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Delegated Powers and Law Reform Committee
Comataidh Cumhachdan Tiomnaichte is Ath-leasachadh Lagh

Human Tissue (Authorisation) (Scotland) Bill: Stage 1

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Delegated Powers and Law Reform Committee

The remit of the Delegated Powers and Law Reform Committee is to consider and report on the following (and any additional matter added under Rule 6.1.5A)—
(a) any—
(i) subordinate legislation laid before the Parliament or requiring the consent of the Parliament under section 9 of the Public Bodies Act 2011;
(ii) [deleted]
(iii) pension or grants motion as described in Rule 8.11A.1; and, in particular, to determine whether the attention of the Parliament should be drawn to any of the matters mentioned in Rule 10.3.1;
(b) proposed powers to make subordinate legislation in particular Bills or other proposed legislation;
(c) general questions relating to powers to make subordinate legislation;
(d) whether any proposed delegated powers in particular Bills or other legislation should be expressed as a power to make subordinate legislation;
(e) any failure to lay an instrument in accordance with section 28(2), 30(2) or 31 of the 2010 Act;
(f) proposed changes to the procedure to which subordinate legislation laid before the Parliament is subject;
(g) any Scottish Law Commission Bill as defined in Rule 9.17A.1; and
(h) any draft proposal for a Scottish Law Commission Bill as defined in that Rule.
(i) any Consolidation Bill as defined in Rule 9.18.1 referred to it in accordance with Rule 9.18.3.

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Introduction

1. At its meetings on 4 September and 5 November 2018, the Delegated Powers and Law Reform Committee considered the delegated powers provisions in the Human Tissue (Authorisation) (Scotland) Bill.[i] The Scottish Government issued a Delegated Powers Memorandum ("DPM").[ii]

2. The Committee submits this report to the lead Committee for the Bill (the Health and Sport Committee) under Rule 9.6.2 of Standing Orders.

3. This Scottish Government Bill was introduced by the Cabinet Secretary for Health and Sport on 8 June 2018.

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i The Bill as introduced is available here.

ii The Delegated Powers Memorandum is available here.

Overview of the Bill

4. The Bill introduces a "deemed authorisation" system for deceased organ and tissue donation for the purposes of transplantation (otherwise known as a "soft opt out" system). It amends the provisions of the Human Tissue (Scotland) Act 2006 (" ***the 2006 Act*** "), in relation to the authorisation of removal and use of parts of the body of a deceased person for transplantation, and other specified purposes (research, education or training and audit or quality assurance).

5. The Bill also aims to introduce more flexibility in the timing of the authorisation process, as well as more clarity on authorisation for "pre-death procedures", which may be carried out to increase the likelihood of a successful transplant. Provisions for authorisation by and on behalf of children (under 16 years) are updated, and additional circumstances in which authorisation can be given for children are included.

6. The Bill is in 4 Parts:

   - Part 1 provides an overview of the Bill structure.
   - Part 2 adds to the existing duties of the Scottish Ministers under the 2006 Act to promote information and awareness about authorisation of transplantation and pre-death procedures, and to establish and maintain a register of information relating to decisions to authorise, or not authorise, donation.
   - Part 3 includes provisions which amend the 2006 Act in relation to the authorisation of removal and use of part of the body of a deceased person, including providing for "deemed authorisation" of organ and tissue donation for adults, for the purposes of transplantation of common types of organ and tissue; specific provisions regarding authorisation by or on behalf of a child; a framework for authorisation for pre-death procedures in order to allow successful transplantation; and setting out duties to inquire into the views of the potential donor.
   - Part 4 sets out various general and final provisions, including an interpretation section and some consequential amendments.

Delegated Powers Provisions

7. At its meeting on 4 September 2018, the Committee agreed that it was content with the powers contained in:

   - section 7(2)
   - section 18(2)
   - section 25, and
   - section 28.

8. At that meeting, the Committee also agreed to write to the Scottish Government to raise questions in relation to section 3(2) (Establishment and maintenance of register) and section 22(1) (inserting new sections 16B(1) and 16C(1) of the 2006 Act - Pre- death procedures relating to transplantation).

9. The questions asked by the Committee and the Scottish Government's response are reproduced in the Annex to this report.

Recommendations

10. **The Committee agreed that it could accept the powers contained in sections 3(2) and 22(1) in principle, and that the exercise of the powers is subject to the affirmative procedure.**

11. **Accordingly, the Committee reports that it is content with the delegated powers provisions contained in the Bill.**

Annex

LETTER FROM THE SCOTTISH GOVERNMENT OF 2 OCTOBER 2018 RESPONDING TO THE COMMITTEE'S QUESTIONS ON THE BILL

Human Tissue (Authorisation) (Scotland) Bill at Stage 1

Thank you for your letter of 5 September 2018 asking for more explanation about the above Bill. The response from the Scottish Government is set out below with the Committee's questions in bold.

Section 3(2)- Establishment and maintenance of register

- **Power conferred on: The Scottish Ministers**
- **Power exercisable by: Regulations**
- **Parliamentary procedure: Affirmative**

Section 3(2) inserts new sections 2A to 2C to the Human Tissue (Scotland) Act 2006 and places a duty on Scottish Ministers to make arrangements for the establishment of "the Register".

The Committee asks the Scottish Government to explain the following, in relation to the powers contained in the proposed new sections 2A(1), 2B and 2D of the 2006 Act, as inserted by section 3(2) of the Bill:

(a) The DPM explains that it is intended that NHS Blood and Transplant will be authorised under the proposed new section 2B(1) as the "register organisation" to establish and maintain the Register.

Why is it considered appropriate that this is not specified in the Bill, for approval by the Parliament?

The intention is that the provisions will provide a clear statutory foundation for the Organ Donor Register ("ODR") in Scotland, including the collection and use of data relating to people's decisions about donation of organs and tissue after death, with the Bill also making it clear that the primary duty to establish and maintain the Register is placed on Scottish Ministers.

The Scottish Government considers that it is appropriate for Scottish Ministers to be able to authorise another person to be able to establish and maintain the Register on their behalf and considers that it is also appropriate that it should be for Scottish Ministers to be satisfied that an organisation carrying out functions on their behalf is also able to do so on an ongoing basis. It is therefore considered appropriate that Scottish Ministers should be able to make arrangements for a person to exercise this function by authorisation, without the need for the person to be specified in legislation. This is particularly in circumstances where the duty is clearly placed on Scottish Ministers, with appropriate safeguards around with whom and for what purposes the information is shared.

Currently, NHS Blood and Transplant ("NHSBT") has responsibility for maintaining the ODR for all of the UK including Scotland and it is intended that this will continue after the Bill is enacted. The exercise of this power to authorise will enable these arrangements to

be continued. However, while not currently anticipated, there could be circumstances in the future when the ODR may be maintained under different arrangements and it is also considered appropriate that this should be left to Ministerial authorisation, particularly as with current arrangements, it would be appropriate for Scottish Ministers to be satisfied on an ongoing basis that the organisation carrying out these functions is able to do so.

There is also a duty on Scottish Ministers to publish information about the arrangements (section 2B(3)) which will ensure that there is transparency about who may be authorised to deliver the functions relating to the Register on their behalf.

(b) Why is it considered appropriate that the appointment of the "register organisation", and any future changes in appointment, could be made as part of the arrangements decided upon by the Scottish Ministers for the establishment and maintenance of the Register, and so the appointment (in terms of proposed new section 2B) would require only the publication of information about the "register organisation" decided upon by Ministers, and not Parliamentary approval by means of the regulations which would contain provision in relation to the Register?

For similar reasons to the answer in (a), the Scottish Government considers that it is appropriate that Scottish Ministers should be able to authorise another person to establish and maintain the Register on their behalf, and it is not necessary to to include this in regulations. This is is also the most appropriate way to enable NHSBT to continue to maintain the ODR on their behalf.

There is a precedent for the approach taken in section 2B(1) as it is similar to the approach to the Adoption Register in the Children and Young People (Scotland) Act 2014 where Scottish Ministers were able to authorise an organisation to carry out their functions in relation to the Adoption Register, established under that Act (see section 75 of the 2014 Act, which inserts section 13B into the Adoption and Children (Scotland) Act 2007). It was, however, recommended that a duty was placed on Scottish Ministers to publish details of the arrangements made. Such a duty has been included in the Bill, whereby Scottish Ministers must publish information about the arrangements made (new section 2B(3)).

(c) In what circumstances could it be appropriate to use regulations under the proposed new section 2D(2) to modify the listing of the Health Boards, Special Health Boards and the Common Services Agency (CSA) in new section 2C(2), with whom Register information may be shared?

Which other persons might be listed in future, and in what circumstances could it be proposed to remove any of those Boards or the CSA from the list?

The Scottish Government considers that it would be appropriate to use regulations to reflect any changes which might occur in the future. This could include other organisations not listed who acquire a role in the donation and transplantation process and require to receive or share information from the registration organisation.

Identifying a suitable opportunity to amend the primary legislation could result in lengthy delays and could be detrimental to patients awaiting transplantation if, for example, donation could not proceed because the organisation who was not previously listed in section 2C(2) was unable to receive information from the registration organisation to fulfil its role.

However, changes made by way of regulations would maintain the clarity around the sharing of information which the Bill seeks to achieve and provide an expedient way of seeking the approval of Parliament.

(d) The proposed new section 2D(1) is framed as a general power by regulations to make provision in relation to the Register.

Can you please explain in what circumstances this power could be used, where those circumstances would not be enabled by the various provisions which the regulations may in particular include as set out in new section 2D(2), combined and supplemented by the powers to make ancillary provisions in section 25 of the Bill?

The power in new section 2D(1) is included as a general power which could be used to allow the ODR to be expanded, for example, and therefore enable future potential changes to be made without the need for primary legislation. The Scottish Government considers that it is helpful to include the list of examples of how the power might be used, set out in new section 2D(2), to make it clear that that the general power in subsection (1) can be used in those ways.

While these examples are included it is also recognised that if the ODR in future is expanded to include a wider range of information or allow information to be shared with a wider range of organisations it may be desirable to include additional provisions, for example about how the information may be used. The general power in new section 2D(1) would allow this, and other appropriate changes, and therefore provide the flexibility to enable the Register to fully and appropriately adapt to future changes.

Section 22(1) (inserting new sections 16B(1) and 16C(1) of the 2006 Act) – Pre death procedures relating to transplantation

- **Power conferred on: The Scottish Ministers**
- **Power exercisable by: Regulations**
- **Parliamentary procedure: Affirmative**

Section 22 amends the 2006 Act to provide for a system for authorisation of “pre death procedures”. These are medical procedures carried out primarily for the purpose of increasing the likelihood of successful transplantation of a part of a person’s body after death.

The Committee asks the Scottish Government to explain the following, in relation to the powers in section 22(1) (inserting proposed new section 16C(2) of the 2006 Act).

The reason provided in the DPM for prescribing “Type A procedures” and “Type B procedures” separately in secondary legislation is to “keep pace with medical developments which may have an impact on the nature and necessity of pre-death procedures without recourse to primary legislation” (paragraph 36 of the DPM).

However, the proposed new section 16C(2)(a)(i) to (iii) would enable regulations to make provision about the circumstances in which Type B procedures may be carried out, the way in which the carrying out of Type B procedures may be authorised, and the process for authorisation. For Type A procedures, those requirements would be set out in the proposed new sections 16D to 16F of the 2006 Act.

(1) Why therefore is it appropriate that for Type B procedures, the matters stated in new section 16C(2)(a)(i) to (iii) should be specified in regulations rather than in the Bill?

Type B procedures are those which might not be considered as routine as Type A procedures and could potentially include more novel procedures, the use of which may also develop over time. Therefore, the Scottish Government considers that while the ability to prescribe these procedures allows the framework for authorisation to the procedures to be responsive to medical developments without needing to make changes in primary legislation, the requirements which may be considered to be appropriate to apply to different types of Type B procedure should also be flexible. For example, it may be that it is considered that a particular procedure is capable of being authorised by a person's nearest relatives and the person themselves, a different procedure might be considered so novel as to require advance explicit authorisation by the person.

Enabling provision to be made in regulations not only ensures this flexibility but also allows the framework for authorisation to be responsive to change. For example, a particular procedure may also over time become more routine and familiar and enabling changes by secondary legislation means that changes to requirements can also keep pace with these developments without the need to introduce primary legislation.

This is also in circumstances where any requirements are additional to those set out in section 16E, which apply to both Type A and Type B procedures. The regulations will also be subject to affirmative procedure, enabling Parliament to fully consider any draft regulations if they are laid.

(2) Could examples be provided of what Type B procedures could be prescribed in the regulations, and what for different procedures might be so specified?

Type B procedures and associated requirements would only be specified after consultation, therefore the following is only a potential example.

Procedures which involve the the administration of certain medication to improve the flow of blood to organs (anticoagulant medication), and so improve the likelihood of successful transplantation are examples of procedures which Scottish Ministers might consider specifying as Type B procedures. In particular, administration of this type of medication might not currently be considered or generally understood to be part of the donation process and so authorisation for donation, including deemed authorisation, might not be considered sufficient authorisation for the procedure itself to be carried out prior to death.

In these circumstances it may be that express authorisation for the procedure by a nearest relative, taking into account the person's most recent views, or expressly by the person might be considered to be an appropriate additional requirement. As mentioned above, this would be in addition to the requirements in section 16E which apply to both Type A and Type B procedures and include that the carrying out of the procedure is not likely to cause more than minimal discomfort or is not likely to harm the person.