



Law Society
of Scotland

Stage 3 Briefing

The Human Tissue (Authorisation) (Scotland) Bill

June 2019



Introduction

The Law Society of Scotland is the professional body for over 11,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's solicitor profession.

We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

We have previously engaged with the Scottish Parliament on a number of occasions in relation to proposals focused on organ donation. During the parliamentary passage of the Transplantation (authorisation of removal of organs etc.) (Scotland) Bill we submitted written evidence¹ and provided oral evidence² to the Scottish Parliament's Health and Sport Committee. In March 2017, we submitted a consultation response to the Scottish Government consultation: Organ and Tissue Donation and Transplantation - increasing numbers of successful donations.³ In relation to the present Bill, The Human Tissue (Authorisation) (Scotland) Bill, we submitted written evidence⁴ to the Health and Sport Committee and provided oral evidence before the committee on 27 November 2018.⁵ We circulated our Stage 1 brief⁶ to all MSPs ahead of Stage 1 debate on 26 February 2019. At Stage 2 we submitted several amendments for consideration by members of the Health and Sport Committee.

If you would like to discuss this paper, or if you would like more information on the points that we have raised, please do not hesitate to contact us. Contact details can be found at the end of the paper.

¹ <http://www.lawscot.org.uk/media/604859/hea-transplantation-authorisation-of-removal-of-organs-etc-scotland-bill-final-12-10-15.pdf>

² <http://www.parliament.scot/parliamentarybusiness/report.aspx?r=10247>

³ <https://www.lawscot.org.uk/media/9563/hea-organ-and-tissue-donation-and-transplantation-consultation-law-society-of-scotland-response.pdf>

⁴ <https://www.lawscot.org.uk/media/360960/03-09-18-hea-the-human-tissue-authorisation-scotland-bill-call-for-evidence-response.pdf>

⁵ <http://www.parliament.scot/parliamentarybusiness/report.aspx?r=11810&mode=pdf>

⁶ <https://www.lawscot.org.uk/media/361834/human-tissue-authorisation-scotland-bill-stage-1-briefing-law-society-of-scotland-feb-19.pdf>

General comments

While the Health and Medical Law Sub-committee support the promotion of good public health and health equality, we are not in position to comment on whether Scotland should move to a soft opt-out system for organ donation. However, we do believe that it is important to highlight what we consider to be the underpinning themes to any legislation which implements a soft opt-out system, and themes that have consistently been the focus of our previous submissions.

Overview of the Transplantation (authorisation of removal of organs etc.) (Scotland) Bill

The Bill before the Scottish Parliament has the effect of reversing the current law in relation to organ donation. Organ donation and transplantation is currently underpinned under the provisions of the Human Tissue (Scotland) Act 2006.⁷ The 2006 Act provides that for organs or tissue to be donated, the donor themselves must provide authorisation. Alternatively, the nearest relative may provide authorisation at the point of, or after, the death of the person from whom the organs or tissue are to be donated from. Therefore, the current position is that organ and tissue donation operate on a 'opt-in' basis. This is the opposite to the effects of the Bill, which proposes a 'soft' opt-out – or 'deemed authorisation'.

It is not proposed to repeal the 2006 Act. The current Bill, in seeking to achieve its policy intent, makes significant amendments to the 2006 Act which shall remain in force.

The policy intent of the Bill, by introducing a 'soft' opt-out – or 'deemed authorisation' process, is to increase the availability of organs and tissue for transplantation, and therefore reduce the number of those awaiting a transplant and the associated deaths which occur each year whilst awaiting the availability of suitable organs. To this aim, the Bill seeks to introduce a system where three options are provided;

1. Opt-in – where a potential donor may expressly record their authorisation for donation,
2. Opt-out – where a potential donor may expressly 'remove' authorisation, or
3. Deemed authorisation – this would be, under the provisions of the Bill, the default option if the donor did not expressly state their wishes, in effect the donor does nothing to record their wishes.

The third option 'deemed authorisation' would only apply to those over the age of 16 years, with the capacity to understand the effects and meaning of deemed authorisation and who are resident in Scotland for over 12 months. In relation to those under the age of 16, authorisation would be sought from those with parental rights and responsibilities. For children over the age of 12, as is the current position, they would

⁷ <https://www.legislation.gov.uk/asp/2006/4/contents>

be able to opt-out or opt-in. Where a child under the age of 12 has expressly opted in or out, then these express wishes cannot be overridden.

The Bill does not set out the nature or types of the organs or tissue to which the provision of the bill will apply. However, those organs to which it does not apply will be set out in regulations. We previously recommended that a draft of these regulations excluding excepted body parts should be made available to MSPs before Stage 3 of the Bill. Setting these out within regulations, would allow for the type of organs to be donated to be controlled and amended to reflect medical needs, research and advancements.

Summary of the provisions of the Bill

The Bill is set out in four parts;

Part 1 provides a brief overview of the 2006 Act and the structure of the current Bill.

Part 2 sets out the duties of the Scottish Ministers, amending those in the 2006 Act to support the amended provisions. This includes the duty to promote information and awareness of the new provisions, how transplantation may be authorised and how this can be deemed. In addition, it provides for the creation of a register to record those who expressly opt-in and opt-out. The register is not a public register, but a duty is placed to release information from the register to specified persons. These include, for example, the Health Board and the donor's nearest relative or, in the case of a child, those having parental rights and responsibilities.

Part 3

Sections 4-11 relate to authorisation of, or on behalf of, an adult and provide that an adult may expressly record their wishes (opt-in or opt-out) in the relevant register and that the adult retains the right to withdraw their express wishes. Where no express wishes have been recorded, section 7 provides that authorisation for donation is to be deemed (except in cases where the adult lacks capacity or has not been resident in Scotland for 12 months or the organ in question is an 'excepted body part'. Section 8 provides for authorisation to be given by a nearest relative where the potential donor has been resident for a period of less than 12 months and has not expressly made known their wishes. Section 9 provides for authorisation by the nearest relative where the potential donor lacked capacity to understand the nature and consequence of deemed authorisation and where no express wishes have been recorded. Section 10 provides for authorisation where the organ is an 'excepted body part'. The nearest relative may authorise removal if the potential donor did not expressly opt out and the nearest relative has no actual knowledge of the donor's most recent view. Section 11 provides provision allowing the nearest relative to authorise organs for purposes other than transplantation.

Sections 12-17 set out the provision relation to authorisation by or on behalf of a child. Children, those under the age of 16, are exempted from deemed authorisation for the purposes of the Bill. Where a child is under the age of 16 years, authorisation would be sought from the person with parental rights and responsibilities or the nearest relative. Where a child is over the age of 12 years, they retain the current right to opt-in. The Bill's provisions also confer the right to opt-out. Where a child over the age of 12 has chosen to record their wishes, then this cannot be overridden by the wishes of the person holding parental rights and responsibilities.

Sections 18-21 set out general provisions relating to authorisation, such as the steps necessary for a person who is visually impaired or unable to write to opt-out of deemed consent and the removal of body parts for the purposes of quality assurance.

Section 22 sets out the provision relating to pre-death procedures and provides the authorisation process under which the procedures may be carried out. There are two separate procedures, Type A procedure and Type B procedure. The Bill does not expressly state the nature of either type of procedure, but leaves this to be set out in regulations. It is expected that Type A will include routine testing, for example blood/urine etc. This type of procedure could be carried out under deemed authorisation. Type B procedures are expected to be more invasive tests. These will not be carried out under deemed authorisation.

Section 23 places a duty on the health care worker to take steps to ascertain the wishes of the potential donor, which includes inquiring if there was an express wish of authorisation or opt-out. Where there is no express wish, then the health care worker must inquire if the adult is a non-resident or is an adult who is incapable of understanding the nature and consequence of deemed authorisation.

Part 4 sets out provisions relating to consequential amendments to the 2006 Act which result due to the main provisions of the Bill.

Summary of comments in relation to Stage 3

Educating the public and raising awareness.

Following our earlier submission suggesting that public awareness and information will be paramount to ensuring the policy intent is realised, we were pleased to note that, following Stage 2 amendments, there will be a duty on Scottish Ministers to promote an awareness and information campaign annually.

We are also supportive of the policy intent behind Section 3 2E, which was also introduced as a Stage 2 amendment and places a duty to promote opportunities for individuals to consider registering their status.

However, although we support the policy intent behind the provision, we believe that there is a common theme and policy intent in relation to section 3(2) 2E and section 2(3). It would therefore helpful and avoid any duplication for there to be a single provision relating to an awareness campaign and promoting opportunities.

Therefore, we are supportive of the proposed Scottish Government amendments (amendment 1 and 2) which seek to delete the respective sections 2(3) and 2E and replace with a provision which effectively combines the policy intent of both.

Review / report clause

We are also pleased to note the Stage 2 amendment introducing a duty on Scottish Ministers to carry out a review and report on the impact of the introduction of deemed consent by virtue of section 6D, with the review period being five years from the introduction of the Act. This duty is set out currently at section 27A.

However, we note the amendment proposed by Lewis McDonald MSP (amendments 3 and 4) to delete section 27A and replace this with a new section. The proposed amendments, in our view, will strengthen the framework of the Bill, going beyond the reporting requirements of the current section 27A and ensuring that Scottish Ministers, in performing their duty under, in particular, sections 1(1)(d) and (e), effectively and pro-actively promote public awareness information. Such a provision will allow the effectiveness of the information and awareness activity to be measured and evaluated to ensure they are targeted so as to achieve policy intent. In addition, it will also ensure that other aspects and provisions of the Bill, which are also crucial to the policy intent, are evaluated and reported upon accordingly.



For further information, please contact:

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