



The Scottish Parliament
Pàrlamaid na h-Alba

Nigel Don MSP
Convener
Delegated Powers and Law Reform
Committee
c/o Clerk to the Committee
Room T1.01
Scottish Parliament

Anne McTaggart MSP
M1.11
Scottish Parliament

19 November 2015

Dear Nigel

Transplantation (Authorisation of Removal of Organs etc) (Scotland) Bill at Stage 1

I refer to the letter of 3 November 2015 sent by the Assistant Clerk to your Committee, in which she sought, on behalf of the Committee, an explanation of a number of matters in relation to the above Bill.

My responses to the Committee's queries are set out below.

Section 2 – designation of authorised investigating persons

The Committee asked for an explanation of what other persons, or categories of persons, might be designated as authorised investigating persons, apart from NHS staff.

The term 'authorised investigating persons' (or AIPs) refers to those individuals who would be tasked with establishing whether organs may be removed from a deceased adult.

Paragraph 41 of the policy memorandum makes clear that the authorised investigating persons are to be health professionals (appointed under regulations made by Ministers).

The Bill is drafted in this way to allow Scottish Ministers to decide which health professionals would be best placed to take on any additional tasks resulting from the Bill. Given the particular skill and expertise that these tasks will require it is anticipated that Ministers would only designate NHS staff.

The Committee is correct that the power is drawn in a way that would allow Scottish Ministers to designate people from outwith the NHS as AIPs. This is not the intention of section 2A and I would therefore be happy to consider a stage 2 amendment to the Bill to draft the scope more narrowly to apply to relevant health professionals within the NHS.

The Committee asked for an explanation of the NHS clinical or administrative roles or grades that might be appropriate for designation.

My understanding is that both specialist nurses for organ donation and clinician leads for organ donation currently carry out many of the tasks that an authorised investigating person would be expected to do, and as such they would be the most appropriate roles and grades to take on any additional tasks that result from the Bill. This would be similar to the recent implementation of the Human Transplantation (Wales) Act 2013, where NHSBT updated the policies and processes applicable to those roles.

The Committee asked for an explanation of why the negative procedure is considered to be more suitable than the affirmative procedure for scrutiny of the regulations to designate authorised investigating persons.

The scope of this power is narrow and specific, as it can only be used to designate persons (or classes of person) as authorised investigating persons (AIPs), and cannot, for example, be used to further define their powers or duties, create rules or guidance, or amend existing legislation. The content of the regulations is therefore likely to be uncontroversial and the negative procedure should be sufficient.

Section 16 – Regulations in relation to certain adults resident outside Scotland

The Committee asked the Member to consider whether this power could more suitably be exercised by a “super-affirmative” form of procedure which would enable the Parliament to consider an initial draft of the regulations. What in this context would the advantages and disadvantages of applying such procedure be (for the Parliament and others), in comparison with the affirmative procedure?

As section 16 provides Scottish Ministers with the power to amend the parent Act (the Human Tissue (Scotland) Act 2006) I thought it appropriate that any proposed regulations should require the Parliament’s express approval. This regulation-making power will require some careful exercises of judgement, for example in assessing any other jurisdiction’s opt-out organ donation system to determine whether it is sufficiently similar to the one proposed in the Bill to make it reasonable for people normally resident in that jurisdiction to be made subject to a Scottish soft opt-out system.

The recent changes to the UK Organ Donor Register mean that people can now opt in, opt-out, and nominate and provide contact details for up to two appointed representatives to make a decision on their behalf. It is not difficult to see that in the future, should England and Northern Ireland (who have just agreed Stage 1 of an opt-out Bill) join Wales in implementing a soft opt-out system of organ donation, the Register could easily be used to gain authorisation or make a decision on organ donation for an adult resident anywhere in the UK.

The super-affirmative procedure would provide the Parliament with two scrutiny opportunities, enabling committees to take evidence from people who may be affected by the changes and those who are to implement them and to propose

modifications to the regulations. This level of scrutiny would seem appropriate in areas where there may be conflicting views or where there are controversial issues to consider. However, this level of scrutiny may not be necessary for all proposed changes, for example adding an area within the UK as an opt-out jurisdiction. In this case the affirmative procedure may be adequate.

The super-affirmative procedure is a more time consuming and onerous approach to considering regulations. The Parliament would need to be satisfied that this was the necessary approach to considering all regulations to include adults, who were not resident in Scotland, in the soft opt-out system of organ donation.

I trust that the above is sufficient to respond to the Committee's questions.

Yours sincerely,

A handwritten signature in cursive script, reading "Anne McTaggart". The ink is grey and the signature is fluid and stylized.

Anne McTaggart MSP