

POLICY NOTE

THE HUMAN TISSUE (AUTHORISATION) (SCOTLAND) ACT 2019 (COMMENCEMENT NO. 2) REGULATIONS 2021

SSI 2021/108 (C. 6)

The above instrument is made by Scottish Ministers in exercise of the powers conferred by sections 29 (2) of the Human Tissue (Authorisation) (Scotland) Act 2019 (“the Act”) and is not subject to any parliamentary procedure.

Summary Box

The purpose of this instrument is to bring The Human Tissue (Authorisation) (Scotland) Act 2019 into effect in its entirety on 26 March 2021.

Policy Objective

The policy objectives relating to the Act are set out in the Policy Memorandum which accompanied the Bill for the Act (“the Bill”). The link below shows the passage of the Bill through Parliament and includes the Policy Memorandum:

<https://beta.parliament.scot/bills-and-laws/bills/human-tissue-authorisation-scotland-bill>

The Act amends the Human Tissue (Scotland) Act 2006 to introduce a deemed authorisation (or “opt-out”) system of deceased organ and tissue donation for transplantation. It will also introduce a framework for the authorisation and carrying out of medical procedures to facilitate transplantation (termed in the Act as “pre-death procedures”) and place duties on the Scottish Ministers in relation to transplantation and pre-death procedures and in relation to the register.

The Policy Memorandum confirms the policy intention of Scottish Ministers to carry out a high profile public information campaign over at least 12 months before commencement of the system, to raise awareness about the law change and its implications. The need for a sufficient duration before introduction of the new system to raise awareness about the change was discussed during parliamentary consideration of the legislation. Following this consideration Scottish Ministers intended to introduce the new system in Autumn 2020, however due to the need to respond to the COVID-19 pandemic its implementation was postponed.

Approach to commencement

The Act received Royal Assent on 18 July 2019. Sections 25, 26, 29 and 30 came into effect on 19 July 2019, the day after Royal Assent.

The Human Tissue (Authorisation) (Scotland) Act 2019 (Commencement No. 1) Regulations brought into effect the following sections of the Act on 11 October 2019:

- section 1 in full (overview of the Act).
- section 7 for the restricted purpose of allowing regulations in relation to ‘excepted body parts’ to be made under new section 6D(5) and for the specific purpose of carrying out consultation before the laying of those regulations.

- section 23 for the restricted purpose of allowing regulations relating to ‘pre-death procedures’ to be made under new sections 16B(1) and 16C(1) (Type A procedures and Type B procedures respectively) and for the specific purpose of carrying out consultation before the laying of those regulations.

These Regulations bring into force the remaining provisions in the Act on 26 March 2021.

Consultation

No formal consultation was carried out in relation to this Order. However, formal consultation took place before the Bill was introduced. The consultation documentation relating to the Bill can be found at: <https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/>

Impact Assessments

11. No impact assessments have been carried out in relation to this order. All relevant impact assessments were completed in relation to the Bill prior to its introduction to Parliament

- Link to the Equality Impact Assessment (EQIA):
<https://www.gov.scot/publications/human-tissue-authorisation-scotland-bill-equality-impact-assessment/>
- Link to the Children’s Rights and Wellbeing Impact Assessment (CRWIA):
<https://www.gov.scot/publications/human-tissue-authorisation-scotland-bill-childrens-rights-wellbeing-impact-assessment/>
- Link to the Data Protection Impact Assessment (DPIA):
<https://www.gov.scot/publications/human-tissue-authorisation-scotland-bill-data-protection-impact-assessment/>
- Link to the Business and Regulatory Impact Assessment (BRIA):
<https://www.gov.scot/publications/human-tissue-authorisation-scotland-bill-business-regulatory-impact-assessment/>

Financial Effects

12. The costs of the Bill were subject to a Financial Resolution agreed by the Parliament. Details of the costs are contained in the Financial Memorandum: <https://beta.parliament.scot/-/media/files/legislation/bills/previous-bills/human-tissue-authorisation-scotland-bill/introduced/financial-memorandum-human-tissue-authorisation-scotland-bill.pdf>.

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