Executive Note

The Human Tissue (Scotland) Act 2006 (Maintenance of Records and Supply of Information Regarding the Removal and Use of Body Parts) Regulations 2006 SSI/2006/344

The above instrument is being made in exercise of the powers conferred by section 19(1) of the Human Tissue (Scotland) Act 2006 ("the 2006 Act"). The instrument is subject to the negative resolution procedure.

Policy Objective

Section 19(1)(a) of the 2006 Act carries forward the provisions of section 3(1) of the Human Organ Transplants Act 1989. The existing Regulations under that section of the 1989 Act are the Human Organ Transplants (Supply of Information) Regulations 1989 (SI 1989 No. 2108). The 1989 Act is being repealed for Scotland by the 2006 Act and the 1989 Regulations made under it will fall away as a result.

The supply of information has, under present legislation, proceeded on a UK basis, in keeping with the arrangements for the allocation of organs for transplantation supervised by UK Transplant. It is essential that the UK-wide collection and analysis of transplantation data should continue under the new legislation so that the data is consistent with data collected previously under the 1989 Act and associated Regulations.

It is also essential that future Scottish data should be consistent with the data which will be collected and analysed in future in the rest of the UK. The equivalent to section 19(1)(a) of the 2006 Act is section 34 of the Human Tissue Act 2004, and the Department of Health is making Regulations under that section, the Human Tissue Act 2004 (Supply of Information) Regulations 2006. The intention is to make the terms of the Regulations under the 2006 Act as close as possible to those being made under the 2004 Act in order to ensure consistency of approach to future data collection and analysis.

The draft Regulations also take account of the information requirements for Scotland set out in paragraph 3(1)(e) of the NHS Blood and Transplant Directions 2005.

It is also essential that the Regulations reflect the information requirements associated with the programmes of living donation scrutinised by the Human Tissue Authority.

The draft Regulations apply to organs or parts of organs. The information requirements relating to tissue used for transplantation will be specified in the Regulations which are being drafted under section 2(2) of the European Community Act 1972 to transpose into Scots law the provisions of the EU Directive on the Safety of Tissue and Cells.

The Regulations place record keeping requirements on registered medical practitioners who remove a body part for transplantation, and on persons who receive a body part for research, education, training or audit purposes. The Regulations also require any registered medical practitioner who removes or receives a body part for transplantation, and certain other specified persons who receive a body part for research, education, training or audit purposes, to provide both NHSBT and their local Health Board with certain specified information. In some cases, such as those where a living donor remains alive for many years after donating

an organ or part of an organ, the records will have to be maintained for a considerable length of time, possibly longer than the working life of the registered medical practitioner concerned. The Department will consider with NHSBT and others what practical guidance needs to be offered in these cases.

Financial Effects

The instrument itself has no financial effects on the Scottish Executive or any other organisation. The provision of Scottish data by UK Transplant or the Human Tissue Authority is covered by the general agreements between the Executive and each of these bodies.

Regulatory Impact Assessment

The draft Regulations have no impact on businesses, charities or voluntary bodies. The data will be used above all for audit, as an essential tool for assessing the effectiveness of the use made of the organs or parts of organs used for transplantation purposes.

Health Department: Healthcare Planning Division
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