Human Transplantation (Wales) Bill: Summary of changes made at Stage 2

Introduction
This document sets out the main changes made to the Human Transplantation (Wales) Bill (“the Bill”) during Stage 2 proceedings.

Background
The Bill was introduced by Lesley Griffiths AM, Minister for Health and Social Services, on 3 December 2012, and was remitted by the Business Committee to the Health and Social Care Committee (“the Committee”) for Stage 1 scrutiny. Following a change in ministerial portfolios in March 2013, Mark Drakeford AM took over as the Member in charge of the Bill from 18 March 2013.

The Committee published its Stage 1 report in March 2013. The Constitutional and Legislative Affairs Committee also published a report on the Bill’s subordinate legislation provisions in the same month. The Bill was approved unanimously at Stage 1 by the Assembly following a debate on its general principles in Plenary on 16 April 2013.

Stage 2 commenced on 17 April. A total of 42 amendments were tabled, 21 by the Welsh Government. The Committee met to consider and dispose of the amendments on 22 May 2013.

Further information about the Bill (as introduced) is available in a Bill Summary prepared by the Research Service.

Amendments agreed at Stage 2
All the Welsh Government’s 21 amendments were agreed. Of the 21 non-Government amendments tabled, one was agreed, eight were not agreed, three were withdrawn, one was not moved, and a further eight fell.

The most significant changes made to the Bill are summarised below:

Consent to donation

- Amendments 1 and 4 provided that novel and composite forms of transplantation should not be covered by deemed consent. Instead, the consent arrangements for these types of transplantations will be set out in future regulations, which would be subject to the superaffirmative procedure. This will, therefore, allow for novel forms of transplantation, provided there is express consent. This was as a result of recommendation 17 of the Committee’s Stage 1 report.

- Amendment 14 required a code of practice issued by the Human Tissue Authority to give practical guidance on how to assess the information provided by relatives and friends, according to a ‘hierarchy of information’ rather than a ‘hierarchy of relationships’. It was aimed at helping clinicians to decide which of two competing pieces of information was more likely to have validity when considering the transplantation of organs from a deceased person.

- Amendment 36, tabled by Darren Millar AM, extended the residency criterion from the proposed six months to 12 months. Therefore, someone will have had to be ordinarily resident in Wales for a 12-month period before their consent to donation can be deemed.
Appointed representatives

- **Amendments 2, 3, and 5 through to 10** altered the cases in the tables in sections 4 and 5 of the Bill to make it clear that, where an appointed representative is unable to act, consent passes to a person in a ranked qualifying relationship.

- **Amendment 11** set out that, if it is not reasonably practicable to contact an appointed representative within the time available, the clinician may judge that that representative is unable to give consent.

These amendments gave effect to recommendation 7 of the Committee’s Stage 1 report.

Living donation

- **Amendment 12** gave effect to a commitment given by Lesley Griffiths AM, the former Minister for Health and Social Services, to the Constitutional and Legislative Affairs Committee, namely that the only grounds on which donation could go ahead in specific cases involving living adults lacking the capacity to consent to donation would be on a test of the best interests of the potential donor. The circumstances in which such grounds would apply are to be set out in regulations subject to the superaffirmative procedure.

Subordinate legislation

All the amendments in group 8 gave effect to commitments given by the Minister during the Stage 1 debate in the Chamber based on the recommendations of the Constitutional and Legislative Affairs Committee.

- **Amendment 17** ensured that Welsh Ministers would be required to conduct a public consultation on any Order seeking to alter the ranking of a qualifying relationship set out in section 27(4) of the Human Tissue Act 2004, thereby making it subject to the superaffirmative procedure.

- **Amendment 18** related to the Human Tissue Authority’s code of practice. The code is subject to the negative procedure in Parliament under the 2004 Act, but the amendment provided that such a code of practice would be subject to the affirmative procedure in the National Assembly.

- **Amendment 20** also introduced the superaffirmative procedure for any regulations or Orders relating to: organs to be excluded from deemed consent (in relation to novel and composite forms of donation); people who may not act as appointed representatives; and identifying those who can be on the list of qualifying relations.

Commitments made by the Minister

During Stage 2 proceedings, the Minister made various commitments to consider and discuss issues raised by the following amendments ahead of the Stage 3 debate. The details are as follows:

**Communication campaign**

- Darren Millar AM tabled amendment 25 asking for an annual campaign to promote transplantation, but withdrew the amendment following the Minister’s commitment to table a similar amendment at Stage 3. The Minister also said that he would consider Members’ points about placing a requirement on the face of the Bill for the Minister to make an annual statement on progress to Plenary.

- Darren Millar AM also tabled amendments 28 and 29, which would have made it obligatory for people to appoint only one nominated representative, rather than one or more. The Minister gave a commitment to consider the matter further in consultation with the Department of Health, with a view to tabling a similar amendment at Stage 3.
Next steps

An amended version of the Bill has been prepared by the Legislation Office.

Stage 3 began on 23 May 2013 (the day after Stage 2 proceedings were completed). The date for Stage 3 proceedings in Plenary has yet to be agreed. Once agreed, it will appear on the Business statement and announcement and will be published on the Bill page.

All amendments to be considered at Stage 3 must be tabled at least five working days before the day on which they are due to be considered by the Assembly. Amendments should be tabled through the Legislation Office (legislationoffice@wales.gov.uk).

Further information

For further information on the Bill, please contact the Legislation Clerk, Sarah Beasley (sarah.beasley@wales.gov.uk).