Tissue (Authorisation) (Scotland) Bill [As Amended At Stage 2]

Supplementary Delegated Powers Memorandum

Introduction

1. This supplementary memorandum has been prepared by the Scottish Government in accordance with Rule 9.7 of the Parliament's Standing Orders to assist the Delegated Powers and Law Reform Committee in its consideration of the Human Tissue (Authorisation) (Scotland) Bill. This memorandum describes provisions in the Bill conferring power to make subordinate legislation which were either introduced to the Bill or amended at Stage 2.
2. The contents of this memorandum are entirely the responsibility of the Scottish Government and have not been endorsed by the Scottish Parliament. This supplementary memorandum should be read in conjunction with the Delegated Powers Memorandum published to accompany the Bill on introduction.

Revised and new delegated powers

3. The amended or new delegated powers in the Bill at Stage 2 are listed below, with a short explanation of what each power allows, why the power has been taken in the Bill and why the selected form of Parliamentary procedure has been considered appropriate.

Section 3(2) – Establishment and maintenance of register – power to make provision about the register (inserts new section 2D into the Human Tissue (Scotland) Act 2006)

This document relates to the Human Tissue (Authorisation) (Scotland) Bill as amended at Stage 2 (SP32A)

Power conferred on: the Scottish Ministers
Power exercisable by: regulations made by Scottish statutory instrument
Parliamentary procedure: affirmative
Revised or new power: revised

Provision

4. Section 3(2) of the Bill amends the Human Tissue (Scotland) Act 2006 (“the 2006 Act”) to make provision about the establishment and maintenance of a register (“the Register”) and to confer functions on the Scottish Ministers to give effect to this, including the power to authorise a person to establish and maintain the Register.

5. Section 3(2) also amends the 2006 Act to make provision about disclosure of information from the Register (new section 2C of the 2006 Act), and in particular lists those to whom information may be disclosed (new section 2C(2) of the 2006 Act). Amendments at Stage 2 made changes to the list to better reflect who information needs to be shared with. The power to amend the list was included in the Bill at introduction in new section 2D of the 2006 Act. Minor amendments were made to this power in consequence of the amendments which were made at Stage 2 to section 2C(2)(c) of the 2006 Act.

Reason for taking the power

6. It is intended that Scottish Ministers will use this power in section 2D to make changes to adapt to any changes in the system of organ and tissue donation in future. For example, the list of persons in section 2C(2) may need to be modified to include other people who become involved in organ and tissue donation for transplantation in the future. The purposes facilitated by the establishment and maintenance of the Register, the information which the Register must include and the purposes for which information from the Register may be disclosed would also need to change if the Register were expanded to support research, education, training, audit and quality assurance.

Choice of procedure

7. The power in new section 2D of the 2006 Act allows changes to be made to provisions which are set out in primary legislation. It is therefore considered that the affirmative procedure continues to be the appropriate level of scrutiny for the exercise of this power.

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Section 21 - Removal and use of part of a body of deceased person: further requirements – power to authorise removal of part of a body in accordance with regulations (section 11 of the 2006 Act)

Power conferred on: the Scottish Ministers
Power exercisable by: regulations made by Scottish statutory instrument
Parliamentary procedure: negative
Revised or new power: revised (in relation to 2006 Act power)

Provision

8. Section 11(1) of the 2006 Act provides that removal of a body part for transplantation must be undertaken by a registered medical practitioner or someone authorised to do so in accordance with regulations. Regulations can provide for a registered medical practitioner to authorise the removal by a non-practitioner. The current Regulations provide that a registered medical practitioner may authorise any person provided that they are satisfied that the person undertaking the retrieval is sufficiently qualified and trained to perform the operation competently.

9. Amendments were made at Stage 2 to the powers in section 11(1) and (2) of the 2006 Act to make these regulations to clarify that the regulations may authorise a person or description of person and also that the regulations may enable a registered medical practitioner to authorise a person or description of person.

Reason for taking the power

10. The amendments to the delegated power in section 11(1) and (2), when taken with other amendments to section 11, clarify that an authorisation need not be given on a case-by-case basis and that an authorisation need not be given to an individual but can be given to a group. The amendments ensure that the regulation making power may be exercised to authorise a person or a description of persons. The amendments will also enable regulations to be made which will permit a registered medical practitioner to authorise a person or description of person.

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Choice of procedure

11. This is a clarification of an existing power. Regulations under section 11(1) of the 2006 Act are subject to the negative procedure. The provisions of the Bill do not change this. It is considered that negative procedure is appropriate to enable changes to be made to the authorisation(s) to respond to practice development and medical progress.

Section 22(1) –Pre-death procedures relating to transplantation – power to specify Type A procedures (new section 16B(1)).

Power conferred on: the Scottish Ministers
Power exercisable by: regulations made by Scottish statutory instrument
Parliamentary procedure: affirmative
Revised or New Procedure: revised

Provision

12. Section 22 of the Bill amends the 2006 Act to provide for the carrying out and authorisation of pre-death procedures, which are medical procedures carried out for the purpose of increasing the likelihood of successful transplantation.

13. The Bill provides for two types of procedure, Type A and Type B. Type A procedures are those which could be considered to be more routine and readily understood as part of the donation process. Both types of procedure will be able to be specified in regulations. New section 16B(1) of the 2006 Act, inserted by section 22(1) of the Bill, enables Scottish Ministers to specify Type A procedures, but only where Ministers are of the view that the requirements in section 16E of the Bill relating to the carrying out of the procedures are sufficient. Type B procedures are those which might be considered to be more novel, and potentially might not be considered to be part of the donation process so the requirements in section 16E of themselves might not be considered to be adequate.

Reason for taking the power

14. To enable procedures to be described as accurately as possible section 16B(1A), introduced at Stage 2, clarifies that the power in section 16B(1) can also be used to make different provision for different

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procedures or categories of procedure and in particular may specify that a procedure carried out in a particular manner is a Type A procedure. This will mean that the power may be used to more accurately describe procedures, including that a particular procedure is Type A only if it is carried out in the way, or on a part of the body, specified in the regulations. In addition it will further enhance the ability to respond to future medical developments by enabling more flexibility in how procedures may be described, along with enabling a more accurate distinction to be made between Type A and Type B procedures.

Choice of procedure

15. This is a clarification of the existing power in section 16B(1) of the Bill which is subject to affirmative procedure (see section 22(2)). The regulations made under section 16B(1) will form part of a system of authorisation for pre-death procedures which will support transplantation. Affirmative procedure is therefore still considered an appropriate level of scrutiny for the use of the power.

Section 26(1A) – Interpretation – Meaning of “health worker”; power to give directions (new section 16J(6) of the 2006 Act)

Power conferred on: the Scottish Ministers

Power exercisable by: directions

Parliamentary procedure: none

Revised or New Procedure: new

Provision

16. Section 26 of the Bill adds provisions relating to the interpretation of the 2006 Act as amended by the Bill. New section 16K provides definitions which will apply to sections 1 to 16J of the 2006 Act. This includes that “health worker” has the meaning in section 16J, inserted at stage 2.

17. New section 16J sets out that “health worker” in sections 1 to 16K of the 2006 Act, as amended by the Bill, means a registered medical practitioner, a registered nurse or a person authorised by registered medical practitioner, a registered nurse, a Health Board, a Special Health Board, the Common Services Agency for the Scottish Health Service (“CSA”). Subsection (3) enables an authorisation to be general, so does not need to be given to each individual health worker and subsection (4)

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requires that an authorisation can only be given if it is considered that the people authorised have the appropriate skills, qualifications or experience to carry out the function.

18. Section 16J(6) enables Scottish Ministers to give directions, either specific or general, to those who may give authorisations under section 16J(1), and subsection (7) requires that such directions must be complied with.

Reason for taking power

19. The power under section 16(6) will be used, if needed, to continue to ensure that appropriately qualified and trained persons are involved in delivering functions under the Bill. The directions will be able to be given generally or in specific cases, or in relation to particular functions of the health worker. It is envisaged that any directions issued may relate – amongst other things – to the skills, qualifications and expertise which a person must have in order to be (and remain) authorised. Since it is envisaged that the power may be used in relation to individual cases, and directed at specific people or bodies, including Health Boards, it is appropriate that it is exercised by direction.

Choice of procedure

20. As the power may be used to address specific individual circumstances, an administrative power of direction is the most appropriate vehicle. Ministerial directions are not subject to parliamentary scrutiny.

Section 26(1A) – Interpretation – Meaning of “health worker”; power to modify (new section 16J(8))

Power conferred on: the Scottish Ministers

Power exercisable by: regulations made by Scottish statutory instrument

Parliamentary procedure: affirmative

Revised or New Procedure: new

Provision

21. New section 16J(8) will enable Scottish Ministers to modify the list of those people who are defined as health workers for the purposes of the 2006 Act. It will also allow modification of the list of who may authorise a person to exercise the functions of a health worker under sections 6A to 16I of the 2006 Act (functions relating to authorisations and pre-death

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procedures). For clarity, section 16J(8) sets out that the power to modify includes the power to add to, amend or remove any entry from the list.

Reason for taking the power

22. The ability to make changes to the lists in future in secondary legislation will ensure that the statutory framework is able to adapt to changes in how healthcare, and in particular how services relating to the donation and transplantation process might be delivered in the future without the need to for primary legislation.

Choice of procedure

23. Affirmative procedure is considered to be appropriate for this power, as it can be used to amend the 2006 Act.

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