

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

DELEGATED POWERS MEMORANDUM

INTRODUCTION

1. This memorandum has been prepared by the Non-Government Bills Unit on behalf of Anne McTaggart MSP. Its purpose is to assist the consideration by the Delegated Powers and Law Reform Committee, in accordance with Rule 9.6.2 of the Parliament's Standing Orders, of provisions in the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill conferring powers to make subordinate legislation. It describes the purpose of each of the subordinate legislation-making 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.

OUTLINE OF BILL PROVISIONS

2. This Bill enables the removal of parts of the body of a deceased adult for transplantation where the adult has not recorded an objection to this, provided that certain criteria are met. It also enables an adult resident in Scotland to appoint a proxy to make decisions about removal and use of organs for transplantation after his or her death. These purposes are achieved through amendment of the Human Tissue (Scotland) Act 2006 ("the 2006 Act"), which will remain the principal primary legislation in this area. The Bill also makes various consequential amendments to the 2006 Act.

3. Section 1(1) of the Bill requires the Scottish Ministers to ensure that approved registers are in place prior to the "first appointed day" (defined in section 18(1)). This is the day on which the main provisions of the Bill will come into force. These registers are to enable an adult resident in Scotland to record free of charge a proxy appointment, an objection to the removal and use of organs for transplantation or a withdrawal of either. Section 1(2) requires the Scottish Ministers to run a publicity campaign on the changes introduced by the Bill between the first and second appointed days. The latter is also defined in section 18(1) and is the first day on which it will be permitted to remove organs following authorisation by operation of law. Section 1(3) makes consequential amendments to section 1 of the 2006 Act.

4. Section 2 enables the Scottish Ministers to designate persons or categories of persons as authorised investigating persons for the purposes of the 2006 Act. This is a key role in assessing whether there is either proxy authorisation or authorisation by operation of law for the removal of organs.

5. Sections 3-4 and 8-14 make amendments to the 2006 Act which are consequential on the main provisions of the Bill. These amendments deal with matters such as the insertion of appropriate cross-references to the new provisions on proxy authorisation and authorisation by operation of law, the resolution of conflicting decisions made by an adult concerning removal and use of organs after death and the formal statements to be made by an authorised investigating person prior to removal in cases of proxy authorisation or authorisation by operation of law.

6. Section 5 inserts a new section 6A into the 2006 Act, providing for and regulating the process of obtaining proxy decisions. Section 6(1) inserts a new section 6B providing for authorisation by operation of law for the removal and use of organs after death for transplant. The section sets out the criteria which must be met before such authorisation will exist and key steps to be taken by the authorised investigating person as part of the process. Section 6(2) provides that authorisation by operation of law does not apply until such day as the Scottish Ministers may appoint (the “second appointed day” in terms of section 18(1)), which must be at least 6 months after the first appointed day. This interval provides time for the publicity campaign referred to in section 1(2) to take place and for adults registered in Scotland who wish to record objections or appoint proxies to do so. Section 7 resolves the issue of conflicting decisions by an adult about removal for transplantation after death where it is not clear which decision was most recent.

7. Section 15 makes consequential amendments to the Adults with Incapacity (Scotland) Act 2000 (which was itself amended by the 2006 Act). Section 16 enables the Scottish Ministers to modify the 2006 Act (as amended by the Bill) by regulations in relation to adults dying in Scotland but resident in other jurisdictions which provide for authorisation by operation of law. Section 17 requires the Scottish Ministers to report to the Parliament on the effectiveness of the changes made by the Bill. Sections 18-20 deal with interpretation, commencement and short title.

RATIONALE FOR SUBORDINATE LEGISLATION

8. The powers to make subordinate legislation contained in the Bill are explained in detail in the following paragraphs, but in considering if and how provision should be made in subordinate legislation rather than on the face of the Bill the member has had regard to—

- the need to strike a balance between the importance of ensuring full Parliamentary scrutiny of the core provisions of the Bill and making proper use of Parliamentary time;
- enabling a flexible and responsive approach on matters of administrative detail;
- the need to respond to future legislative developments in relation to human transplantation, including those in other jurisdictions.

DELEGATED POWERS

Section 2 – Designation of authorised investigating persons

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

Provision

9. Section 2A of the 2006 Act (as inserted by section 2 of the Bill) enables the Scottish 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). 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 inserted sections 6A and 6B. The member envisages that designation is likely to be 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.

Reason for taking power

10. The member considers that the Scottish Ministers, in consultation with NHS interests, are best placed to determine which staff should be allocated this responsibility. There may also be a need for the content of the regulations to change over time, in line with alterations to clinical and administrative roles within the NHS.

Choice of procedure

11. As the relevant regulations are likely to be largely technical in content and expressed in terms of NHS grading and staffing arrangements, the negative procedure is considered appropriate.

Section 6 (2) – Fixing of second appointed day

Power conferred on: the Scottish Ministers
Power exercisable by: regulations made by Scottish statutory instrument
Parliamentary procedure: no procedure

Provision

12. Section 6(2) provides that no removal for transplantation is authorised under section 6B of the 2006 Act (as inserted by section 6(1)) before such day as the Scottish Ministers may appoint by regulations (the “second appointed day” in terms of section 18(1)). This day must be at least 6 months after the day on which the main provisions of the Bill come into effect (the “first appointed day” under section 18(1)). The interval between the two provides time for the publicity campaign required by section 1(2) to run and for adults resident in Scotland to record objections or appoint proxies if they wish. Under section 1(1), registers enabling the recording of objections and proxy appointments require to be in place from the first appointed day.

Reason for taking power

13. The ability to fix the second appointed day in regulations (rather than having section 6B automatically come into full effect 6 months after the first appointed day) enables the Scottish Ministers to delay the coming into effect of authorisation by operation of law where they feel this is appropriate. This could be in light of a number of factors such as effectiveness of the publicity campaign or readiness of NHS staff.

Choice of procedure

14. This power is analogous to the power to set the date of commencement of any provision of an Act. The same effect could have been achieved by providing for staged commencement in section 19. This method was chosen in order to enable all the textual amendments to the 2006 Act to come into force at the same time (so that the reader is not confused by references to a non-existent section 6B) while ensuring that the minimum 6 month gap between the majority of the Bill's provisions coming into effect and the commencement of authorisation by operation of law is preserved. It is standard for commencement powers to be subject to no Parliamentary procedure and this reflects the administrative nature of commencement of provisions which have already been agreed by the Parliament.

Section 16 – Adults resident in other jurisdictions subject to authorisation by operation of law

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

Provision

15. 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 authorisation 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 section 6B. Such adults would not have had the opportunity to record any objection to removal.

16. There are however a number of other countries around the world which have “opt-out” systems (authorisation by operation of law) of different types and subject to different conditions. Within the UK, 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 well increase in future. 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 section 6B. Section 16 enables the making of regulations modifying the 2006 Act (as amended by the Bill) to make particular provision for these situations.

Reason for taking power

17. Uniform provision on the face of the Bill in relation to all jurisdictions operating systems of authorisation by operation of law may well be inappropriate, given the differences between the various systems and the likelihood of these systems changing, and new ones emerging, over

time. Some will be much closer to the provisions of the Bill and 2006 Act than others. Consultation with the relevant jurisdictions might well be considered appropriate. There is also a balance to be struck between the benefits of providing for these situations and the resources expended in doing so. Where making provision in relation to a particular jurisdiction would be unlikely to free up significant additional numbers of organs for transplant, doing so may well not be worthwhile. The member believes that such cost-benefit judgements are best made by the Scottish Ministers.

Choice of procedure

18. As regulations made under section 16 would modify the terms of primary legislation, and might well be the subject of public interest and debate, the affirmative procedure is considered appropriate.

Section 19(2) – Commencement

Power conferred on: the Scottish Ministers
Power exercisable by: regulations made by Scottish statutory instrument
Parliamentary procedure: no procedure

Provision

19. Section 19(1) provides for various provisions of the Bill to come into force on the day after Royal Assent. Under section 19(2), the remainder of the provisions are to come into force on the day appointed by the Scottish Ministers.

Reason for taking power

20. Given that commencement of the main provisions of the Bill is not to take place before appropriate registers have been opened for use (section 1(1)) and the need to have a publicity campaign ready to begin on commencement, it is considered to be sensible to allow the Scottish Ministers to fix the commencement date, rather than tying them to a day set down in advance regardless of readiness. The need to ensure appropriate staff training within the NHS may also be relevant.

Choice of procedure

21. Section 19(2) does not provide for any Parliamentary procedure. This is standard for commencement provisions and reflects the administrative nature of commencement of provisions which have already been agreed to by the Parliament.

*This document relates to the Transplantation (Authorisation of Removal of Organs etc.)
(Scotland) Bill (SP Bill 72) as introduced in the Scottish Parliament on 1 June 2015*

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