

EXPLANATORY MEMORANDUM

The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015 Regulations 2015

This Explanatory Memorandum has been prepared by the Health and Social Services Group and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015. I am satisfied that the benefits outweigh any costs.

Mark Drakeford AM
Minister for Health and Social Services
9 September 2015

1. Description

The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015 (“the Persons who Lack Capacity Regulations”) describe the process for deeming the consent for living donation from people who lack the capacity to consent for themselves, when it is in their best interest.

It is important to note that these Regulations are concerned with live donation as opposed to deemed consent for deceased donation covered in section 4 of the Human Transplantation (Wales) Act 2013 (“the 2013 Act”). Deceased persons who lacked the capacity to understand deemed consent are treated as excepted adults under section 5 of the 2013 Act.

The Persons who Lack Capacity Regulations will come into force on 1 December 2015.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

The Committee’s attention is drawn to the fact that the Persons who Lack Capacity Regulations are part of a package of subordinate legislation to be made under the Human Transplantation (Wales) Act 2013. These comprise (the regulations which are the subject of this Explanatory Memorandum are shown in bold):

- The Human Transplantation (Appointed Representatives) (Wales) Regulations 2015 (these Regulations);
- The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015;
- **The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015** and
- The Human Tissue Authority Code of Practice 2015 on the Human Transplantation (Wales) Act 2013

The above Regulations and Code of Practice are laid before the National Assembly for Wales at the same time for approval. A separate Explanatory Memorandum has been prepared for each instrument.

3. Legislative background

The Human Transplantation (Wales) Act 2013 comes fully into force on 1 December 2015.

The purpose of the 2013 Act is to change the way in which consent, for the purposes of transplantation, is to be given to organ and tissue donation in Wales. The 2013 Act introduced two concepts, “express consent” and “deemed consent”. It provides that in the absence of express provision in relation to

consent, consent will be deemed to have been given in most cases. This means that, after death, a person's consent will be deemed to have been given unless they had expressed a wish for or against donation, or appointed a representative to make the organ donation decision on their behalf.

There are several exceptions to deemed consent, including children; those who are not ordinarily resident in Wales; and those who lack capacity to understand the notion of deemed consent. In such cases, express consent (which has the same meaning as appropriate consent set out in the Human Tissue Act 2004 ("the 2004 Act") will apply. It is also the case that if a family member or friend of long standing can provide information to show the deceased person objected to donation, then deemed consent will not apply. This involvement of family and friends in the discussion around organ donation is why the system is termed a "soft opt-out" system. In addition, consent will not be deemed in respect of so-called novel forms of transplantation or to living donation.

4. Purpose and intended effect of the legislation

The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015 are made under section 9(2) of the 2013 Act. The 2013 Act covers all consent to donation in Wales for the purposes of transplantation, both from deceased and living donors. For living donors, in the vast majority of cases, the consent which would be given to donation would be the person's own, express consent. However, there are some cases where the person may be unable to give consent.

The purpose of the Persons who Lack Capacity Regulations is to ensure that the arrangements for living people who lack the capacity to consent to organ or tissue donation will remain the same after the commencement of the 2013 Act as the current arrangements which apply on an England and Wales basis.

Section 9 of the 2013 Act gives Welsh Ministers the ability to regulate in relation to the circumstances in which consent can be deemed for a living person who lacks the capacity to consent. This section has the same effect as Section 6 of the 2004 Act, but relates to a transplantation activity carried out in Wales.

Regulations made under the 2004 Act (Part 2, Regulation 3 of the Human Tissue Act 2004 [Persons who Lack Capacity to Consent and Transplants] Regulations 2006 [S.I. 2006/1659]) set out strict provisions where people who lack capacity to consent to living donation can have their consent deemed to certain transplantation activities, including where it is in their best interests. The Welsh Government wishes to maintain these strict provisions in Wales after the new law comes into force.

This section is separate from the concept of deemed consent to deceased donation, which is set out in section 4 of the 2013 Act. It is important to note that the Welsh Ministers' regulation making power is limited to specifying the circumstances in which a living person who lacks capacity can be deemed to consent to the storage and use of relevant material from their body.

A person who has died and lacked the capacity to consent during life, including being able to decide to have their consent deemed, would be described as an “excepted adult” as set out in section 5 of the 2013 Act and as such would be exempt from deemed consent for organ donation after death.

5. Consultation

Feedback from the consultation was generally positive. Of respondents that answered the question the majority felt that the regulation was clear and effective.

There was a certain amount of confusion from some respondents as to whether the Regulations related to deceased or living donors. Questions were also raised about the period of time a person would have to lack capacity prior to becoming eligible for their consent to be deemed. Some of these comments seemed to stem from the confusion about deceased donors (for which the answer is laid out in the draft Code of Practice). However some seemed to be relevant to living donors.

The Mental Capacity Act does not create a minimum time for someone’s mental impairment to have lasted before they lack capacity stating that “the impairment or disturbance (may be) permanent or temporary.” As a result of this, and the fact there will be a best interests test before the consent of any living donor is deemed, it was not felt necessary to put a time requirement into the Regulations.

However, in order to address the comments received in the consultation, the Explanatory Note to the Persons who Lack Capacity Regulations has been amended to include the wording “This section applies where a **living** adult lacks capacity to consent to organ donation and no decision is in force”. The word “living” has also been included before adult in the rest of the Explanatory Note.

6. Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment is not considered necessary in respect of the Persons who Lack Capacity Regulations. They impose no direct costs and are part of operationalising the 2013 Act. The costs associated with the Act were assessed at the time of its introduction and revised in June 2013 following Stage 2 scrutiny of the Bill.

Link to the Explanatory Memorandum and full Regulatory Impact Assessment for the 2013 Act:

[http://www.assembly.wales/laid%20documents/pri-ld9121-em-r%20-%20revised%20explanatory%20memorandum%20human%20transplantation%20\(wales\)%20bill-25062013-247379/pri-ld9121-em-r-e-english.pdf](http://www.assembly.wales/laid%20documents/pri-ld9121-em-r%20-%20revised%20explanatory%20memorandum%20human%20transplantation%20(wales)%20bill-25062013-247379/pri-ld9121-em-r-e-english.pdf)