

Joint Committee on Health Pre-Legislative Scrutiny of the General Scheme of the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2019

(16 October 2019)

Opening Statement by Mr. Michael Conroy, Principal Officer, Department of Health

Introduction

Good morning. I would like to thank the Chairman and members of the Committee for the opportunity to address you on this draft legislation. As the Chairman said, I am joined today by Helen O'Brien, Assistant Principal.

I hope to provide this hearing with the background to the Government decision to approve the General Scheme of a Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill, and to briefly outline the main provisions.

Background

The General Scheme of a Human Tissue Bill will create a modern legislative framework for consent for activities involving human organs and tissue.

The introduction of legislation in this area is a priority for the Minister for Health and it will give effect to two commitments in the Programme for Government:

- to prioritise the passage of the Human Tissue Bill; and
- to propose legislation for family consent and an opt-out register for organ donation.

The General Scheme proposes to:

- regulate the removal, retention, storage, use and disposal of human tissue from deceased persons;

- provide general conditions for the removal, donation and use of organs and tissues from deceased and living persons for the purposes of transplantation; and
- provide for an opt-out system of consent for organ donation, and for an associated register.

The principles underlying the proposals are:

- consent to be the defining principle underpinning activities involving human organs and tissue;
- protection of the bodily integrity of the individual before and after death;
- respect for the autonomy of the individual and the rights of the bereaved; and
- promotion of the public health benefits of organ donation and post-mortem examination.

The key recommendation of the *Report of Dr Deirdre Madden on Post-Mortem Practices and Procedures* (December 2005) was that *no hospital post-mortem examination should be carried out, and no organ retained for any purpose whatsoever, without authorisation*. The General Scheme will extend this principle to transplantation, anatomical examination, education & training and public display.

The development of this General Scheme has been a collaborative process. Two public consultations on the proposals were held, the latest in 2017. Stakeholders consulted through the drafting process included patient representative groups, the Medical Council, the Health Information and Quality Authority, the Health Products Regulatory Authority, the Office of the State Pathologist, the Coroner's Society of Ireland, the Department of Justice & Equality and the Office of the Attorney General.

The proposed legislation is designed to be compatible with the Assisted Decision-Making Capacity Act and the Coroners Acts. It will repeal the Anatomy Act 1832.

Main Provisions of the General Scheme

The General Scheme is comprised of 6 Parts.

Part One deals with standard provisions such as interpretation. It includes provisions for the storage, handling, transportation, disposal and return of organs and tissue.

Organ Donation & Transplantation

Part Two outlines provisions in relation to transplantation. The General Scheme covers the transplant of both organs and tissues and outlines the requisite consent provisions in regard to deceased and living donors.

Transplantation is currently the only available treatment for end-stage heart, lung and liver failure. It is the most cost-effective treatment for end-stage kidney disease, and it brings enormous clinical and social benefits to patients who would otherwise remain on dialysis.

The success of transplantation, in terms of life years gained and improvements in quality of life for patients, as well as advances in treatment generally, has resulted in an increase in the number of patients for whom transplantation is considered to be a viable option. At end September this year, 577 people were on transplant waiting lists in Ireland, 499 of whom were on the kidney transplant list. Worldwide, the most significant problem affecting transplant programmes is the shortage of suitable organs to transplant.

Opt-Out System

The General Scheme proposes to introduce an opt-out system of organ donation. This approach has been widely adopted across Europe.

Currently the decision on organ donation in the case of a deceased person rests with that person's next-of-kin, even in cases where the deceased person had an organ donor card or had indicated their wish to be an organ donor on their driving licence.

Under the proposed opt-out system, consent will be deemed unless a person has, while alive, registered his or her wish not to become an organ donor after death. The intention is to make organ donation the norm in situations where donation is possible.

A 'soft out-out system' is proposed. Even though consent is deemed, the next-of-kin will in practice always be consulted prior to removing any organ. If the next-of-kin objects to the deemed consent, the donation will not proceed. Feedback from the public consultations, and from organisations involved, support the continued role of the next-of-kin in the final decision on individual organ donations.

Under the proposed system, individuals who do not wish to donate can opt-out. An Organ Donation Opt-Out Register will be established and maintained by Organ Donation & Transplant Ireland (ODTI). If an individual has opted-out through including his/her details on the Register, they will not be considered for organ donation after their death and the views of the family will not be sought. The ODTI has commenced work on setting up the Register. Appropriate safeguards will be included to ensure that the information is correct, that it represents the individual's current views and that GDPR requirements are met. Only the individual involved will be able to include him or herself on the Register. Also, it will be possible for individuals to remove their name from the Register at any time.

The proposed soft opt-out system recognises the practical need for family co-operation to obtain social and medical information about the donor. Safeguarding a future potential organ recipient involves the completion of a comprehensive donor lifestyle questionnaire which requires the co-operation of the next-of-kin.

The introduction of a soft opt-out system of organ donation is part of a range of initiatives being taken to increase the availability of organs for donation. These include:

- the establishment of a National Organ Procurement Service;
- the appointment of clinical leads for organ donation and organ donation nurse managers in each Hospital Group;

- the planned National Organ Retrieval Service; and
- the retrieval of organs in more complex donor cases.

The legislative proposals will be accompanied by a publicity campaign. The aim will be to boost organ donation, ensure that people understand the opt-out system and encourage them to share their wishes in regard to organ donation with their families.

The General Scheme also provides for consent procedures and general conditions on the removal, donation and use of organs and tissue from living persons for transplantation and for human application.

The Bill includes a provision to prohibit the trafficking of organs and the removal and transplantation of organs outside of an official transplant centre, thus facilitating Ireland's ratification of the Council of Europe Convention against Trafficking in Human Organs.

Post-Mortem Practice and Procedure

Part 3 of the General Scheme covers Pathology Practice or post-mortems. This involves hospital post-mortems, or non-coroner post-mortems, only.

The General Scheme outlines:

- the consent required for a hospital post-mortem;
- who can undertake a post-mortem;
- the purposes for which a post-mortem may be undertaken; and
- provisions on the retention, storage, use, disposal and return of organs and tissue from deceased persons following a post-mortem.

The legislation will stipulate that individuals may not be paid for organs and tissue that has been removed as part of a post-mortem, and that such organs and tissue cannot be used for commercial purposes.

Anatomical Examination

Part 4 covers anatomical examination. The Anatomy Act 1832 will be repealed and replaced with provisions that are appropriate to the

current requirements of medical education. Provisions governing consent for anatomical examination, as well as the practice, licensing and governance of such examination, are included.

The central pillar of these provisions is informed consent. An adult may, prior to their death, consent to the donation of their body or body parts for anatomical examination. Full and clear information should be provided outlining the nature of the anatomical examination activities, the length of time the donated body or body parts will be retained, arrangements for disposal and any other information deemed appropriate.

The General Scheme provides that anatomical examination, for the purposes of studying the structure of the human body, may only be practiced in a licensed institution - one of the 5 anatomy schools in Ireland.

Anatomical examination, for the purposes of ongoing education and training on surgical and clinical procedures, may only be practiced using a specimen loaned or transferred from a licenced institution. The import and export of specimens for anatomical examination is also covered.

Public Display of Bodies

Part 5 provides that a licence will be required for the public display of bodies after death and outlines the requirements to be fulfilled when applying for a licence. The provisions also outline the consent arrangements required, and stipulate that only individuals who are authorised by the Medical Council may import or export specimens for public display.

Offences and Penalties

Offences and Penalties are outlined in Part 6.

Conclusion

Work has commenced on the drafting of the Bill in collaboration with the Office of Parliamentary Counsel. The Department hopes to be in a position to seek Government approval to publish the Bill by the end of Q1 2020 and that, subject to other legislative priorities, the Bill will progress through both Houses of the Oireachtas by end Q3 2020.

I would like to thank the Chairman and the Committee for undertaking this pre-legislative scrutiny of the General Scheme. We look forward to receiving the Committee's report which will make a valuable contribution to the further development of the legislation.