ORGAN DONATION (DEEMED CONSENT) BILL

Memorandum concerning the Delegated Powers in the Bill for the Delegated Powers and Regulatory Reform Committee

A. INTRODUCTION

1. This memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee to assist with its scrutiny of the Organ Donation (Deemed Consent) Bill ("the Bill"). The Bill was brought from the House of Commons to the House of Lords on 29 October 2018. This memorandum identifies the provisions of the Bill that confer powers to make delegated legislation. It explains in each case why the power has been taken and explains the nature of, and the reason for, the procedure selected.

B. SUMMARY OF THE BILL

2. The Bill sets out amendments to the Human Tissue Act 2004 ("the 2004 Act") to bring in a system of deemed consent in England. Unless someone has made a decision to donate/not donate, or has nominated a representative to deal with the issue of consent after their death, the presumption will be in favour of organ donation. Deemed consent is to apply in respect of the removal, storage and use of organs and tissue from a deceased adult.

Clause 1: "Appropriate consent" to adult transplantation activities: England

3. Clause 1 amends section 3 of the 2004 Act to introduce deemed consent by changing the definition of "appropriate consent" in respect of adults. Deemed consent will apply in the absence of express consent/non-consent by the adult or a person appointed by the adult to deal with the issue of consent in relation to the transplantation activity.

4. Further, the amendments to section 3 of the 2004 Act set out that deemed consent will apply unless—

a. a relative or close friend (listed in section 54(9) of the 2004 Act) provides information that would lead a reasonable person to conclude that the deceased would not have consented;
b. the deceased person was an excepted adult (as defined by new s.3(9) of the 2004 Act), namely:

   i) he had not been ordinarily resident in England for a period of at least 12 months immediately before he died; or,

   ii) he had, for a significant period before his death, lacked capacity to understand that deemed consent would apply. (We are minded to follow the approach in Wales and set out in practical guidance that a 'significant period' will be 12 months, though it can be determined on a case by case basis).

c. the transplantation would be 'novel' (see further paragraphs 9-16 below).

Clause 2: Consequential amendments

5. Clause 2 makes amendments to the 2004 Act as a consequence of the amendments made by clause 1 of the Bill. The amendments ensure that organs and tissue removed under the deemed consent system in England can continue to be stored and used for transplantation in Northern Ireland.

6. Clause 2 also inserts two new subsections ((8ZA) and (8ZB)) into section 27 of the 2004 Act. These new provisions place a duty on the Human Tissue Authority (HTA) to issue Codes of Practice to give practical guidance on how deemed consent will work in practice, including guidance about the provision of information by a family member or friend of the deceased to override the presumption of consent.

7. This clause also amends section 52 of the 2004 Act so that the Secretary of State's delegated power to make regulations to exclude novel transplants from deemed consent is subject to the affirmative procedure. It also sets out with whom the Secretary of State must consult with when making such regulations.

Clause 3: Extent, commencement and short title

8. Clause 3, which comes into force on Royal Assent, provides that the Bill extends to England, Wales and Northern Ireland (but the deemed consent provisions only apply in respect of transplantation activities carried out in England). Clause 1 and 2 will come into force on a date, or dates, appointed by the Secretary of State by regulations. The short title for the Act is the Organ Donation (Deemed Consent) Act 2018.

C. ANALYSIS OF DELEGATED POWERS BY CLAUSE

Clause 1(5) "Appropriate consent" to adult transplantation activities: England
Power conferred on: Secretary of State
Power exercised by: Regulations made by Statutory Instrument
Parliamentary Procedure: Affirmative resolution

Introduction

9. Novel forms of transplant are new, rare or more controversial transplantations (such as faces or limbs). The policy position is that deemed consent should not apply to novel transplants, and that express consent should continue to apply.

10. Clause 1(5) creates a delegated power for the Secretary of State to make regulations to list the novel transplants to which deemed consent will not apply.

11. The clause adds new section 3(9), which provides definitions for use in the interpretation of new section 3(6A). One of those definitions is "permitted material" which is defined as "relevant material other than relevant material of a type specified in regulations made by the Secretary of State". This definition will be used in new subsection (6A) of section 3 of the 2004 Act and has the effect that the new provision about deemed consent will not apply in relation to relevant material of a type specified in regulations made by the Secretary of State.

12. “Relevant material” is defined in section 53 of the 2004 Act, as material which consists of or includes human cells but does not include gametes, embryos outside the human body, or hair and nail from the body of a living person. This is a wide definition which would capture all organs and most tissues, including organs and tissues which are not currently, or only rarely, used in transplantations, such as faces or limbs. It is intended that the power in new s.3(9) will be used to define “permitted material” so that the deemed consent provisions would not apply to novel forms of transplant.

Effect of the provision

13. The provision will enable the Secretary of State to make regulations specifying relevant material that will not be permitted material to which deemed consent to activities for the purposes of transplantation would apply. For relevant material that is not permitted material, i.e. novel transplants, express consent will therefore continue to apply.

Justification of the Delegation

14. Delegation is necessary to ensure flexibility to amend the list of novel transplants, in order to account for changes over time in research, technology, clinical practice, new ways of transplantation, or where rare types of transplant become more common and acceptable to the public. The list is likely to be detailed and may need adjusting more often than Parliament can be expected to legislate for by primary legislation, so it is not considered to be practical to set the list out on the face of the Bill.

15. It is important to maintain consistency with Wales and the proposed approach in Scotland, to minimise any confusion for the public and healthcare professionals. The Bill is similar to the deemed consent legislation in Wales because Welsh Ministers have a similar power in the Human Transplantation (Wales) Act 2013. The Human Transplantation (Excluded Relevant Material)

(Wales) Regulations 2015[1] provides a useful exemplar of the exercise of the delegation power. A similar approach is proposed in the Human Tissue (Authorisation) (Scotland) Bill.

16. It is considered appropriate that the delegated power to make regulations is subject to the affirmative procedure to afford Parliament the opportunity to scrutinise the instrument. There were over 17,000 responses to the consultation on deemed consent to organ donation showing that it is an area many people are interested in so the affirmative procedure provides an important safeguard to ensure the appropriate degree of parliamentary scrutiny.

Clause 2(4) Consequential amendments

Power conferred on: Human Tissue Authority

Power exercised by: Code of Practice

Parliamentary Procedure: see section 29 2004 Act – 'made negative procedure'

Introduction

17. The Human Tissue Authority (HTA) may prepare and issue codes of practice for the purpose of giving practical guidance and laying down the standards expected in relation to persons carrying on activities within its remit.

18. Section 26 of the 2004 Act lists matters on which the HTA must give guidance, and specifies that it is to give guidance on consent to certain activities (further prescribed in section 27).

19. Clause 2(4) of the Bill inserts two new subsections into section 27 of the 2004 Act so the HTA is under a duty to give practical guidance on deemed consent.

20. Section 28 sets out the regulatory purpose of the Codes which it that, while failure to observe a provision of a code of practice will not itself make a person liable to any proceedings, the HTA may take account of observance or failure

[1] 2015/1775

to observe a provision of a code of practice dealing with a matter that is subject to a licence requirement when carrying out its licensing functions.

21. The HTA ensures that human tissue is used safely and ethically, and with proper consent. It regulates organisations that remove, store and use tissue for research, medical treatment, post-mortem examination, teaching and display in public. It approves organ and bone marrow donations from living people. The HTA is an executive non-departmental public body, sponsored by the Department of Health and Social Care.

Effect of the provision

22. The provision will require the HTA to issue a code to give practical guidance on the circumstances in which a person is deemed to have consented, and guidance about the provision of information by a person in a qualifying relationship which would lead a reasonable person to conclude that the person would not have consented to donation.

Justification of the Delegation

23. Delegation is necessary because the codes will cover detailed matters and would likely be sizeable documents which would need to be easily reviewed and updated as and when necessary - more often than Parliament can be expected to legislate for by primary legislation. It would not be practicable to include this information on the face of the Bill nor would it be consistent with the current provisions for issuing guidance on consent under the 2004 Act. Delegating this power has a strong, uncontroversial precedent given that the HTA are already responsible for codes in this area and have the relevant expertise to issue such guidance and to engage with stakeholders.

24. Sections 29 of the 2004 Act sets out the parliamentary procedure for the approval of codes which is that a draft code is sent to and approved by the Secretary of State and laid by him or her before both Houses of Parliament, and the 40-day period must elapse without either House resolving not to approve the draft. The 40-day period is defined in section 29(6) of the 2004 Act.

25. HTA codes issued under the new section 27(8ZA) and (8ZB) (inserted by clause 2(4) of the Bill) will be subject to the same parliamentary procedure. If the Secretary of State does not approve the draft code, he must give reasons to the HTA. It is proposed that this will ensure a balance between the need for a process which allows for detailed guidance and an expeditious response to changes in circumstances and the need for Ministerial oversight and accountability.

Clause 3(3) Extent, commencement and short title

Power conferred on: Secretary of State
Power exercised by: Commencement regulations
Parliamentary Procedure: nil

Introduction

26. Clause 3(3) of the Bill provides that clauses 1 and 2 of the Bill come into force on such day or days as the Secretary of State may by regulations made by statutory instrument appoint.

Effect of the provision

27. The delegated power enables the Secretary of State to bring clauses 1 and 2 of the Bill into force on a day or days appointed in the statutory instrument.

Justification of the Delegation

28. Delegation of this power is necessary because different provisions of the Bill need to come into force at different times. The three main examples of this need are:

    a. If the Bill receives Royal Assent, the public will need to be made aware of deemed consent and given time to make a decision as to consent and to make that decision known. There will be a year-long communication campaign to publicise the provisions before they come into force.

b. The HTA is to issue a code outlining practical guidance around deemed consent. The code will need to have completed its parliamentary procedure before deemed consent comes into force so commencement of clause 2(4), which inserts new subsections (8ZA) and (8ZB) into section 27 of the 2004 Act, will need to allow for this.

c. Clause 2(2) concerns Northern Ireland and therefore a legislative consent motion (LCM) is required. A LCM has not yet been obtained because the Northern Ireland Assembly does not currently have a sitting Executive, but this delegated power allows for flexibility to accommodate for when it does. (If the deemed consent provisions of the Bill are brought into force prior to Clause 2(2), relevant material removed in England will be able to be stored and used in Northern Ireland if the same consent requirements in Northern Ireland (as set out in the 2004 Act – i.e. express consent) have been met, until such time as clause 2(2) is brought into force.)

29. Therefore, flexibility is needed for the commencement provisions and it would not be suitable to put this on the face of the Bill. The commencement regulations of the Bill will not be subject to any parliamentary procedure and will come into force on that day or days appointed. It is common that commencement regulations are not subject to parliamentary procedure and there is no reason to deviate from that approach in this case.

Department of Health and Social Care
29 October 2018