

EXPLANATORY MEMORANDUM

The Human Transplantation (Appointed Representatives) (Wales) 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 (Appointed Representatives) (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 (Appointed Representatives) (Wales) Regulations 2015 (“the Appointed Representatives Regulations”) describe persons who may not act as an appointed representative for the purposes of giving consent to organ donation.

The Appointed Representatives 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 Appointed Representatives 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;**
- 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 for approval at the same time. A separate Explanatory Memorandum has been prepared for each instrument.

3. Legislative background

The Human Transplantation (Wales) Act 2013 (“the 2013 Act”) 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 (Appointed Representatives) (Wales) Regulations 2015 are made under section 8(10)(b) of the 2013 Act. The 2013 Act allows for the appointment, either by a child or an adult, of a representative whose role it would be to give express consent on behalf of the individual making the appointment. This means that a person is able to nominate another individual to deal after death with the issue of consent to donation. The appointed representative may be asked to carry out the specific instructions of the deceased person, or be allowed by them to make any decision on their behalf, as they see fit.

Appointments made by adults under either the 2013 Act or the 2004 Act will be effective across Wales, England and Northern Ireland. Under the 2013 Act, children may appoint a representative but there is no such provision in the 2004 Act. Therefore such an appointment made in Wales would not be recognised in England or Northern Ireland. Consent would then be sought from a person with parental responsibility or, where no such person exists, a qualifying relation.

The Welsh Ministers can regulate to specify any category of person who may not become an appointed representative (for either an adult or a child) under Section 8(10)(b) of the 2013 Act. The 2004 Act also contains a similar provision, but no regulations have been made by the Secretary of State on who may not act as an appointed representative.

The Appointed Representative Regulations exclude people who lack capacity from becoming appointed representatives. Although people are not expected to have detailed knowledge of organ donation, a person should be able to comprehend the decision they are being asked to make on behalf of the patient.

The Appointed Representative Regulations do not set out any form of test of mental capacity and a broad description, such as that set out at section 3 of the Mental Capacity Act 2005, will be relied upon. This states that a person is unable to make a decision for himself if he is unable:

- to understand the information relevant to the decision,
- to retain that information,
- to use or weigh that information as part of the process of making the decision, or

- to communicate his decision (whether by talking, using sign language or any other means).

In terms of people who lose capacity after the appointment has been made, e.g. through dementia, or another means, then clinicians will make a judgment on whether the person is able to act at the time organ donation is being considered. If they are not able to act, then, as provided for in the 2013 Act, the decision will revert to a qualifying relation.

5. Consultation

A consultation was held between 23 October 2014 and 15 January 2015 on the three sets of draft Regulations set out at section 2 above. In total, seventeen responses to the consultation were received. Four responses were received after the closing date, but were still considered. The latest response was received on 27 January 2015. Not all respondents commented on all of the Regulations and some made no specific comments on the Regulations themselves, preferring instead to make general comments about the new law.

Responses were received from a mixture of individuals, NHS organisations, medical organisations and non-medical organisations, such as charities. One respondent chose to remain anonymous.

Feedback from the consultation on the Appointed Representative Regulations was generally positive. Of respondents who answered the majority felt the Regulations were clear and effective. There were several questions about the process, for example what would happen if someone appointed two representatives who disagreed. However, this is not a matter for the Regulations and there are operational processes in place to deal with disagreements. A concern was raised about the definition of a child, and what age someone could be appointed as a representative. In Section 8(10) of the Act it states that “a person may not act under appointment if the person is a) not an adult or b) is of a description described by regulations made by the Welsh Ministers.” In Section 19 of the Act an adult is described as a person who has obtained the age of 18.

In general it was felt that the queries raised about the draft Appointed Representative Regulations will either be adequately resolved through clinical practice or are already covered on the face of the 2013 Act. To this end no changes were made to the draft Regulation as a result of feedback from the consultation.

6. Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment is not considered necessary in respect of the Appointed Representative 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)