

Human Tissue (Authorisation) (Scotland) Bill

Delegated Powers Memorandum

Introduction

1. This memorandum has been prepared by the Scottish Government in accordance with Rule 9.4A of the Parliament's Standing Orders, in relation to the Human Tissue (Authorisation) (Scotland) Bill. It describes the purpose of each of the subordinate legislation provisions in the Bill and outlines the reasons for seeking the proposed powers. This memorandum should be read in conjunction with the Explanatory Notes and Policy Memorandum for the Bill.

2. The contents of this memorandum do not form part of the Bill, are entirely the responsibility of the Scottish Government and have not been endorsed by the Scottish Parliament.

Outline of Bill provisions

3. The primary purpose of the Human Tissue (Authorisation) (Scotland) Bill ("the Bill") is to introduce a soft opt out system of organ and tissue donation for the purposes of transplantation. It amends the Human Tissue (Scotland) Act 2006 ("the 2006 Act") to add to existing provisions in that Act which provide for authorisation of removal and use of parts of the body of a deceased person for the purposes of transplantation and other specified purposes (research, education or training and audit or quality assurance), and introduces "deemed" authorisation for deceased organ and tissue donation.

4. The Bill also contains some new provisions to supplement the existing statutory framework to ensure it continues to work effectively including introducing more flexibility in the timing of the authorisation process, as well as clarity about authorisation for pre-death procedures which may be carried out in order to increase the likelihood of successful transplantation of donated organs and tissue. Provisions for authorisation by and on behalf of children (people aged under 16 years) are also

updated, and additional circumstances in which authorisation can be given for children are included.

5. The Bill is structured in the following Parts:

- Part 1 provides an overview of the Bill structure.
- Part 2 adds to the existing duties of Scottish Ministers under the 2006 Act to promote information and awareness about authorisation of transplantation and pre-death procedures, and to establish and maintain a register of information relating to decisions to authorise, or not authorise, donation.
- Part 3 includes provisions which amend the 2006 Act in relation to authorisation of removal and use of part of a body by deceased persons, including providing for “deemed authorisation” of organ and tissue donation for adults for the purposes of transplantation of common types of organ and tissue; specific provisions regarding authorisation by or on behalf of a child; a framework for authorisation for pre-death procedures in order to allow successful transplantation; and setting out duties to inquire into the views of the potential donor.
- Part 4 sets out various general and final provisions, including adding an interpretation section, and makes consequential amendments.

Rationale for subordinate legislation

6. The Scottish Government has had regard, when deciding where and how provisions should be set out in subordinate legislation rather than on the face of the Bill, to:

- the need to strike the right balance between the importance of the issue and providing flexibility to respond to changing circumstances;
- the need to make proper use of valuable Parliamentary time; and
- the need to anticipate the unexpected, which might otherwise frustrate the purpose of the provision in primary legislation approved by the Parliament.

Delegated Powers

Part 2 – Scottish Ministers’ Duties

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

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Scottish statutory instrument
Parliamentary procedure: Affirmative

Provision

7. New sections 2A to 2C of the 2006 Act (inserted by section 3(2) of the Bill) confer a function on the Scottish Ministers to make arrangements for the establishment and maintenance of a register (“the Register”).

8. The purposes of the Register are to facilitate—

- the carrying out of the Scottish Ministers’ duty under section 1(a) of the 2006 Act to promote, support and develop programmes of transplantation, and
- the removal - in accordance with the 2006 Act - of organs and tissue for transplantation.

9. These new sections also set out what information the Register must include (section 2A(2)), to whom information may be disclosed from the Register (section 2C(2) and (4)) and for what purposes (section 2C(1)). Section 2B(1) provides that the arrangements under section 2A may authorise another person to establish and maintain the Register.

10. New section 2D enables Scottish Ministers to make provision in regulations in relation to the Register. The regulations may, in particular—

- modify section 2A(1) to add to the Register’s purposes the purpose of facilitating organ and tissue donation for a purpose referred to in section 3(1) of the 2006 Act (i.e. research, education, training, audit or – as added by section 20 of the Bill - quality assurance),

- modify the list in section 2A(2) of information which the Register must include,
- modify the list of persons in section 2C(2) to whom information may be disclosed, to add a person (or persons within a description) whether or not they are within Scotland and remove or vary the description of a person,
- modify the purposes for which information may be disclosed under section 2C(1)(a) or (b).

Reason for taking power

11. It is intended that the Scottish Ministers will exercise their power in section 2B(1) of the Bill to authorise NHS Blood and Transplant (“NHSBT”) to establish and maintain the Register. NHSBT maintains the existing Organ Donor Register (“ODR”) which currently holds information about decisions in relation to authorisation for donation for transplantation purposes made by persons across the UK.

12. The purposes of the Register (set out in section 2A(1) of the Bill) and the information which must be included in the Register (set out in section 2A(2) of the Bill) reflects the information which is currently held on the ODR (i.e. information relating to decisions to authorise, or not to authorise, donation for transplantation). The purposes and the list of information may need to change in future to reflect developments in how the Register operates, e.g. if the ODR is expanded to include information relating to decisions to authorise, or not to authorise, donation for research, education, training, audit or quality assurance.

13. The information disclosure provisions in section 2C of the Bill reflect current information sharing arrangements which are in place to ensure the donation and transplantation system works in future as now.

14. The purposes for which information may be disclosed under section 2C(1)(a) and (b) of the Bill are related to transplantation only. It will be necessary to modify section 2C(1)(a) and (b) if, for example, the ODR is expanded to support donation for research, education, training, audit or quality assurance.

15. The persons listed in section 2C(2) (i.e. Scottish health bodies) with whom Register information may be shared will need to be modified to list other persons that are involved in organ and tissue donation for

transplantation and, if the ODR is expanded to support research etc, to list persons involved in organ and tissue donation for those purposes.

16. There may also need to be changes to adapt to any changes in the system of organ and tissue donation in Scotland in future, including to reflect developments in medical science. The power provides the flexibility to be able to adapt to changing circumstances without the need to introduce primary legislation.

Choice of procedure

17. The power allows changes to be made to the purposes of the Register, the information which is to be held on the Register, for what purposes and to whom it may be disclosed. These changes are likely to include making changes to provisions which are set out in primary legislation. It is therefore considered that the affirmative procedure would provide the appropriate level of scrutiny for the exercise of this power.

Part 3 – Authorisation of Removal and Use of Part of Body of Deceased Person

Section 7(2) (Deemed authorisation for transplantation as respects adult) inserts new section 6D(5) into the 2006 Act – power to specify “excepted body part”.

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Scottish statutory instrument
Parliamentary procedure: Affirmative

Provision

18. New section 6D(5) enables Scottish Ministers to specify in regulations parts of a body in relation to which deemed authorisation of removal and use for the purpose of transplantation does not apply.

19. Section 7(2) of the Bill adds a new section 6D to the 2006 Act which provides that in certain circumstances an adult is deemed to have authorised the removal and use of a part of the adult’s body after the adult’s death for transplantation. This does not apply to an excepted body part (section 6D(2)(c)).

20. The policy is that deemed authorisation will only apply to the body parts which are commonly donated. Authorisation for donation of those

parts which are less common, which could include a person's face or limbs, will only be able to be given expressly by the person or, in certain circumstances, by a nearest relative. This power will enable Ministers to list the body parts which are not commonly transplanted and should therefore be excepted from deemed authorisation, after consultation.

Reason for taking the power

21. This approach will allow consideration to be given to which body parts may be considered to be able to be authorised in this way, and will enable changes to be made in future which reflect developments in medical practice and transplantation. This will also allow the system of authorisation set out in the 2006 Act to be flexible enough to be able to adapt and respond to these changes without the need for primary legislation.

Choice of procedure

22. The exercise of the power will impact on the scope of deemed authorisation, and may be used to widen or narrow, depending on developments in clinical practice and views obtained during consultation, the types of body parts in relation to which authorisation may be deemed. The Scottish Government therefore considers that affirmative procedure provides the appropriate level of Parliamentary scrutiny.

Section 18(2) (Power to make provision about decisions) inserts new section 10C(1) into the 2006 Act - power to make provision about decisions.

Power conferred on: The Scottish Ministers

Power exercisable by: Regulations made by Scottish statutory instrument

Parliamentary procedure: Affirmative

Provision

23. New section 10C(1) enables Ministers to make provision about the manner in which, or to whom, certain decisions under the Bill are to be given. Those decisions are—

- authorisations for the removal and use of body parts for purposes set out in section 3(1) of the 2006 Act,
- declarations that authorisation is not given for those purposes, and

- authorisation for pre-death procedures relating to transplantations (see Chapter 5 of the Bill).

24. Section 10C(2) enables regulations made under subsection 10C(1) to modify the 2006 Act.

25. The Bill makes changes to the provisions in the 2006 Act which currently set out how decisions about authorisation may be given, and to whom. For example, that express authorisations for transplantation may be in writing or given to the register organisation (ODR) orally or in writing, this reflects the current methods of joining the ODR e.g. via the Organ Donation Scotland website. Provision is also made about how opt-out declarations must be made, and for both express authorisations and opt-out declarations how these may be made if it is for another purpose referred to in section 3(1) of the 2006 Act (i.e. research, education, training, audit or quality assurance). This is not only to make clear how and to whom decisions about authorisation may be given, but also to reflect current practice and processes which are available to give effect to decisions. The ODR has changed since the 2006 Act came into force now including the addition of the option to “opt-out”, and the provisions in the Bill reflect this.

Reason for taking the power

26. It is foreseeable that additional or alternative provision on these matters may be required in future, as methods for the transmission and recording of information continue to develop. The power will allow changes to be made which reflect evolving practice and ensure that the statutory framework can adapt accordingly. It is considered that this type of provision, which enables how decisions may be given effect to, would be suitable to be made by Ministers exercising powers in secondary legislation.

Choice of Procedure

27. The Government is of the view that as the exercise of the power is likely to involve making textual amendments to the 2006 Act, the affirmative procedure is appropriate.

Section 22(1) (Pre- death procedures relating to transplantation) inserts new section 16B(1) into the 2006 Act – power to specify a pre-death procedure of category of procedure as a Type A procedure for the purposes of sections 16D to 16F of the 2006 Act.

Power conferred on: The Scottish Ministers

Power exercisable by: Regulations made by Scottish statutory instrument

Parliamentary procedure: Affirmative

Provision

28. Section 22 of the Bill amends the 2006 Act to provide a system for authorisation of “pre-death procedures”, which are medical procedures carried out primarily for the purpose of increasing the likelihood of successful transplantation of a part of a person’s body after death.

29. There are two types of pre-death procedures: Type A procedures and Type B procedures. A distinction is made between Type A and Type B procedures in the respective enabling powers in sections 16B(1) and 16C(1). The Bill sets out the minimum standards as to authorisation and pre-conditions, and procedures will be prescribed as Type A only where Ministers are of the view that the requirements set out in the Bill are sufficient in light of the nature of the procedure in question i.e. minimally invasive or routine, and which people may be expected to readily understand (on the basis of public information campaigns) to be undertaken in order for donation and transplantation to be successful.

30. New section 16B enables the Scottish Ministers to specify in regulations a Type A pre-death procedure or category of pre-death procedure for the purposes of new sections 16D to 16F which set out restrictions on carrying out of Type A (and Type B) procedures, the circumstances in which they may be carried out and how Type A procedures are authorised. Regulations specifying Type A procedures may only do so if, after consultation with any appropriate parties, Scottish Ministers consider it appropriate that the carrying out of the procedure is in accordance with new section 16E which includes that the procedure is authorised if there is an authorisation (express or deemed) in place for removal and use of body parts for transplantation.

Reason for taking the power

31. The system of authorisation for pre-death procedures is included in the Bill to provide a clear framework for authorisation for these procedures.

The reason for prescribing the permitted procedures in secondary legislation (rather than on the face of the Bill) is to ensure that the statutory framework is capable of responding appropriately and without undue delay to developments in medical practice and care.

32. The ability to prescribe these in secondary legislation will ensure that they fully reflect current practice, particularly as the regulations will only be made after consultation on the content of the draft regulations. It will also enable the list to be changed, after consultation, without the need for primary legislation as it is important that there is flexibility and an ability to respond to developments in practice and medical progress.

Choice of Procedure

33. Affirmative procedure as this is considered to offer an appropriate level of scrutiny given that regulations made using this power will form part of a system of authorisation of pre-death procedures which support transplantation.

Section 22(1) (Pre- death procedures relating to transplantation) inserts new section 16C (1) into the 2006 Act – power to specify a pre-death procedure of category of procedure as a Type B procedure for the purposes of sections 16D and 16E of the 2006 Act.

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Scottish statutory instrument
Parliamentary procedure: Affirmative

Provision

34. New section 16C of the 2006 Act enables Ministers to specify in regulations pre-death procedures or categories of procedure as a Type B procedure for the purposes of new section 16D and 16E of the 2006 Act, which set out restrictions on carrying out those procedures and the circumstances in which they may be carried out. Type B procedures are procedures which people may not be expected to readily understand to be part of the donation process, but which are carried out with the aim of increasing the likelihood of successful transplantation. Type B procedures will also only be prescribed where Ministers are of the view that additional or more robust requirements should apply before they are carried out, as compared to Type A procedures. These would be procedures which may be less routine or more complex to carry out.

35. These procedures, or types of procedure, will be specified only after consultation on the content of the draft regulations. Regulations specifying a Type B procedure may also set out the circumstances in which such procedures may be carried out, the way they may be authorised, the process for authorisation and how the procedure is carried out (section 16C(2)). A Type B procedure may only be specified if Scottish Ministers consider that it should be subject to the additional requirements in section 16C(2) which are additional to the requirements in section 16E. This means that the pre-conditions imposed by section 16E and which apply to Type A procedures, including an assessment that the procedure is not likely to cause more than minimal discomfort and is not likely to cause harm, would also apply to Type B procedures.

Reason for taking power

36. Specifying Type B procedures in secondary legislation will also enable the donation and transplantation process to keep pace with medical developments which may have an impact on the nature and necessity of pre-death procedures without recourse to primary legislation. This means the system of authorisation will be able to respond appropriately and flexibly to developments in practice, while also ensuring that appropriate safeguards apply to the carrying out of these procedures.

Choice of Procedure

37. As with the power to prescribe Type A procedures, affirmative procedure is considered an appropriate level of scrutiny given that the regulations will form part of a system of authorisation of pre-death procedures which support transplantation.

Section 25 (1) (Ancillary provision)

Power conferred on: The Scottish Ministers

Power exercisable by: Regulations made by Scottish statutory instrument

Parliamentary procedure: Affirmative procedure if adding to, replacing or omitting text in an Act, otherwise negative procedure.

Provision

38. This provision enables the Scottish Ministers to make any incidental, supplementary, consequential, transitional, transitory or saving provisions as they consider appropriate for the purposes of the Bill or any provision made under the Bill. The regulations may modify any enactment.

Reason for taking power

39. As with any change to the law, the Bill may give rise to a need for a range of ancillary provisions. The power is needed to ensure that the policy intentions of the Bill are achieved if further changes are found to be necessary as a result of provisions in the Bill. The power is wide-ranging because a smooth introduction of deemed authorisation, and associated changes to the system of authorisation in the 2006 Act is vital to the continued effective system of donation and transplantation.

40. The power will also allow the Scottish Ministers to make further changes should there be any unforeseen issues (for example, to align authorisation with changes in the other regimes including the Adults With Incapacity (Scotland) Act 2000 with which it interacts). Without the power, it may be necessary to make further primary legislation to deal with a matter which is clearly within the policy intentions of the Bill. The Scottish Government considers that this would not be an effective use of resources by the Scottish Parliament or the Scottish Government.

41. The power is limited to the extent that it can only be exercised if the Scottish Ministers consider it appropriate for the purposes of, in connection with, or for giving full effect to any provisions in the Bill or any provision made under the Bill.

Choice of procedure

42. Section 25(3) requires regulations made for the purposes of section 25(1) to be subject to affirmative procedure if they contain a provision which adds to, replaces or omits any part of the text of an Act. Any other regulations made under this section are subject to negative procedure. These procedures are typical for ancillary powers and ensure an appropriate level of Parliamentary scrutiny depending on the nature of the provision to be made.

Section 28 – Commencement

Power conferred on: The Scottish Ministers

Power exercisable by: Regulations made by Scottish statutory instrument

Parliamentary procedure: laid, no procedure (in accordance with section 30(2) of the Interpretation and Legislative Reform (Scotland) Act 2010)

Provision

43. This provision allows the Scottish Ministers to commence provisions in this Bill (other than sections 2, 4, 22, 24, 25, 28 and 29, which come into

force on the day after Royal Assent) on such day as they appoint by regulations. Different days may be appointed for different purposes and the regulations may include transitional, transitory or saving provision and may also make different provision for different purposes.

Reason for taking power

44. It is usual for the Scottish Ministers to have powers over the commencement of Bills. It is considered appropriate for the substantive provisions of the Bill to be commenced at such time as the Scottish Ministers consider to be suitable particularly for stakeholders. This flexibility will also allow for an appropriate period of time to elapse before commencement of the new provisions on authorisation, so that sufficient public information about these changes may be put in place before deemed authorisation takes effect.

Choice of procedure

45. As is now usual for commencement regulations, the default laying requirement applies (as provided for by section 30 of the Interpretation and Legislative Reform (Scotland) Act 2010). This is considered appropriate because the policy behind the provisions will have already been considered by the Parliament during the passage of the Bill.

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